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Original Article

Acute Systemic Complications of Intravitreal Bevacizumab and Triamcinolone Injections – a Comparative Study

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Abstract

Introduction: Macular edema is a common visual threatening complication in patients with diabetic retinopathy and retinal vein occlusion. The injection of intravitreal drugs, such as anti-vascular endothelial growth factor (anti-VEGF) and corticosteroids, revolutionized the treatment of these diseases.

Aim: To compare and assess the acute systemic complications of intravitreal bevacizumab and triamcinolone injections in patients with diabetic retinopathy and retinal vein occlusion.

Materials and methods: The study population included 211 patients with diabetic retinopathy and retinal vein occlusion who required intravitreal injections of bevacizumab and triamcinolone. In this study, 118 patients had generally received intravitreal injections with bevacizumab and the rest (93 patients) injections with triamcinolone. Experimental data, including demographic information, number of injections, the history of comorbidities, intraocular pressure, and systemic hypertension before and after injections, were recorded on specific forms following groups' classification. In addition, the incidence of various complications was investigated during one month after the intravitreal injections.

Results: In the present study, we included 211 patients (mean age 62.41±11.34 years, median - 63 years). The results showed that there was no significant correlation between the injectable drug and changes in increased intraocular pressure (IOP) (p=0.66). No significant difference was detected for systemic hypertension in any of the studied groups. On the other hand, the incidence of complications of blood sugar, facial skin redness, neurological problems of TIA and CVA, myocardial infarction, vascular problems after injection, and ocular complications were estimated to be zero, 1.4, 0, 0.8, 0, and 6.1%, respectively.

Conclusions: Overall, the results indicated a prevalence of 1.4% for systemic complications and a prevalence of 6.1% for ocular complications. Accordingly, it seems that intravitreal injections of both drugs studied in the present study are placed in the group of low complication medications.

Keywords

bevacizumab, complication, macular edema, systemic, triamcinolone

INTRODUCTION

Diabetic retinopathy (DR) is considered to be one of the most important complications of diabetes and one of the causes of blindness and visual impairment. Overall, approximately 75% of people with type 1 diabetes develop retinopathy, while about 50% of people with type 2 diabetes may develop this complication.[1] It has also been reported that about 25% of people with diabetes may develop macular edema.[2] Macular edema is the principal cause of diabetes-related vision loss in patients with DR. In addition, retinal vein occlusion (RVO) is another common cause of macular edema.

Intraocular injection is one of the current treatment techniques that can be employed in macular edema therapy. According to various reports, intravitreal injection of triamcinolone, used alone or in combination with laser therapy, is effective in treating diabetic macular edema. It was also stated that intravitreal injection of 4 mg of this drug resulted in increasing visual acuity and decreasing central macular thickness.[3] Some studies have reported different well-known side effects, such as elevated intaocular pressure (IOP), cataract, and endophthalmitis for intravitreal injections of triamcinolone and other steroids.[4] Intravitreal injections of anti-vascular endothelial growth factor (anti-VEGF) drugs including ranibizumab and bevacizumab (IVB) are also employed in treating macular edema.[5] Moreover, it was observed that injection of bevacizumab significantly reduced retinal neovascularization in patients with proliferative diabetic retinopathy (PDR) and previous panretinal photocoagulation.[6] Also, intravitreal injection of systemic bevacizumab can increase the risk of ischemic stroke, transient ischemic attack, and myocardial infarction.[7] In some studies, it has been observed that intravitreal injection of bevacizumab to treat age-related macular degeneration (AMD) led to a temporary increase in systolic blood pressure.[8] Also, it has been reported that intravitreal injection of this drug can lead to possible ocular side effects and systemic medication-related side effects, including hypertension and cerebrovascular accidents. The findings of the above reports indicate that the intravitreal applications of this drug, even in low doses, can lead to complications' incidence of corneal ulcer, chemosis, lens damage, and eye inflammation and systemic complications of hypertension, cerebrovascular accidents, allergic rashes, and female sexual dysfunctions.[9] Although numerous studies have been examined to assess and compare the effects of intravitreal injections of the two drugs applied in the present study in treating macular edema, limited studies have been performed to evaluate and compare the systemic and ocular side effects of these drugs.

AIM

This study aimed to assess and compare the acute systemic complications of intravitreal injections of bevacizumab and triamcinolone in patients with diabetic retinopathy and retinal vascular occlusion.

