

## The Real Clinical Surgery Practice of Diabetic Macular Edema in Russia

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Nowadays, both in the whole world and in the Russian Federation, an avalanche-like increase in the incidence of diabetes mellitus (DM) is observed, and the number of patients with diabetic retinopathy (DR) and diabetic macular edema (DME) is increasing. All these diseases dramatically reduce vision, quality of life, can lead to permanent loss of vision and, ultimately, to disability.

Actively and effectively used worldwide, antiangiogenic therapy has its own peculiarities in Russia because of its high cost, violation of the methodology of use, remoteness of patients from places of care, and low awareness of both patients and doctors about the effectiveness of therapy and its prescribing schemes. Unfortunately, we often encounter a late start of treatment, a delay between the identification of indications for the administration of an injection of angiogenesis inhibitors (AI) and its implementation, the violation of the scheme for the use of AI (refusal to perform loading injections, insufficient number of maintenance injections).

In Russia, in the official State Register at the end of 2019, there were more than 4.5 million people with DM (half of patients with diabetes are not diagnosed with the disease). The prevalence of diabetes among adults (18 years of age and older) with DM type 1 is 27.2%, and with DM type 2 - 13.0%. More than 650,000 patients with visual impairment in DM have diabetic retinopathy (DR), secondary neovascular glaucoma, complicated diabetic cataracts, various transient visual impairments and dry eye syndrome.

A mandatory diagnostic method for DME is optical coherence tomography (OCT). This method allows not only to make a qualitative and quantitative assessment of the state of the retina, but also to suggest the patient's response to treatment due to the analysis of prognostic markers. However, this equipment is not always available for primary care of ophthalmologic

care because of its cost and requires special skills and knowledge from a research doctor.

Currently, three main methods are recommended and applied in Russia for the treatment of DME: antiangiogenic therapy, the use of a prolonged corticosteroid implant (mainly as a second-line therapy), laser retinal coagulation (LRC), and vitrectomy (in the presence of traction macular syndrome). Each of these methods has its own indications, advantages and disadvantages. The possibilities of LRC and vitrectomy have already been repeatedly studied, the indications for their conduct are indicated, the effectiveness of their use was proved. In this article, we would like to pay more attention to the possibilities of the treatment of AI. Of the antiangiogenic drugs for intravitreal administration in the treatment of DME, two drugs are officially registered in our country: ranibizumab (Lucentis, Novartis) and aflibercept (Eylea, Bayer). In fairness, it must be said that some off-label ophthalmologists use the drug bevacizumab (Avastin, Novartis), which was used in oncology, but is not officially intended for intravitreal administration in our country.

Currently, in many European countries and on the American continent, LRC is losing the status of a standard in the treatment of DME. But even in these countries, in order to optimize antiangiogenic therapy and reduce the number of necessary injections, the effectiveness of the combined approach is studied, which implies the use of AI with subsequent LRC. This option is quite common in the Russian Federation due to the low adherence of patients to treatment and their financial problems. Therefore, in the case of a positive result (a decrease in the height of the retinal edema) after performing even one injection of an AI, the ophthalmologist tries to fix the result using the subsequent focal or panretinal LRC.

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The data of the LUMINOUS multicenter observational study conducted in our country, among others, showed insufficient use of AI. The average number of injections per year per patient with DME in Russia was only 2.2. Obviously, this is clearly not enough, since the method of treating AI provides for the mandatory use of monthly loading injections, and then maintenance injections. The insufficient number of injections has led to the fact that in real clinical practice in Russia, patients not only do not add, but on average even lose a little vision after using AI. This suggests that the method of treating AIs is used incorrectly, which in turn not only discredits the technique, but also seriously damages patients who lose their eyesight.

Analysis of the volume of purchases of AI (aflibercept and ranibizumab) confirms the conclusion that in Russia there is insufficient use of them and we can talk about one of the lowest security of AI among other European countries, taking into account the population and when converted to 1000 people. In 2018, only 0.3 bottles of the drug were purchased per 1000 people, while for other European countries this figure was from 4 to 20 bottles. Possibly, the low provision of the AI population is one of the reasons for the insufficient effectiveness of the antiangiogenic therapy of DME conducted by Russian ophthalmologists. In addition, an insufficiently responsible attitude of patients to their health plays a huge role - the lack of regularity of observation by an endocrinologist, ophthalmologist, cardiologist, nephrologist and other specialists.

In recent years, methods for treating retinal diseases both around the world and in Russia have advanced far ahead, demonstrating previously unattainable effectiveness. Nevertheless, in our country these patients account for 1/4 of all visually impaired people.

The low level of provision of AI in patients in Russia indicates an unsatisfactory state of affairs in this area. The necessary loading injections of AI and an increase in the availability of antiangiogenic drugs will all help to achieve high rates of efficacy of AI therapy, which is comparable with the results of many foreign studies and will improve unfavorable statistics for the growth of blindness and disability due to ocular complications of diabetes, including in young working people age.

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