Original Article

Effect of sodium hyaluronate eye drops combined with tobramycin, dexamethasone and pranoprofen eye drops in the treatment of dry eye after phacoemulsification

Hongwei Lu, Yongqing Guan, Yudan Su, Na Nan, Yazhen Yuan

Purpose: To investigate the clinical effect of sodium hyaluronate eye drops combined with tobramycin, dexamethasone, and pranoprofen eye drops in the treatment of dry eye after phacoemulsification. **Methods:** Medical records of 188 patients with dry eye after phacoemulsification, treated in our hospital from August 2020 to August 2021, were included and divided into groups based on the type of dry eye treatment. Patients in the control group (n = 90) were treated with tobramycin, dexamethasone, and pranoprofen eye drops. Patients in the test group (n = 98) were treated with sodium hyaluronate, tobramycin, dexamethasone, and pranoprofen eye drops. The tear secretion test (TST), film rupture time (BUT), corneal fluorescence staining (FS) score, levels of interleukin (IL)-6, and tumor necrosis factor (TNF)-α before the treatment and at 1 month follow-up, the overall total effective rate and the number of completely cured cases were compared between the two groups. Multiple linear regression was used to calculate coefficients for predicting clinical variables. Ordinal logistic regression was used to compute coefficients and odds ratios for predicting effective scores. **Results:** The total effective rate in the observation group (99%) was significantly higher than that in the control group (80.00%). After the treatment, the TST and BUT indexes of the observation group were higher compared to the control group, and the FS score of the observation group was lower than that of the control group. TNF-α and IL-6 levels of the observation group were lower compared to the control group. Logistic regression analysis demonstrated that the differences in the effective rate and clinical variables between the two groups remained significant after adjusting for the effect of age. **Conclusion:** A combination of sodium hyaluronate, tobramycin, dexamethasone, and pranoprofen eye drops for the treatment of dry eye after phacoemulsification can improve the curative effect, reduce corneal fluorescein staining and inflammatory factor index levels compared to the treatment regimen lacking sodium hyaluronate eye drops.

Key words: Phacoemulsification cataract extraction, pranoprofen eye drops, sodium hyaluronate eye drops, tobramycin dexamethasone, xerophthalmia

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Phacoemulsification is considered a routine treatment for cataract and can effectively improve the patient's condition. However, the surgery may cause direct damage to the ocular surface, resulting in corneal nerve cross-section and loss of goblet cells and leading to dry eye.[1,2] Previous studies showed that the incidence of dry eye after phacoemulsification is about 9.8% and that it causes symptoms such as eye dryness, photophobia, and feeling of a foreign body that can complicate the recovery.[3] Therefore, it is important to prevent and treat dry eyes after Phacoemulsification. Dry eye treatment methods include artificial tears and anti-inflammatory eye drops, usually applied independently. Whereas these treatments can improve the symptoms, their effect is not ideal.[4] Other treatments for dry eye include gland transplantation and lacrimal duct embolization,[5–8] but the treatment processes are complex and can cause secondary eye trauma, which is not conducive to the recovery of postoperative vision. Combined medication regimens have been used in the treatment of dry eye after phacoemulsification, but evidence of their effectiveness is scarce. The usual combination includes tobramycin/dexamethasone eye drops that are mainly composed of antibiotics and glucocorticosteroids combined for their anti-inflammatory effect.[9] Pranoprofen is a non-steroidal anti-inflammatory medication available as eye drops and is often used following phacoemulsification to promote wound healing.[10] Sodium hyaluronate eye drops are a form of artificial tears that moisturize the conjunctiva and corneal epithelium.[11] Previous studies demonstrated that the postoperative use of sodium hyaluronate improves the symptoms and signs of dry eye syndrome after cataract surgery.[12] The main goal of the current retrospective study is to assess the effectiveness of adding sodium hyaluronate eye drops to tobramycin/dexamethasone

Departments of Ophthalmology the Fourth Hospital of Hebei Medical University, Shijiazhuang City, Hebei Province, China

Correspondence to: Dr. Yazhen Yuan, Departments of Ophthalmology the Fourth Hospital of Hebei Medical University, 12 Jiankang Road, Shijiazhuang City, Hebei Province - 050000, China. E-mail: ssylhw4343@163.com

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eye drops and pranoprofen in phacoemulsification patients with postoperative dry eye, compared to patients that are treated with the regimen lacking sodium hyaluronate.

