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Clinical Observation of Recombinant Bovine Basic Fibroblast Growth Factor Eye Gel Combined with Tobramycin Dexamethasone Eye Drops in the Treatment of Dry Eye Syndrome in Patients after Cataract Surgery

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Abstract: *Objective:* To evaluate the therapeutic effect of recombinant bovine basic fibroblast growth factor (rbFGF) eye gel combined with tobramycin-dexamethasone (TOB-Dex) eye drops on dry eye syndrome (DES) after cataract surgery. *Methods:* 86 patients with DES after cataract surgery, admitted from November 2021 to November 2023, were randomly divided into groups. The observation group included 43 patients treated with rbFGF eye gel combined with TOB-Dex eye drops. The reference group included 43 patients treated with TOB-Dex eye drops alone. Multiple indicators, including total effective rate and clinical symptom scores, were compared between the two groups. *Results:* The total effective rate in the observation group was higher than in the reference group ($P < 0.05$). Before treatment, there were no differences in clinical symptom scores, serum factors, or disease severity scores between the two groups ($P > 0.05$). Three weeks after treatment, the observation group had lower clinical symptom scores, serum factors, and disease severity scores compared to the reference group ($P < 0.05$). The adverse reaction rate in the observation group was lower than in the reference group ($P < 0.05$). *Conclusion:* rbFGF eye gel combined with TOB-Dex eye drops can improve the clinical efficacy for patients with DES after cataract surgery, alleviate disease symptoms, reduce inflammatory responses, and have fewer adverse reactions.

Keywords: Recombinant bovine basic fibroblast growth factor eye gel; Tobramycin-dexamethasone eye drops; Cataract surgery; Dry eye syndrome

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1. Introduction

The high incidence of cataracts is related to factors such as population aging, dietary structure adjustments, and environmental changes. Typical symptoms include decreased vision, blurred vision, and refractive changes. Surgery is a common treatment method, with various techniques like phacoemulsification and intraocular

lens implantation used to remove lesions and restore the physiological function of the lens, achieving a high success rate [1,2]. However, the mechanical stimulation from these surgical techniques can damage corneal endothelial function, leading to complications like corneal edema or dry eye syndrome (DES), affecting long-term outcomes. Therefore, tobramycin-dexamethasone (TOB-Dex) eye drops are often used postoperatively to improve the blood-aqueous barrier function, block the rapid proliferation of epithelial cells, and exert anti-inflammatory effects. Combined with recombinant bovine basic fibroblast growth factor (rbFGF) eye gel, it can significantly improve corneal edema and relieve DES symptoms, showing a synergistic effect with TOB-Dex eye drops [3]. Based on this, this study selected 86 patients with DES after cataract surgery to evaluate the therapeutic effects of rbFGF eye gel combined with TOB-Dex eye drops.

2. Materials and methods

2.1. General information

From November 2021 to November 2023, 86 patients with DES following cataract surgery were admitted to the hospital. They were randomly divided into two groups using a random number table. The observation group consisted of 43 patients, with a male-to-female ratio of 25:18; the age range was 41 to 69 years, with an average age of 56.94 ± 4.12 years; the disease course ranged from 3 weeks to 6 months, with an average of 3.05 ± 0.47 months. The reference group also consisted of 43 patients, with a male-to-female ratio of 26:17; the age range was 40 to 68 years, with an average age of 56.72 ± 4.27 years; the disease course ranged from 2 weeks to 6 months, with an average of 3.09 ± 0.37 months. There was no significant difference between the groups ($P > 0.05$).

Inclusion criteria: Diagnosed with cataracts through ophthalmic examination; met surgical indications; post-surgery DES symptoms such as dry eyes and foreign body sensation; Schirmer's test results showing tear secretion less than 10 mm/5 min; normal communication ability; tear film breakup time (TFBUT) less than 10 seconds; clear consciousness.

Exclusion criteria: Combined with other eye diseases; diagnosed with primary DES; accompanied by organ or tissue lesions; allergic to study medications; combined with consciousness disorders; withdrew from the study midway.

2.2. Methods

Both groups underwent phacoemulsification combined with intraocular lens implantation. Postoperatively, the reference group was treated with TOB-Dex eye drops: 8 times daily for the first week, 6 times daily for the second week, and 4 times daily for the third week, with 1–2 drops each time. In addition to this regimen, the observation group also applied rbFGF eye gel postoperatively, applying a small amount of gel to the affected area three times daily for 3 weeks.

2.3. Observation indicators

(1) Clinical symptom scores: A 4-grade scoring method was used, including conjunctival hyperemia, tearing, anterior chamber inflammation, and photophobia, with scores ranging from 0 to 3 for each symptom, with higher scores indicating more severe symptoms.

