Subjective Changes in Vision of Patients with Diabetic Macular Edema Treated with Ranibizumab

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SUMMARY

Aim: To evaluate changes in the subjective perception of visual acuity in everyday life during intravitreal ranibizumab treatment in patients with diabetic macular edema using the Slovak version of the international NEI VFQ-25 questionnaire.
Material and Methods: In a prospective study, 48 eyes of 30 treatment-naive patients were evaluated, and met the indication criteria. We determined best-corrected visual acuity in letter score (LS), intraocular pressure (IOP), central retinal thickness (CRT) and total macular volume (TMV). Patients received the NEI VFQ-25 questionnaire before the first and then after three, six and twelve months of treatment.
Results: Before treatment, LS averaged 68.1 letters, IOP 17.6 mmHg, CRT 480.5 µm, and TMV 11.2 mm^3. After twelve months of intravitreal treatment, LS averaged 72.6 letters, IOP 17.0 mmHg, CRT 332.4 µm, and TMV 9.3 mm^3.
Comparison of data relating to subjective perception of vision before and after twelve months of treatment: perception of general health improved by 7%, vision in general improved by 15%, eye pain decreased by 8%, near vision improved by 12%, distance activities improved by 5%, social functioning improved by 4%, mental health improved by 6%, difficulties with functioning improved by 16%, dependency improved by 1%, driving improved by 2%, color vision improved by 7%, and peripheral vision improved by 9%.
Conclusion: We determined that anti-VEGF ranibizumab treatment improved objective parameters after one year of intravitreal therapy in LS, CRT and TMV. Subjective changes in visual perception improved in all the monitored parameters after one year of treatment.
Key words: diabetic macular edema, endothelial growth factor blockers, subjective changes in vision, ranibizumab (Lucentis)

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INTRODUCION

Diabetic ocular complications are chronic disorders, which we classify among microvascular complications. In developed countries they are the main cause of blindness in the population of working age [1,2]. Worsening of the chronic condition leads to the development of functional disorders of vision. This results in a deterioration of the individual's quality of life. Evaluation of quality of life appears to be a suitable indicator of health. We are able to assess visual functions by means of objective measurements such as examination of central visual acuity on special optotypes, while assessment of the condition of peripheral vision is possible with the aid of perimetric examination, and assessment of structural changes on the retina and optic nerve by imaging methods.

In the publication we prospectively monitored subjective changes of vision during the course of intravitreal treatment with ranibizumab in patients with diabetic macular edema (DME). We used the Slovak version of the National Eye Institute Visual Function Questionnaire 25 (NEI VFQ-25). This questionnaire was complied in 1998 by Mangione et al. [3,4]. The Slovak version of the NEI VFQ-25 questionnaire is a valid and reliable tool for measuring quality of life of patients with DME, but to date it has not been officially validated [4,5]. Over the course of six months each patient received five intravitreal injections of the pharmaceutical in question, and for the following six months the patients were transferred to a treat and extend regimen (T&E).

The NEI VFQ-25 questionnaire consists of a basic set of twenty-five questions focused on visual functions, with eleven sections relating to vision directly, overall assessment of vision, difficulties encountered during activities with near and distance vision, limitations placed on social life and symptoms of mental health caused by vision, difficulties with driving a motor vehicle, limitations of peripheral vision, color vision and eye pain, plus a single supplementary question relating to assessment of the patient's overall condition of health [4,5].

In recent years the relationship between subjective perception of health and the results of visual functions has attracted international attention. Rees previously published findings that disorder of sight influences the results reported by the patient. Individuals with ocular complications of diabetes state subjectively more negative results than those without the presence of ocular complications of diabetes [6]. Trento published a study in which he stated that loss of sight as a consequence of diabetes may also influence the individual's perception of vision [7]. Individuals with reduced visual acuity in connection with DME assessed their overall condition of health as relatively low [8]. Overall, the results stated by patients reflect the emotional impact of treatment and the influence of diabetic retinopathy on their quality of life [9].

MATERIAL AND METHOD

The aim of our study was to evaluate changes of subjective perception of visual acuity in everyday life during the course of intravitreal treatment with ranibizumab in patients with diabetic macular edema, with the aid of the Slovak version of the international questionnaire NEI VFQ-25.