MATERIALS AND METHODS

The present study, a prospective cross-sectional study, was performed on 211 patients with diabetic retinopathy (118 patients) and patients with retinal vascular occlusion (93 patients) referred to the Poustachi ophthalmology clinic affiliated to Shiraz University of Medical Sciences, Shiraz, Iran. In general, all patients with DR and individuals with RVO, who currently received the first intravitreal injection of bevacizumab or triamcinolone (or patients with at least three months after their last injections), met the inclusion criteria. On the contrary, the exclusion criteria in this study included patients with a history of intraocular surgery (except for patients with uncomplicated intraoperative cataract surgery), patients with uncontrolled hypertension or diabetes, people with underlying diseases (e.g., uveitis which can cause macular edema), and patients with complaints of decreased vision other than macular edema (e.g., retinal dystrophy and optic atrophy).

Then, demographic information, number of injections, injected drugs (bevacizumab or triamcinolone), the history of underlying medical conditions (diabetes and systemic hypertension), intraocular pressure, and systemic hypertension before injections were recorded on specific forms. It should be emphasized that injectable drug kinds (bevacizumab or triamcinolone) were selected based on patient-specific considerations.

One group was treated with triamcinolone acetonide 2 mg in 0.5 ml, and another group received bevacizumab 1.25 mg in 0.05 ml as the intravitreal injection. It should be noted that all intravitreal injections were performed in a sterile fashion with betadine 5% solution in the 4 mm area from the superotemporal limbus by an experienced ophthalmologist under topical anesthesia with 1% tetracaine eye drops. Chloramphenicol eye drops were used following the injection process, and immediately funduscopy and intraocular pressure measurement were performed with a pneumatic tonometer. In addition to the above, all patients underwent the ophthalmological evaluation, including measurement of best visual acuity using the Snellen chart, Goldmann applanation tonometer, slit-lamp examination with dilated pupil using 90 lenses, and indirect ophthalmoscopes before injection. Also, systemic complications that happened during the first month after injection processes were investigated in the patients in the present study.

The above complications included cerebrovascular accident, myocardial infarction, acute coronary syndrome, hypertension, facial skin redness, itchy diffuse rash, subconjunctival hemorrhage, corneal abrasion, and vitreous hemorrhage.

Collected data were analysed using SPSS software (version 22). Also, frequency distribution and mean indices were employed for descriptive information and mean and

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standard deviation indices for quantitative data. Due to non-normal distribution of data, non-parametric tests such as chi-square, Fisher's exact test, Mann-Whitney, Kruskal-Wallis one-way analysis of variance, and Mauchly's test of sphericity were applied. *P* value <0.05 was used to compare the means of the data.

RESULTS

The present study included 211 patients at the mean age of 62.41±11.34 years (with a median of 63 years), in which the youngest and the oldest patients were 31 and 90 years old, respectively. In general, 104 men with a mean age of 62.93±12.49 years and 107 women with a mean age of 62.08±10.09 years participated in this study.

In this study, 118 patients (55.92%) with a mean age of 63.67±12.06 and 93 patients (44.07%) with a mean age of 10.36±61.20 years received bevacizumab and triamcinolone, respectively, based on experimental treatments. Patients with RVO and DME in the group treated with bevacizumab were 44 (37.3%) and 74 (62.7%) patients, while in the group treated with triamcinolone - 29 (31.2%) and 64 (68.8%) patients, respectively. In addition, 42 (35.6%) and 76 (64.4%) patients receiving bevacizumab were without and with a history of bevacizumab injection, respectively, while all participants treated with triamcinolone (93 patients or 100%) included patients without a history of triamcinolone injection, although 78% of these patients previously had a history of bevacizumab injection. In addition, the average number of IVB injections in the group treated with bevacizumab was 3.91±3.86, and in the group treated with triamcinolone was 4.35±3.91. The obtained results of the Mann-Whitney test showed that the number of injections in the triamcinolone group was significantly higher (p<0.001) than in another group. Furthermore, in relation to the history of diseases, the results showed that patients with a history of diabetes, hypertension, and both diabetes and hypertension were respectively 56 (26.5%), 27 (12.8%), and 93 (44.1%) patients **(Table 1)**.