(2) Serum factors: Before treatment and after 3 weeks of medication, 4 mL of fasting venous blood was collected, centrifuged for 10 minutes at 3,000 rpm, and the serum was separated. Procalcitonin (PCT) was measured using electrochemiluminescence; interleukin-6 (IL-6), tumor necrosis factor-α (TNF-α),

and IL-4 were measured using enzyme-linked immunosorbent assay (ELISA).

(3) Disease severity scores: The corneal fluorescein staining score (FL) was used: no corneal epithelial staining scored 0–3, punctate staining scored 4–7, and patchy staining scored 8–10. The Ocular Surface Disease Index (OSDI) was also used, which includes 12 items in three categories: ocular symptoms (3 items), visual function (6 items), and environmental triggers (3 items). Each item is scored from 0 to 4. The total score is calculated as the sum of all item scores ÷ number of items answered × 25, with a maximum score of 100. Higher scores indicate more severe disease.

(4) Adverse reactions: These include rash, nausea and vomiting, anorexia, and headache.

2.4. Evaluation criteria for efficacy

(1) Cured: Symptoms disappeared, and slit-lamp examination showed tear secretion infiltrating filter paper over 10 mm.

(2) Significantly effective: Symptoms significantly improved, with tear secretion infiltrating filter paper 5–10 mm.

(3) Effective: Symptoms improved, with tear secretion infiltrating filter paper less than 5 mm.

(4) Ineffective: No change in symptoms or slit-lamp examination results.

2.5. Statistical analysis

Data were processed using SPSS 28.0 software. Measurement data were compared and tested using *t*-tests, while count data were compared and tested using χ^2-tests. Statistical significance was set at $P < 0.05$.

3. Results

3.1. Comparison of total effective rate between the two groups

Table 1 shows that the total effective rate in the observation group was higher than that in the reference group ($P < 0.05$).

Table 1. Comparison of total effective rate between the two groups [*n* (%)]

Group	Cured	Significantly effective	Effective	Ineffective	Total effective rate
Observation group ($n = 43$)	21 (48.84)	15 (34.88)	6 (13.95)	1 (2.33)	42 (97.67)
Reference group ($n = 43$)	18 (41.86)	10 (23.26)	7 (16.28)	8 (18.60)	35 (81.40)
χ^2	-	-	-	-	6.081
P	-	-	-	-	0.014

3.2. Comparison of clinical symptom scores between the two groups

As shown in **Table 2**, before treatment, there was no significant difference in clinical symptom scores between the two groups ($P > 0.05$). After 3 weeks of treatment, the clinical symptom scores in the observation group were lower than those in the reference group ($P < 0.05$).

3.3. Comparison of serum factors between the two groups

Before treatment, there was no significant difference in serum factors between the two groups ($P > 0.05$). After 3 weeks of treatment, the serum factor levels in the observation group were lower than those in the reference group ($P < 0.05$). See **Table 3** for more details.

Table 2. Comparison of clinical symptom scores between the two groups before and after treatment (mean ± SD; points)

Group	Conjunctival hyperemia		Tearing		Anterior chamber inflammation		Photophobia	
	Before	After	Before	After	Before	After	Before	After
Observation group (n = 43)	2.03 ± 0.37	0.38 ± 0.11	2.01 ± 0.35	0.60 ± 0.17	1.97 ± 0.37	0.22 ± 0.08	2.34 ± 0.35	1.02 ± 0.29
Reference group (n = 43)	2.04 ± 0.32	0.57 ± 0.19	1.98 ± 0.38	0.89 ± 0.19	1.99 ± 0.39	0.39 ± 0.10	2.31 ± 0.38	1.33 ± 0.31
t	0.134	5.675	0.381	7.459	0.244	8.705	0.381	4.789
P	0.894	0.000	0.704	0.000	0.808	0.000	0.704	0.000

Table 3. Comparison of serum factors between the two groups before and after treatment (mean ± SD)

Group	PCT (μg/L)		IL-6 (ng/L)		TNF-α (pg/ml)		IL-4 (μg/L)	
	Before	After	Before	After	Before	After	Before	After
Observation group (n = 43)	3.22 ± 0.37	0.21 ± 0.09	1,325.95 ± 81.32	311.67 ± 18.24	288.68 ± 24.61	127.81 ± 15.32	3.31 ± 0.41	1.03 ± 0.27
Reference group (n = 43)	3.24 ± 0.35	0.38 ± 0.10	1,326.66 ± 82.08	567.39 ± 24.09	287.81 ± 23.84	203.65 ± 18.92	3.34 ± 0.45	1.48 ± 0.31
t	0.258	8.286	0.040	55.495	0.167	20.428	0.323	7.178
P	0.797	0.000	0.968	0.000	0.868	0.000	0.747	0.000

3.4. Comparison of disease severity scores between the two groups

Before treatment, there was no significant difference in disease severity scores between the two groups (P > 0.05). After 3 weeks of treatment, the disease severity scores in the observation group were lower than those in the reference group (P < 0.05), as shown in **Table 4**.