The prospective observation of the patients took place at the Department of Ophthalmology at the University Hospital in Nitra in the period of 2021–2023 and at the University Hospital and Clinic in Nové Zámky in the period of 2023–2025, following prior consent to inclusion within the cohort and approval of the study by the ethical commission. Patients with DME, who had not previously received any intravitreal treatment and who met the indication criteria set by the health insurance company for on-label treatment with ranibizumab, were included in the study.

Diagnosis of DME incorporated: determination of best corrected visual acuity (BCVA) on ETDRS optotype, measurement of intraocular pressure (IOP), examination of the anterior segment of the eye on a slit lamp and biomicroscopy of the ocular fundus in mydriasis and OCT. In the OCT examination we concentrated on the values of central retinal thickness (CRT) and total macular volume (TMV).

Patients received the NEI VFQ-25 questionnaire before the first application, and then after three, six and twelve months of treatment.

BCVA was determined with the aid of the protocol of the early treatment diabetic retinopathy study (ETDRS tables), concentrating on the precise letter score (LS) [10]. IOP was measured by non-contact method and in the case of discrepancies by applanation. CRT and TMV were automatically measured on an OCT instrument. We performed OCT on the instrument Spectralis, Heidelberg Engineering.

We commenced treatment in the form of a minimum of three consecutive injections at monthly intervals (saturation phase of treatment) in accordance with the summary of product characteristics (SPC) of the pharmaceutical until the maximum response to treatment was achieved. We subsequently continued with the treatment within a T&E regimen according to the latest standard procedures on the page of the Ministry of Health of the Slovak Republic valid as of July 1, 2022 [11].

We statistically processed the results of our study in the Excel program. Normality of the data was tested with the aid of a Shapiro-Wilk test. The results were then assessed with the aid of a Wilcoxon two-sample paired test. The significance level alpha was 0.05.

Inclusion criteria

We abided by the indication criteria set by the health insurance company for the approval of intravitreal treatment with ranibizumab:

- Type 1 diabetes mellitus (DM) without glycated hemoglobin (HbA1c) or type 2 DM with HbA1c ≤ 8.0%, in which the examination should be no older than three months
- BCVA within the range of 20/25–20/200, in monocular cases 20/25–20/320
- CRT ≥ 400 µm or if diabetic edema does not respond to laser treatment and CRT ≥ 300 µm
- Changes in the macula are not of an irreversible character and there are no present signs of accompanying disorder of the macula

Treatment is covered up to the attainment of maximum response to treatment: after the initial saturation phase, maximum response to treatment is considered to incorporate the following: condition of macula without fluid/edema, or stabilization of fluid/edema in the macula at three consecutive visits, or BCVA does not improve at three consecutive visits [11].

Exclusion criteria

We chose the following exclusion criteria: presence of other retinal disorders, e.g. occlusion, age-related macular degeneration (AMD) or other disorders which may have an influence on changes of visual acuity or noncompliance in attending appointments for the set treatment [11].

Processing of the results of our cohort

The prospective study included 30 patients, in whom 48 eyes were evaluated (in the case of 18 patients both eyes were included in the study). The cohort consisted of 12 women (40%), in whom 17 eyes were evaluated, and 18 men (60%), in whom 29 eyes were evaluated. The mean age was 61 years (age range 26–84 years). The median and modus were 64 years.

The cohort included 7 patients (23%) with type 1 diabetes. The mean age of the group of type 1 diabetics was 43 years (range 26–60). One 84-year-old female patient

(3%) had hemolytic anemia and for her the HbA1c value was not relevant, she received injections as an exception for her basic diagnosis. The cohort included 22 patients (73%) with type 2 diabetes. The mean HbA1c value was 7.22%. The mean age was 67 years (range 54–84).

We demonstrated statistical significance between the value of HbA1c and LS, CRT and TMV ($p < 0.05$).

Of the cohort of thirty patients, sixteen patients drove motor vehicles at the time of realization of the study. Fourteen patients did not drive. Of these patients, eight had never driven, five had stopped driving mainly for other reasons, and one patient had stopped driving both be-cause of sight and for other reasons.