The relationship between the kind of injected drug and IOP changes is shown in **Fig. 1**. In general, Mauchly's sphericity test was employed for the above findings, and the results displayed a non-significant relationship between the kind of injected drug and IOP changes. In this test, p=0.666 and F(1.93, 401.4)=0.395. Mean and standard deviation of injected drugs for IOP, before injections, one day after injections, and one month after injections are presented in **Table 2**. According to the results, it can be observed that IOP values more than 21 during one month after drug injection were observed in just 15 patients (7.1%) so that eight patients were for the bevacizumab injection group and seven patients for the triamcinolone injection group. In other words, there was no significant difference between both groups in terms of the number of people with IOP above 21 in one month after injection operation (p=0.81).

Mann-Whitney U test and Mauchly's sphericity test were used to investigate the relationship between the

Table 1. Demographic information of the studied patients

Sources of variation		Bevacizumab (n=118)	Triamcinolone (n=93)	*P*- value
Sex	Female	58 (49.2 %)	49 (52.7 %)	0.61
	Male	60 (50.8 %)	44 (47.3 %)	
Age	20-40	6	4	0.96
	41-60	42	33	
	More than 60	56	70	
Diagnosis	RVO	44 (37.3%)	29 (31.2%)	0.35
	DME	74 (62.7%)	64 (68.8%)	
History of underlying diseases	Diabetes	28 (23.7%)	28 (30.1%)	0.16
	Hypertension (high blood pressure)	19 (16.1%)	8 (8.6%)	
	Diabetes and hypertension	48 (40.7%)	45 (45.4%)	
	Without underlying diseases	23 (19.5%)	12 (12.9%)	

RVO: retinal vein occlusion; DME: diabetic macular edema

Table 2. The mean and standard deviation for IOP under the application of drug injected

	Bevacizumab (n=118)	Triamcinolone (n=93)
The mean IOP before injections	15.78±3.58	15.79±3.14
The mean IOP at one day after injections	15.28±3.43	15.60±3.44
The mean IOP during one month after injections	15.53±3.35	15.73±3.01

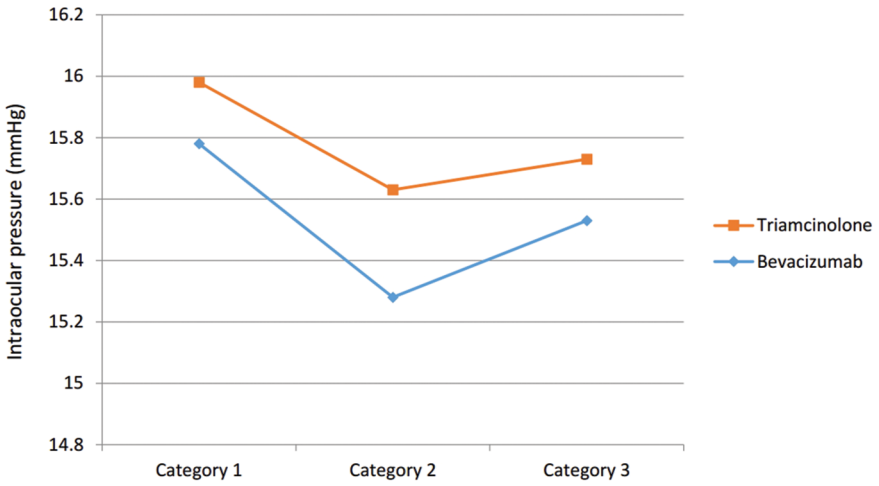

Figure 1. Correlation between IOP and type of injections.

injected drugs and the change processes of blood pressure between and within groups, respectively. The results presented in **Table 3** revealed that the kind of injected drugs caused no significant difference in systolic, diastolic, and mean blood pressure between two groups before and after injection (p>0.05), although it was shown that without considering the kind of injected drugs, significant differences were seen for changes in systolic blood pressure (p=0.017 with F(1.18, 325.5)= 2.13), diastolic blood pressure (p=0.027 with F(1.78, 373.5)=3.83) and mean blood pressure (p=0.001 with F(1.94, 407.01)=10.04) within each groups during before and after injections **(Table 3)**. According to the data inserted in **Table 4**, it can be seen that the mean systolic blood pressure decreases 1 day after injection operations were achieved equal to 18.63 mmHg for bevacizumab and equal to 6.86 mmHg for triamcinolone treatments. On the other hand, the results of drug injections after one month showed that systolic blood pressure