Methods

Medical records of 188 patients with dry eye after phacoemulsification, treated in our hospital from August 2020 to August 2021, were retrospectively divided into the control group (90 patients treated with tobramycin, dexamethasone, and pranoprofen eye drops) and the test group (98 patients treated with sodium hyaluronate, tobramycin, dexamethasone, and pranoprofen eye drops). All patients adjusted the dosage according to the symptoms and continued to use the medications for 4 weeks.

Treatment protocols are summarized in Table 1. Tobramycin dexamethasone eye drops were obtained from ALCON-COUVREURN.V., Rijksweg, Belgium; H20150119; the pranoprofen eye drops were obtained from Senju Pharmaceutical, Fukusaki, Japan; H20130682; the sodium hyaluronate eye drops were obtained from Nengden factory of Shentian Pharmaceutical, China; H20171192.

In cases of adverse reactions such as blepharitis and eyelid dermatitis, patients were instructed to stop the medication.

The detailed list of inclusion and exclusion criteria is reported in Table 2.

The Medical Ethics Association of our college approved this study (no. 2021KY308, date: 2021-11-25).

Collection indicators and efficacy evaluation

We extracted basic patient information and the following related indicators 1 month after the operation from the patient records: (1) TST results, tear break-up time (BUT), and corneal fluorescence staining (FS) score; (2) levels of serum tumor necrosis factor (TNF-α) and interleukin-6 (IL-6) before and 1 month after treatment; (3) clinical efficacy evaluation criteria.

Table 1: Treatment regimen

Drug (concentration)	Dosage (drops)	Times/day
Tobramycin (15 mg)/dexamethasone (5 mg)	1-2	4
Pranoprofen (1 mg/ml)	1-2	4
0.3% Sodium hyaluronate (0.4 ml/1.2 mg)	1-2	5-6

Table 2: Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Meeting the diagnostic criteria for dry eye after phacoemulsification[13]	Intraoperative posterior capsule rupture and severe decompensation of corneal function
Aged 40 to 80 years	Other conjunctival, corneal, and iris diseases
Recorded avoidance of drugs that could affect the studied outcome	Sjogren's syndrome, rheumatoid arthritis, mental diseases
Availability of complete medical records	Loss to follow-up

To assess the TST, the examiner folded the 5-mm end of a tear detection filter paper and inserted it into a third of the conjunctival sac. The patient was instructed to close the eyes for five minutes, and the examiner measured the moist length of the filter paper and recorded the data.

To assess the tear BUT, the examiner instilled one drop of 2% fluorescein into the conjunctival sac of the eye and asked the patient to blink three times, keep the eyes open, and look straight ahead while the examiner scanned the cornea with a cobalt blue light and measured the time from the last blink to tear film rupture.

The FS score was calculated after corneal fluorescence staining through a slit lamp cobalt blue light (no staining, zero points; little visible staining, one point; moderately visible staining, two points; abundantly visible staining, three points).

TNF-α and IL-6 levels were measured as follows: 3 ml of venous blood was collected under fasting conditions, and centrifuged for 15 minutes at a rate of 3000 rpm, with a centrifugation radius of 8 cm. The plasma was separated, and the levels of TNF-α and IL-6 in the serum were measured by the enzyme-linked immunosorbent assay. The appropriate kits were purchased from Wuhan bode Biotechnology Co., Ltd.

We stratified the clinical efficacy of the treatments into three classes: cure (disappearance of all symptoms; TST >10 mm; FS score of zero), highly effective treatment (significant reduction of symptoms; 10 mm ≥ TST ≥ 5 mm; FS score of one); moderately effective treatment (reduced symptoms; TST <5 mm; FS score of two); and ineffective treatment (no improvement in symptoms; TST <5 mm; FS score of 3). The effective rate was calculated as follows:

Effective rate = (number of cures + number of highly effective treatments + number of moderately effective treatments)/total number of patients × 100%.