When processing the results of the international questionnaire (without optional questions) we proceeded according to their own manual and recommendations [12].

Results of objective parameters of treatment

In one patient, after ten months of treatment retinal detachment developed in one of the eyes included in the study, with subsequent surgical solution, and after 12 months of treatment this eye was not included in the resulting cohort. We thus processed a cohort of 47 eyes of 30 patients.

The patients received an average of 7 intravitreal injections in the first year of treatment. Our cohort included 38 eyes of 24 phakic patients. Of these, 8 eyes of 5 patients underwent cataract surgery during the course of the one-year observation period.

After 3 months of treatment LS increased on average by 4.4 letters ($p < 0.05$). After 6 months of treatment LS increased by an average of 5.4 letters ($p < 0.05$). After one year of treatment LS increased by an average of 4.4 letters ($p < 0.05$).

After 3 months of treatment IOP decreased by an average value of 0.1 mmHg ($p = 0.48$). After 6 months of treatment IOP recorded an increase by an average value of 0.5 mmHg ($p < 0.05$). In the values of IOP after one year of treatment we recorded a decrease in the mean value by 0.6 mmHg ($p < 0.05$).

After 3 months of treatment we recorded a decrease in the mean value of CRT by 142.5 μm ($p < 0.05$). After 6 months of treatment we recorded a decrease in the mean value of CRT by 154.2 μm ($p < 0.05$). After one year of treatment we recorded a decrease in the mean value of CRT by 148.1 μm ($p < 0.05$).

After 3 months of treatment we recorded an average reduction in the value of TMV by 1.5 mm^3 ($p < 0.05$). After 6 months of treatment TMV was reduced on average by 2.0 mm^3 ($p < 0.05$). After one year of treatment we recorded an average reduction in mean value of TMV by 1.9 mm^3 ($p < 0.05$).

The results of the objective measurements during the course of the observation period are also processed in Table 1.

Results of subjective perception of treatment

The results of subjective perception before intravitreal treatment, after 3 months, six months and one year of treatment in percentages according to twelve subscales are presented in Table 2.

Comparison of the data of subjective perception of vision before the commencement of intravitreal treatment and after 3 months of intravitreal treatment according to the twelve subscales: perception of general health improved by 6%, vision in general improved by 13%, eye pain was reduced by 8%, near vision improved by 5%, distance activities improved by 4%, social functioning improved by 4%, mental health improved by 7%, problems with functioning improved by 8%, dependency on others improved by 5%, driving deteriorated by 2%, color vision improved by 6% and peripheral vision improved by 5%.

Comparison of data of subjective perception of vision before treatment and after 6 months of intravitreal treatment: perception of general health improved by 5%, vision in general improved by 13%, eye pain was reduced by 8%, near vision improved by 5%, distance activities improved by 8%, social functioning improved by 8%, mental health improved by 9%, problems with functioning improved by 16%, dependency on others improved by 6%, driving improved by 6%, color vision improved by 7% and peripheral vision improved by 4%.

Comparison of data of subjective perception of vision before treatment and after one year of intravitreal treatment: perception of general health improved by 7%, vision in general improved by 15%, eye pain was reduced by 8%, near vision improved by 12%, distance activities improved by 8%, social functioning improved by 8%, mental health improved by 6%, problems with functioning improved by 16%, dependency on others improved by 1%, driving improved by 2%, color vision improved by 7% and peripheral vision improved by 9%.

Table 1. Processing of the results of objective changes in vision before intravitreal treatment, after 3, 6 and 12 months of treatment with ranibizumab

	Before treatment	After 3 months of treatment	After 6 months of treatment	After 12 months of treatment
LS (letters)	68.1 ±14.3	72.6 ±10.8	73.5 ±11.2	72.6 ±11.7
VOT (mmHg)	17.6 ±3.7	17.5 ±4.2	18.1 ±4.3	17.0 ±4.1
CRT (μm)	480.5 ±183.5	338.1 ±94.5	326.3 ±100.6	332.4 ±99.1
TMV (mm^3)	11.2 ±2.7	9.6 ±1.5	9.2 ±1.3	9.3 ±1.4

LS – letter score, IOP – intraocular pressure, CRT – central retinal thickness, TMV – total macular volume