Table 3. Systemic blood pressure process based on the kind of drug injected

		Bevacizumab (n= 118)	Triamcinolone (n= 93)	P^{μ}- value	P^{β}-value
Systolic blood pressure	Before injections	149.59±20.58	141.28±22.64	0.24	0.017
	One day after injections	130.96±17.90	134.42±17.82		
	One month after injections	128.64±18.98	129.85±16.05		
Diastolic blood pressure	Before injections	84.92±13.53	80.43±12.56	0.17	0.027
	One day after injections	76.06±11.65	75.16±8.68		
	One month after injections	74.71±8.46	72.95±8.92		
Mean blood pressure	Before injections	128.03±16.52	120.99±17.62	0.73	0.001
	One day after injections	112.65±14.03	114.66±13.24		
	One month after injections	110.66±13.34	110.88±12.17		

P^{μ}-value: Mann-Whitney U test between groups, P^{β}-value: Mauchly's sphericity test within groups

Table 4. Changes in SBP and DBP after injection operation by the studied drugs

Mean		Bevacizumab (n=118)		Triamcinolone (n=93)	
		Standard deviation	Mean	Standard deviation	
Changes in SBP	First day	-18.63	18.65	-6.86	21.7
	First month	-2.31	20.75	-4.57	18.65
Changes in DBP	First day	-8.85	11.39	-5.26	8.39
	First month	-1.34	8.28	-2.21	7.25

SBP: systolic blood pressure; DBP: diastolic blood pressure

decreases were obtained 2.31 and 3.31 mmHg in the injection of bevacizumab and triamcinolone groups **(Table 4)**.

In this study, the incidence of ocular complications, including subconjunctival hemorrhage, corneal abrasion, and retinal hemorrhage, was investigated after injection operations. According to the obtained results, subconjunctival hemorrhage was observed in six patients (5%) of the group receiving bevacizumab and four patients (4.3%) of the group receiving triamcinolone (generally in 10 patients or 4.7%), and the incidence of corneal abrasion occurred in only three participants (1.4%). On the other hand, retinal hemorrhage was not observed in any of the studied patients of the present study in the one month after injection treatment. Overall, the results showed that ocular complications occurred in only 6.1% of all investigated participants **(Table 5)**.

The findings presented in **Table 6** confirmed that there was no increase in the mean blood sugar in the patients after both drugs injection operations. On the other hand, three patients (1.4%) developed mild facial skin redness (1 in the bevacizumab group and 2 in triamcinolone testosterone) in the treatment of one day after injection. Despite the history of neurological problems in 15 patients (7.1%) at the beginning experiment, the mentioned complications were not observed in any of the participants during one month after drug injection. In addition to the above, myocardial infarction was also observed for two patients (equivalent to 1.7%) in the group receiving bevacizumab during one month after drug injection treatment. The results of this study also revealed that vascular problems of deep vein thrombosis (DVT) and pulmonary thrombi emboli (PTE) were not observed in any of the patients until one month after injection operations. The incidence of systemic events before and after drug injection is listed in **Table 6**. In general, systemic complications were observed in 1.4% of all patients until one month after injection. **Fig. 2** explains the correlation between the blood sugar process and the type of drug injected based on Mauchly's sphericity test. According to **Fig. 2**, it can be seen that there was no significant correlation between blood sugar and drug type (p=0.232 and F(2, 418)=1.47).

DISCUSSION

Overall, the present study observed that the incidence of systemic complications and ocular complications was estimated to be equal to 1.4% and 6.1%, respectively. Maloney et al. showed that the intravitreal injection of bevacizumab did not increase the risk of critical complications of myocardial infarction compared to steroid drugs.[10] On the other hand, based on our findings, myocardial infarction was observed in only two cases in the group receiving bevacizumab. Also, in the present study, there was not only a non-significant increase (slight increase) in the total mean IOP in the period of one month compared to the treatment of one day after drug injection, but also no significant in-

Table 5. Ocular complications after injection operation

	Bevacizumab (n= 118)	**Triamcinolone (n= 93)**	***p*-value**
Subconjunctival hemorrhage	6 (5 %)	4 (4.3 %)	0.218
Corneal abrasion	0	3 (2.5 %)	0.510
Vitreous hemorrhage	0	0	

Table 6. Systemic complications based on the kind of drug injected

		Bevacizumab (n=118)	**Triamcinolone (n=93)**	***P*-value**
Blood sugar (mg/dl)	Before injections	145.3±72.4	152.3±66.8	0.51
	One day after injections	146.4±64.7	160.1±62.1	0.08
	One month after injections	141.98±57.4	142.8±51.82	0.12
Facial skin redness	One day after injections	1 (0.8 %)	2 (2.2 %)	
	One month after injections	1 (0.8 %)	0	
Neurological problems of TIA and CVA	One day after injection	0	0	
	One month after injections	0	0	
Myocardial infarction	One day after injection	0	0	
	One month after injections	2 (1.7 %)	0	
Vascular problems (PTE and DVT)	One day after injection	0	0	
	One month after injections	0	0	