Table 4. Comparison of disease severity scores between the two groups before and after treatment (mean ± SD; points)

Group	FL score		OSDI score	
	Before	After	Before	After
Observation group (n = 43)	8.32 ± 1.29	4.15 ± 0.74	48.59 ± 4.30	19.28 ± 2.06
Reference group (n = 43)	8.35 ± 1.30	6.11 ± 0.79	48.51 ± 4.27	23.71 ± 2.17
t	0.107	11.874	0.087	9.709
P	0.915	0.000	0.931	0.000

3.5. Comparison of adverse reaction rates between the two groups

Table 5 shows that the adverse reaction rate in the observation group was lower than that in the reference group (P < 0.05).

Table 5. Comparison of adverse reaction rates between the two groups [*n* (%)]

Group	Rash	Nausea and vomiting	Anorexia	Headache	Incidence rate
Observation group (*n* = 43)	0 (0.00)	1 (2.33)	0 (0.00)	1 (2.33)	2 (4.65)
Reference group (*n* = 43)	1 (2.33)	3 (6.98)	1 (2.33)	3 (6.98)	8 (18.60)
χ^2	-	-	-	-	4.074
P	-	-	-	-	0.044

4. Discussion

Cataracts are a common eye disease in middle-aged and elderly populations, characterized by protein clouding in the lens and metabolic abnormalities in the lens, often accompanied by symptoms such as blurred vision and visual field defects, and they have a high risk of causing blindness [4,5]. Currently, surgical treatments like phacoemulsification are the primary therapies for this condition. These procedures can remove the diseased lens and restore visual function through artificial lens implantation, achieving high surgical efficacy. However, these operations can reduce membrane stability, damage the mucin layer of the membrane, and lead to dysfunction of the limbal stem cells, inducing complications such as dry eye syndrome (DES) and thereby reducing postoperative visual quality [6].

TOB-Dex eye drops are commonly used to treat postoperative DES. This compound preparation contains tobramycin and dexamethasone, offering excellent anti-infective and anti-inflammatory effects, which help prevent postoperative inflammatory reactions and reduce eye damage after cataract surgery. However, the overall effectiveness of this medication when used alone is generally moderate, making it difficult to rapidly and stably improve disease symptoms [7]. The active ingredient in the rbFGF eye gel is the recombinant bovine basic fibroblast growth factor, which can accelerate cellular repair processes, promote cell regeneration, enhance lacrimal gland function, and repair damaged ocular cells, thus fundamentally treating DES. The synergistic mechanism of these two combined medications is robust, providing multi-target, multidimensional therapeutic effects, significantly improving DES symptoms [8].

The results indicate that the total effective rate in the observation group was higher than that in the reference group. After three weeks of treatment, the clinical symptom scores, serum factor levels, disease severity scores, and adverse reaction rates in the observation group were all lower than those in the reference group ($P < 0.05$). The reason is that the rbFGF eye gel can effectively bind to the target cells of eye damage, activating the eye's autonomous repair system and promoting rapid differentiation and proliferation of corneal cells, thereby enhancing their self-repair capabilities and alleviating symptoms such as corneal edema [9]. TOB-Dex eye drops, which are antibiotic and corticosteroid medications, have anti-edema and anti-inflammatory effects that also improve corneal edema. The combination of the two medications utilizes various pharmacological mechanisms to exert therapeutic effects, thereby enhancing efficacy and alleviating disease symptoms [10]. Previous studies have found that the pathogenesis of DES is highly related to oxidative stress responses; surgery can increase ocular reactive oxygen species, leading to the overproduction of lipids and elevating the content of oxygen free radicals, thus accelerating the damage to ocular surface tissue cells [11]. The combined medication efficiently fights inflammation while maintaining a relatively moist ocular environment, prolonging drug efficacy and increasing drug concentration in the operated eye, thereby significantly improving inflammatory responses and lowering serum factor levels. More importantly, both drugs are topical treatments and biological preparations, with high bioavailability when administered as eye drops. This accelerates cell regeneration in the mesoderm and ectoderm, maintaining high local drug concentrations in the operated eye without significant toxicity or

first-pass effect, resulting in fewer adverse reactions [12].

In conclusion, the combination of rbFGF eye gel and TOB-Dex eye drops can alleviate symptoms of postoperative DES in cataract patients, reduce disease severity, and lessen inflammatory responses, offering high therapeutic safety and efficacy. These medications can be used as a common treatment for postoperative care in cataract surgery.

Disclosure statement

The authors declare no conflict of interest.

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