Table 2. Processing the results of subjective changes in vision before intravitreal treatment, after 3, 6 and 12 months of treatment with ranibizumab into 12 subscales. The numbers are in percentages. The lower the number, the worse the subjective perception

Scale	Before treatment	After 3 months of treatment	After 6 months of treatment	After 12 months of treatment
General Health	32	37	37	39
General Vision	56	69	69	71
Ocular Pain	70	78	78	78
Near Activities	64	69	69	76
Distance Activities	70	74	78	78
Vision Specific				
Social Functioning	79	83	87	87
Mental Health	65	72	74	71
Role Difficulties	59	67	75	75
Dependency	81	86	88	82
Driving	80	82	86	82
Color Vision	85	91	92	92
Peripheral Vision	80	85	84	89

Results of objective and subjective perception of patients divided into three groups according to gain of visual acuity

We set the parameter for interpretation of the change in the letter score in a comparison of the state before treatment and after 12 months of intravitreal treatment as follows: we considered improvement of LS to be a gain of 5 or more letters, stable vision as LS plus or minus 5 letters, and the last group experienced loss of LS by 5 or more letters. After one year of intravitreal treatment with ranibizumab, in 25 eyes (53%) of 21 patients we recorded an improvement in LS, in 14 eyes (30%) of 13 patients stable LS and in 8 eyes (17%) of 6 patients a loss of LS. A more pronounced deterioration (loss of more than 7 letters) occurred for the following reasons: a patient developed bilateral subcapsular cataract during the course of treatment, which after one year of treatment was resolved by means of a subsequent operation; two patients underwent cataract surgery during the course of treatment, which decompensated DME; one patient (treated in both eyes) suffered a sudden stroke during the course of treatment and had treatment suspended for 3 months; one patient (treated in both eyes) underwent parathyroid gland surgery during the course of treatment and had treatment suspended during that time. The results of changes of LS before treatment and after 12 months of treatment are also presented in Table 3.

According to this distribution, we divided the eyes of the patients into three groups and subsequently processed the results of subjective and objective perception before treatment and after 12 months of intravitreal treatment with ranibizumab. If a patient treated in both eyes recorded an improvement in one eye and a deterioration in the other eye, the results of that patient's subjective perception are in both of these groups. The numerically processed results of subjective perception are also presented in Table 4.

Group 1 (improved patients) after 12 months of treatment: perception of general health improved by 9%, vision in general improved by 13%, eye pain was reduced by 12%, near vision improved by 14%, distance activities improved by 10%, social functioning improved by 9%, mental health improved by 10%, problems with functioning improved by 21%, dependency on others improved by 5%, driving improved by 2% in fifteen patients, color vision improved by 10% and peripheral vision improved by 12%.

Group 2 (stable patients) after 12 months of treatment: perception of general health improved by 7%, vision in general improved by 16%, eye pain was reduced by 6%, near vision improved by 12%, distance activities improved by 6%, social functioning improved by 4%, mental health improved by 6%, problems with functioning improved by 2%, dependency on others was unchanged, driving improved by 2% in eight patients, color vision improved by 11% and peripheral vision improved by 9%.

Group 3 (worsened patients) after 12 months of treatment: perception of general health improved by 4%, vision in general improved by 10%, eye pain worsened by 2%, near vision improved by 8%, distance activities worsened by 3%, social functioning worsened by 5%, mental health improved by 1%, problems with functioning improved by 19%, dependency on others worsened by 12%, driving worsened by 8% in two patients, color vision improved by 4% and peripheral vision improved by 4%.

We also recorded objective changes in these three groups of patients. In the group of improved patients we determined a statistically significant improvement

Table 3. Change in the number of letters before treatment and after 12 months of treatment with any stated reason other than ongoing anti-VEGF treatment