TIA: transient ischemic attack; CVA: cerebral vascular accident; PTE: pulmonary thrombi emboli; DVT: deep vein thrombosis

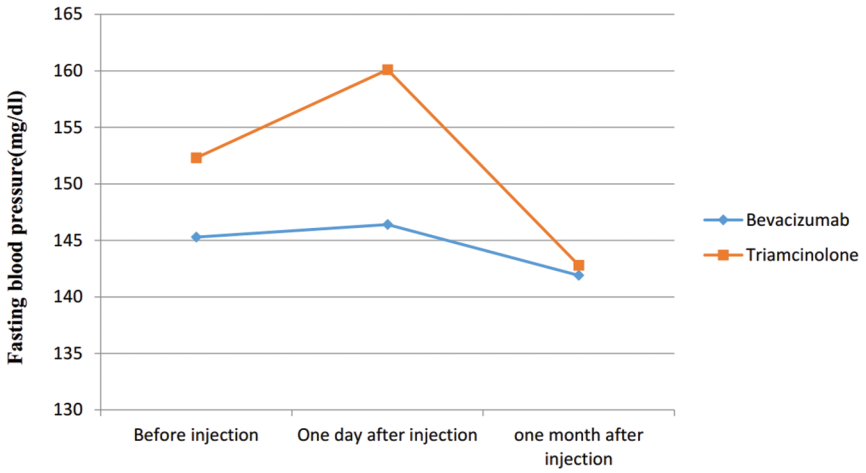

Figure 2. Correlation between blood sugar trends and the kind of drug studied.

crease was observed between the kind of injected drugs and the changes in IOP. Lee et al. found that despite a notable increase in the mean IOP in treatment of 30 minutes after bevacizumab injection, mean IOP decreased significantly in one day and one week after drug injection.[11] On the other hand, an increase in IOP in treatments of one to six months after intravitreal injection of triamcinolone in all patients was reported in a study by Yang et al.[12] It is noteworthy that the previous study had a severe increase in IOP after eight weeks for 30.7% of patients. One of the reasons for the discrepancy between the achieved results of the present study and previous studies (about increasing IOP) may be due to the long-term follow-ups of other studies (regarding the severe increase in IOP after eight weeks).[12]

Also, according to our findings, the occurrence of two cases for facial skin redness (2.2%) was observed one day after drug injection that was detected as the only systemic complication after triamcinolone injection (no increase in systolic blood pressure or ocular pressure). Contrary to our results, Storey et al. reported increases in IOP equal to 13.2% after triamcinolone injection.[13]

In the present study, patients with RVO and DME were assessed equal to 44 (37.3%) and 74 (62.7%) patients for the group receiving bevacizumab and equivalent to 29 (31.2%) 64 (68.8%) patients for the group receiving triamcinolone, respectively. In a similar study by Afrid et al. the mean age was reported in ranges of 61.48±11.21 years and the most common problem for drug injection was diabetic retinopathy (similar to the present study). In addition, the number of injections in the present study in the bevacizumab group was equal to 3.86, which was comparable to injection numbers of the research conducted by Afrid et al.[14]

Our findings also revealed that patients with a history of diabetes, hypertension, and both diabetes and hypertension (**Table 1**) were respectively 56 (26.5%), 27 (12.8%), and 93 (44.1%) patients. In agreement with the above results, histories of hypertension and diabetes mellitus were reported in the study of Prakhar et al. as the highest risk factors for BRVO.[15]

In a clinical trial conducted by Neto et al., the average numbers of drug injections in the groups receiving bevacizumab and triamcinolone were 3.2 and 2.1 times, respectively. On the other hand, the average numbers of the drug injected in this study were 3.91 and 3.8 times for triamcinolone and bevacizumab groups, respectively. Also, although the number of times needed to inject triamcinolone was significantly lower than that for bevacizumab in some other studies[16], the number of times needed to inject triamcinolone was significantly higher than that for bevacizumab in the present study (p<0.001).

In confirmation of our findings, Prakhar et al. reported a significant correlation between gender and the diagnosis of RVO, DME in patients with p=0.004, so that RVO was significantly higher in men than women.[15]

In investigating the correlation between RVO and DME diagnoses with classified age groups, a significant correlation was found with p=0.007 based on the chi-square test, so that the majority of people with RVO and DME were more than 60 years old. Since the aging factor has been reported as a principal risk factor in some studies[17], the higher incidence of these diseases can be justified for people more than 60 years in both studied groups.

