

The Use of Laser Treatment in Combination with Fenofibrate for the Prevention of Diabetic Retinopathy

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Annotation: The primary method of preventing blindness due to diabetes remains retinal laser coagulation. Following the completion of large multicenter studies such as DRS and ETDRS in the early 1990s (which are still considered classic), the main indications and types of laser interventions were established [1,2,3,4]. In the years that followed, the laser treatment techniques proposed by these studies have undergone minimal changes. Most of the work in this field has focused on modifying the DRS-ETDRS methods to reduce various side effects of laser treatment. With the advent of intravitreal injections of crystalline corticosteroids and vascular endothelial growth factor inhibitors, these have been combined with different types of laser interventions. While intravitreal injections of corticosteroids or anti-angiogenic agents did not meet expectations in terms of isolated therapy, they are now actively used as part of combined treatment with laser coagulation, which has proven to be significantly more effective [4,5].

Keywords: Abnormal lipid levels, fenofibrate therapy, diabetic eye disease, swelling of the macula, retinal laser treatment.

Objective: To evaluate the effectiveness of fenofibrate in preventing significant changes in the retina in patients with type 2 diabetes.

Material and methods: The patients were followed up for 12 months. At the initial visit (visit 1), after 6 months (visit 2) and after 12 months (visit 3) all study participants underwent a comprehensive ophthalmological examination, including mandatory photoregistration of standard

areas of the retina and optical coherence tomography. Optical coherence tomography with angiography function was performed to determine the area of macular edema and if neovascularization was suspected. Blood was also collected at each visit to analyze key biochemical parameters. Retinal photography was performed using a TRC-50IX fundus camera from Topcon (Japan) and CT-precisa slide film (100 U) from Agfa (Germany) according to the standard ETDRS technique (1991) [12]. OCT was performed on a Stratus OCT Zeiss (Germany) using the Fast Macular protocols Thickness » and « Macular Thickness ». The thickness and volume of the macula were assessed. The study included 60 patients with type 2 diabetes (35 patients - 70 eyes - the main group, 25 patients - 50 eyes - the control group). Patients of the main group received fenofibrate at a dosage of 200 mg / day, once a day during one of the main meals. Patients of the control group were under observation. All patients (main and control groups) were recommended to follow a diet.

In the main group, the ratio of men and women was almost the same (48.6% and 51.4%), while in the control group, women predominated (76.0%). The average duration of diabetes was 14.13 ± 7.78 years in the main group and 14.57 ± 7.3 years in the control group. The distribution of patients by type of therapy was similar: in the main group, 42.8% took oral hypoglycemic agents, 57.2% received insulin; in the control group - 52.0% and 48.0%, respectively.

Analysis of retinal images showed that in the main group (70 eyes), 18.6% corresponded to ETDRS level 20, 41.4% to level 35, 20.0% to level 43, and 20.0% to level 47. In the control group (50 eyes), background diabetic retinal changes predominated: 10.0% corresponded to level 20, 52.0% to level 35, 24.0% to level 43, and 14.0% to level 47 ETDRS.

The average central macular thickness according to OCT data was 203.2 ± 23.9 μm in the main group and 199.9 ± 24.6 μm in the control group. The volume of the macular retina was 6.86 ± 0.49 mm^3 and 6.90 ± 0.36 mm^3 , respectively.

Analysis of biochemical parameters showed moderately elevated levels of lipoproteins in both groups.

Results: In the main group, there was a significant positive dynamics of the lipid profile: a decrease in the level of total cholesterol, triglycerides, LDL and HDL ($p = 0.001$), while there was a tendency to an increase in the level of HDL, although this change did not reach statistical significance ($p = 0.11$). The level of creatinine in the main group slightly increased ($p = 0.046$), while in the control group its level decreased ($p = 0.047$). The indicators of liver transaminases (ALT and AST) in the main group remained stable ($p = 0.29$ and $p = 0.25$).

The dynamics of blood pressure also showed differences between the groups. In the main group, there were no statistically significant changes in either systolic or diastolic pressure ($p = 0.56$ and $p = 0.96$), while in the control group, there was a significant increase in systolic pressure ($p = 0.03$), while diastolic pressure remained unchanged ($p = 0.92$).

After 12 months of follow-up, diabetic retinopathy (DR) progression was recorded in 12.8% of cases (9 eyes) in the study group, with 2 eyes showing a two-level deterioration according to the ETDRS scale. No signs of retinal neovascularization were detected. Focal laser photocoagulation of macular edema was required in 2.9% of cases (2 eyes in one patient). Retinopathy regression was noted in 7.1% of eyes (5 cases). In the control group, DR progression was recorded in 28.0% of cases (14 eyes), of which 2 eyes showed a two-level deterioration according to the ETDRS scale, and one eye showed a three-level deterioration. Proliferative DR developed in 6.0% of patients (3 eyes in 2 patients), requiring panretinal laser coagulation. Focal laser coagulation of macular edema was necessary in 10.0% of cases (5 eyes in 3 patients). Regression of retinopathy was observed in 4.0% of cases (2 eyes).

Analysis of risk factors for the progression of DR and maculopathy after 12 months revealed significant predictors: an increase in systolic pressure (from 141.41 ± 13.59 mmHg to 156.14 ± 25.23 mmHg; $p = 0.01$), as well as initially high levels of triglycerides (2.10 ± 1.13 mmol/l) and

LDL (1.14 ± 0.51 mmol/l), which decreased during observation ($p = 0.04$).

Significant differences in the parameters of the thickness and volume of the macular retina were also found when comparing patients who underwent laser coagulation with the rest. At the second visit, the average retinal thickness in the laser treatment group was 241.8 ± 41.7 μm , and at the third visit, it was 238.0 ± 74.3 μm . In the group without laser treatment, these indicators were 204.6 ± 21.4 μm and 203.2 ± 25.5 μm , respectively ($p = 0.0001$ and $p = 0.004$). The macular retinal volume in the laser treatment group increased from 7.17 ± 0.23 mm^3 (visit 2) to 7.40 ± 0.73 mm^3 (visit 3), while in the no-coagulation group it remained stable (6.84 ± 0.44 mm^3 and 6.85 ± 0.46 mm^3 , $p = 0.045$ and $p = 0.004$).

Conclusion. The results of the study show that fenofibrate therapy improves lipid metabolism and reduces the likelihood of developing clinically significant retinal changes in patients with type 2 diabetes. Fenofibrate treatment significantly reduces the risk of diabetic retinopathy progression, decreasing it from 28.0% to 12.8% ($p = 0.04$), and also reduces the need for laser therapy from 16.0% to 2.9% ($p = 0.02$). The main risk factors for the progression of diabetic retinopathy and macular edema are increased systolic blood pressure ($p = 0.01$), as well as high levels of triglycerides ($p = 0.04$) and very low density lipoproteins ($p = 0.04$).

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