Letter score before (letters)	Letter score after 12 months (letters)	Difference in number of letters	The reason
75	50	-25	subcapsular cataract
45	70	+25	
50	65	+15	
40	xxx	xxx	after 10 months the eye was discarded due to PPV for amotio retinae
60	80	+20	
75	79	+4	
70	60	-10	cataract surgery during the treatment
80	85	+5	cataract surgery during the treatment
60	75	+15	
80	80	=	
75	80	+5	
70	80	+10	
75	60	-15	cataract surgery during the treatment
90	85	-5	
70	73	+3	
90	90	=	
85	85	=	cataract surgery during the treatment
60	53	-7	during treatment had stroke, treatment interrupted for 3 months
75	74	-1	
65	57	-8	during treatment, patient had parathyroid surgery and treatment was interrupted
75	80	+5	
80	80	=	
68	74	+6	
63	68	+5	
72	80	+8	
75	50	-25	subcapsular cataract
45	42	-3	
30	75	+45	
70	82	+12	
65	75	+10	
75	85	+10	
75	79	+4	
50	75	+25	
35	42	+7	
80	70	-10	cataract surgery during the treatment
80	80	=	
90	85	-5	
70	72	+2	
65	70	+5	
75	85	+10	
75	75	=	during treatment had stroke, treatment interrupted for 3 months
75	80	+5	
70	69	-1	during treatment, patient had parathyroid surgery and treatment was interrupted
55	73	+18	
42	55	+13	
79	78	-1	
78	83	+5	
48	68	+20	

Table 4. Processing the results of subjective changes in vision in three groups of patients (improvement, stability and deterioration) before intravitreal treatment and after 12 months of ranibizumab treatment into 12 subscales. The numerical data are in percentages. The lower the number, the worse the subjective perception.
We established a parameter for interpreting the change in the number of letters in comparison before treatment and after 12 months of intravitreal treatment with ranibizumab: we considered the LS improvement to be a gain of 5 or more letters, we considered the LS change to be stable vision to be a plus 5 and minus 5 letters, and the last group consists of the LS loss of 5 and more letters inclusive

Scale	File improvement patients		Stable patient file		File of deteriorated patients	
	Before treatment	After 12 months of treatment	Before treatment	After 12 months of treatment	Before treatment	After 12 months of treatment
General Health	31	40	31	38	29	33
General Vision	57	70	55	71	50	60
Ocular Pain	67	79	69	75	73	71
Near Activities	64	78	64	76	50	58
Distance Activities	76	86	74	80	65	62
Vision Specific						
Social Functioning	82	91	83	87	84	79
Mental Health	66	76	63	69	55	56
Role Difficulties	56	77	69	81	48	67
Dependency	81	86	81	81	81	69
Driving*	81	83	79	81	79	71
Color Vision	83	93	81	92	88	92
Peripheral Vision	80	92	79	88	71	75

LS – letter score
** in the improved patient group, fifteen patients drove, in the stable patient group, eight patients drove, and in the deteriorated patient group, two patients drove*

in the parameters of LS, CRT and TMV ($p < 0.05$). In the second group of stable patients LS remained unchanged on average after one year of treatment, therefore the change was not statistically significant, while CRT and TMV showed a statistically significant improvement ($p < 0.05$). In the third group of worsened patients we demonstrated a statistically significant worsening of LS ($p < 0.05$) and by contrast an improvement in the parameters of CRT and TMV, which was nevertheless not statistically significant. The values of IOP did not show any statistically significant change in all the subscales during the course of the one-year observation.

DISCUSSION

Diabetic retinopathy is the most common cause of loss of sight in developed countries for the age group of 40 to 65 years [13]. The main cause of loss of sight in diabetic patients is DME [14].

Visual acuity is important for measuring visual function, but does not provide us with sufficient information about how it influences the lives of patients. Visual acuity alone cannot measure recovery after injection, changes in daily activities, satisfaction with vision, visual affliction, depression or loss of social function. In this case another method of measurement is required. A number of types of instruments are able to measure quality of life in the condition of health that is the subject of investigation [15].

Hariprasad et al. state that the aim of their study was to determine the influence of DME on the quality of life of patients with type 2 diabetes mellitus. Patients with type 2 diabetes with macular edema have reduced quality of life in comparison with patients with type 1 diabetes with diabetic retinopathy, glaucoma or cataract. However, quality of life in type 2 diabetic patients with DME was similar as in individuals with AMD [16].