We did not find significant correlations between systolic and diastolic blood pressure changes with the type of injected drugs **(Table 3)**. In both groups, systolic and diastolic blood pressure had a decreasing trend, and the rate of reduction in systolic blood pressure was lower in the group receiving triamcinolone in the treatment of one day after drug injection. In confirmation of the above results, Lee et al. found that systemic blood pressure did not increase until one month after the intravitreal injection of bevacizumab, and diastolic blood pressure in patients significantly decreased in the treatment one day after injection.[11] In this study, the mean blood pressure in both groups was higher before injection operations. It should be noted that numerous factors can be involved in this issue, such as injection stress, differences in blood pressure monitor, differences in follow-up times, the study population and one of the most important causes was patient's missing antihypertensive medication before injections.

In general, there was no significant correlation between the classified age groups of patients in the present study and their systemic pressure in one day and one month after drug injections. The results obtained by the investigation of Ntineri et al. explained that with increasing age, especially for people more than 50 years, systemic hypertension increases in patients, which is consistent with our finding concerning the higher prevalence of hypertension in people of older age.[18]

CONCLUSIONS

Considering that systemic complications generally occurred in 1.4% and ocular complications in 6.1% of patients in this study, it seems that intravitreal injections of both drugs act as low-complication medications so that their intravitreal injections can be employed in the treatment of patients with DME and RVO. However, due to the contradictory outcomes of various studies, especially about the effects of these drugs on intraocular pressure and systemic hypertension, both complications require further attention and research with larger sample sizes and extended follow-ups.

Author contribution

M.K.J., M.A., A.A., and M.Y. contributed to the design and implementation of the study, to the analysis of the results, and to the writing of the manuscript.

Data availability

The data used to support the findings of this study are available from the corresponding author upon request.

Conflict the interest

The authors have no conflict of interest to declare.

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Острые системные осложнения интравитреальных инъекций бевацизумаба и триамцинолона – сравнительное исследование

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Резюме

Введение: Макулярный отёк является распространённым угрожающим зрению осложнением у пациентов с диабетической ретинопатией и окклюзией вен сетчатки. Инъекция интравитреальных препаратов, таких как антиваскулярный эндотелиальный фактор роста (анти-VEGF) и кортикостероиды, произвела революцию в лечении этих заболеваний.

Цель: Сравнить и оценить острые системные осложнения интравитреального введения бевацизумаба и триамцинолона у пациентов с диабетической ретинопатией и окклюзией вен сетчатки.

Материалы и методы: В исследование включено 211 пациентов с диабетической ретинопатией и окклюзией вен сетчатки, которым потребовалось интравитреальное введение бевацизумаба и триамцинолона. В этом исследовании 118 пациентов обычно получали интравитреальные инъекции бевацизумаба, а остальные (93 пациента) – инъекции триамцинолона. Экспериментальные данные, в том числе демографические данные, количество инъекций, сопутствующие заболевания в анамнезе, внутриглазное давление и системная гипертензия до и после инъекций, записывались на конкретных формах после групповой классификации. Кроме того, исследовали частоту развития различных осложнений в течение одного месяца после интравитреальных инъекций.

Результаты: В настоящее исследование включено 211 пациентов (средний возраст 62.41±11.34 года, медиана 63 года). Результаты показали отсутствие значимой корреляции между инъекционным препаратом и изменениями повышенного внутриглазного давления (ВГД) (p=0.66). Достоверных различий по системной гипертензии не выявлено ни в одной из исследуемых групп. С другой стороны, частота осложнений, связанных с сахаром в крови, покраснением кожи лица, неврологическими проблемами ТИА (транзиторная ишемическая атака) и сердечно-сосудистых заболеваний, инфарктом миокарда, сосудистыми проблемами после инъекции и глазными осложнениями оценивалась как ноль, 1.4, 0, 0.8, 0 и 6.1% соответственно.

Заключение: В целом результаты показали распространённость системных осложнений в 1.4% и глазных осложнений в 6.1%. Соответственно, кажется, что интравитреальные инъекции обоих препаратов, изученных в настоящем исследовании, относятся к группе препаратов с низким уровнем осложнений.

Ключевые слова

бевацизумаб, осложнение, макулярный отёк, системный, триамцинолон