Chen et al. in their study presented an overview of the literature on DME in the USA and in selected European countries. The prevalence of DME among diabetic patients in the countries under investigation was within the range of 0.85% to 12.3%. The prevalence and incidence of DME differs depending on the type of diabetes (1 vs. 2), dependency on insulin vs. no insulin dependency, and the duration of the disease (years since diagnosis). A synthesis of the available results indicates that DME has a negative influence on the quality of life of patients in connection with health [17].

In some of our patients we recorded a deterioration of their overall condition of health during the course of treatment (progression of diabetes mellitus and other complications with the basic diagnosis, in some patients their condition was health was complicated by another general health problem such as sudden stroke or parathyroid gland surgery), or ocular complications occurred, such as cataract or surgery for retinal detachment, which had an influence on subjective changes in vision and also on

their overall quality of life. It was necessary to temporarily suspend anti-VEGF treatment of patients. When the patients in question were able to continue in the original anti-VEGF treatment, they were returned to the original pharmaceutical and after the first intravitreal treatment they again subjectively perceived an improvement in their quality of life.

According to the latest recommendations concerning the care and management of DME affecting the center of the fovea, anti-VEGF preparations are recommended in the first line of treatment. At present this is the most effective treatment, which brings an improvement of BCVA in DME without destruction of the retina. A concurrent effect of this treatment is regression of the degree of DR. If patients do not respond sufficiently to this treatment after loading (in DME the 5 initial injections), we also have intravitreal application of corticoids and laser treatment of the retina available [18].

When processing the results of the NEI VFQ-25 international questionnaire (without optional questions) we proceeded according to their own manual and recommendations [12]. At the same time we set the parameter for interpretation of change in the number of letters in comparison before treatment and after 12 months of intravitreal treatment: we considered improvement of LS to be a gain of 5 or more letters, stable vision as LS plus or minus 5 letters, and the last group was loss of LS by 5 or more letters.

The authors of the RIDE and RISE study (phase 3 of clinical experiment) examined the effect of intravitreal treatment in patients with central DME with the aid of the NEI VFQ-25 questionnaire. The participants in the study were divided into three groups: ranibizumab 0.3 mg, ranibizumab 0.5 mg and simulated treatment. The NEI VFQ-25 questionnaire was presented to the participants at the beginning of the study and after 6, 12, 18 and 24 months of treatment. The authors observed that intravitreal treatment improved function in connection with vision, and that the change in the NEI VFQ-25 score was greater in the group treated with ranibizumab 0.3 mg and 0.5 mg than in the group with simulated treatment after 12 and 24 months, regardless of whether the better or worse seeing eye was being treated. These phase 3 studies demonstrated that treatment of DME with ranibizumab probably improves the results of function in connection with sight stated by the patient in comparison with simulation, which further supports the treatment of DME with ranibizumab [19].

In the RELIGHT study, which incorporated 109 patients with DME who received intravitreal treatment with ranibizumab, there was a strong correlation between BCVA in the studied eye and the condition of the eye at the beginning and at the end of the study (better or worse BCVA) and NEI VFQ-25. BCVA in the studied eye correlated strongly with the NEI VFQ-25 score and most of the subscales. Statistically significant improvements were observed in most of the NEI VFQ-25 subscales after 6, 12 and 18 months. Treatment of DME with ranibizumab over an 18-month period led to an improvement of visual functioning and patient satisfaction [20].

In our group of patients we focused on patients with clinically confirmed and diagnosed DME, who were treated intravitreally with ranibizumab in five saturation doses over the course of six months, and subsequently continued in treatment within a T&E regimen, in which the total length of treatment 12 months. In the patients in question we observed subjective changes in vision with the aid of the NEI VFQ-25 questionnaire. The patients completed the questionnaire before treatment, and after three, six and twelve months of intravitreal treatment. We confirmed the results of large clinical trials (RISE, RIDE and RELIGHT), in which our limitation was only the 12-month observation period and the size of our cohort, consisting of 30 patients. We succeeded in demonstrating changes of subjective perception of visual acuity before intravitreal treatment and after twelve months of intravitreal treatment: an improvement was achieved in all the observed parameters.

Bressler et al. in their publication retrospectively divided patients into three groups according to change of LS in the RIDE and RISE studies [21]. In our cohort of patients we drew inspiration from this model and divided our patients into three groups according to LS. In our results from the cohort also it ensues that a majority of patients (53%) gained an improvement of LS during the course of one year of treatment, with a comparison of the results from the RIDE (66.3%) and RISE studies (67.7%). In our cohort 30% of patients had a stable LS, in the RIDE study this was 21.5% and in the RISE study 18.3%. In the RIDE study 12.3% patients had a worsened LS, in the RISE study 14% and in our cohort 17%.

Ranibizumab is a pharmaceutical that was approved and used as standard in the treatment of DME at the time of the realization of our study. Our patients received an average of 7 intravitreal injections during the first year of treatment. We are aware that this represents a burden for the patients and their families – patients must attend regular applications, they must secure transport to the center, undergo examination and the actual process of application, in addition to which there are also risks in connection with treatment. At present we have stronger and more effective molecules available on the market, which enable us to prolong the intervals for up to 6 months. For this reason it is very important to find a preparation to which the patient will respond and gain an anatomical and functional improvement of the finding, for which the longest possible application interval can be set, and which will not constitute a substantial burden for patients and their families.

In the entire cohort of patients we compared LS, CRT and TMV, in which we demonstrated a correlation with subjective perception after one year of intravitreal treatment. We supported the improvement of the objective parameters after one year of treatment (we recorded a statistically significant improvement of LS, CRT and TMV) also with subjective results, in which after one year of tre-

atment there was an improvement in all twelve subscales. We also demonstrated statistical significance between the values of HbA1c and LS, CRT and TMV ($p < 0.05$).

We determined the following results after dividing the patients into three groups according to the change in the letter score (worsening, stable and improvement): in the group of improved patients we determined a statistically significant improvement in CRT, TMV and LS ($p < 0.05$). We confirmed our results also with a subjective improvement in all twelve subscales. In the second group of stable patients LS remained unchanged on average after one year of treatment, thus the change was not statistically significant, while CRT and TMV showed a statistically significant improvement ($p < 0.05$). When processing the results of subjective perception, there was a subjective improvement in eleven subscales, only the category of dependency on others remained unchanged. In the third group of worsened patients we demonstrated a statistically significant worsening of LS ($p < 0.05$) and by contrast an improvement of CRT and TMV, which was nevertheless not significant. In this group of worsened patients, when processing the results of subjective perception we determined that the patients stated an improvement in some categories (in seven subscales), and by contrast a worsening in others (in five subscales). The values of IOP in all subscales did not record a statistically significant change during the course of the one-year observation.

We would like to point out that the published large cohorts of patients (at least 109) had an observation period of 18–24 months. In our cohort we were limited by the size of the cohort of 30 patients, as well as by the limited time period of 12 months. Despite the fact that our cohort included patients who had to suspend treatment for a certain time during the course of the year, we succeeded in demonstrating an improvement in the objective parameters (with the exception of IOP) and in all the subscales of subjective parameters. It was interesting to process the results of an equivalent cohort of patients with a stronger pharmaceutical and to compare the results against one another. Anti-VEGF treatment with ranibizumab is equally effective and has a positive impact on patient quality of life and social functioning, which we succeeded in demonstrating after 12 months of treatment in an improvement of all categories of subjective perception with the aid of the NEI VFQ-25 questionnaire.

CONCLUSION

Diabetic macular edema and diabetic retinopathy, without the presence of severe complications, have a negative influence on the quality of life of patients with diabetes.

We observed subjective perception of changes of visual acuity with the aid of the NEI VFQ-25 questionnaire, containing a set of twenty-five questions, during the course of treatment of patients with diabetic macular edema by means of intravitreal administration of ranibizumab at regular intervals (before treatment, and after three, six and twelve months). After twelve months of intravitreal treatment we recorded an improvement of the results in all the observed parameters.

We selected the following objective parameters: change of best corrected visual acuity, intraocular pressure, central retinal thickness and total macular volume. We demonstrated a statistically significant improvement in the parameters of best corrected visual acuity, central retinal thickness and total macular volume.

In conclusion we would like to summarize and point out that administration of intravitreal treatment with endothelial growth factor blockers (ranibizumab) appears to be a financially expensive treatment, but one which has substantial benefits for patients in terms of their social and regular functioning, as confirmed also by our subjective results after twelve months of treatment.

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