Sample size calculations

The sample size was calculated to test the superiority of the test treatment over the control group. A binary outcome of the effective score (cured, highly effective, or moderately effective vs. ineffective) was the primary outcome of interest, with the effect size based on the difference in proportions of the effective score between the two groups. The significance level (α) and power were set at 0.05 and 0.80, respectively. The total calculated sample size was 170 and 85 for each group.

Statistical analysis

Statistical analyses were performed using R software version 4.1.2.[14] Binary and categorical variables were presented as counts, and % of total and comparisons were made using Chi-square tests. Continuous variables were presented as mean and ± standard deviation (SD), and comparisons were made using two-tailed independent samples t-tests for inter-group (i.e. test vs. control) comparisons and two-tailed paired sample t-tests for intra-group (i.e., before vs. after treatment) comparisons. The study group, along with any general variable that was significant between the groups, was included as independent variables in regression models for predicting clinical variables and effective scores. Multiple linear regression was used to compute coefficients for predicting clinical variables. Ordinal logistic regression was used to compute coefficients and odds ratios for predicting effective

scores. For all tests, *P* values <0.05 were considered statistically significant.

Results

Medical records of 188 patients (90 in the control group and 98 in the test group) were included in the study. As shown in Table 3, the control group included 48 male and 42 female patients with an average age of 61.4 (±10.0) years and an average course of the disease of 3.7 (±2.7) years. The test group included 54 men and 44 women with an average age of 64.0 (±8.0) years and an average course of the disease of 4.1 (±2.7) years. We found that patients in the test group were significantly older than patients in the control group ($P < 0,05$).

As summarized in Table 3, there was no difference in terms of TST, BUT, and FS scores, and the levels of TNF-α and IL-6 between the two groups before the treatment ($P > 0.05$). One month after the treatment, whereas TST and BUT scores in both groups were significantly higher than before the treatment ($P < 0.001$), these indexes were markedly higher in the test group (113.1% change compared to a 60.1% increase in the control group; Table 4). FS scores and the levels of TNF-α and IL-6 in both groups decreased after the treatment ($P < 0.001$). However, these indexes were significantly lower in patients that were treated with sodium hyaluronate, tobramycin, dexamethasone, and pranoprofen eye drops as compared to the control group [$P < 0.001$; Table 4].

We next evaluated the effective scores of patients in both groups. As summarized in Table 4, treatment with sodium hyaluronate, tobramycin, dexamethasone, and pranoprofen eye drops was associated with significantly higher effective scores, compared to treatment with sodium hyaluronate, tobramycin, and dexamethasone only (99% in the test group vs 88.9% in the control group; $P = 0.03$). Moreover, the treatment scheme of the test group resulted in the highest rate of cured patients compared to the control group, with 36.7% of completely cured patients vs 22.2% in the control group ($P = 0.033$), indicating that the test group had significantly better treatment outcomes [Table 5 and Fig. 1].

Because age was significantly associated with the study group, we used logistic regression to adjust for age in the association between the group and each clinical variable. As shown in Table 6, even when adjusted for age, TST, and BUT indexes, FT score and the levels of TNF-α and IL-6 remained strongly associated with the mode of treatment. Similarly, ordinal logistic regression demonstrated that when adjusted for age, the treatment scheme of the test group was significantly associated with having a higher effective score after the treatment [Table 7]. When the study group was used as an independent variable and adjusted for age, the test group was a strong predictor of both a significantly higher effective rate and a higher rate of complete cure [Table 8].

Table 3: Comparison of general variables between the test group and the control group

	Units	Test group (*n*=98)	Control group (*n*=90)	*P*
Age	years	64.0 (8.0)	61.4 (10.0)	0.045*
Gender	male	54 (55.1)	48 (53.3)	0.808
Course of disease	years	4.1 (2.7)	3.7 (2.4)	0.278

All general variables were compared between cases in the test group and cases in the control group, with *P*<0.05 considered statistically significant*. The binary variable is displayed as *n* (%) and compared using a Chi-square test. Continuous variables are displayed as mean (± SD) and compared using a two-tailed independent sample t-test

Discussion

In this study, sodium hyaluronate combined with tobramycin, dexamethasone, and pranoprofen eye drops were used to treat

Table 4: Comparison of clinical variables before and one month after the treatment among the test group (*n*=98) and the control group (*n*=90)

	Group	Before treatment	After treatment	% change	*P*
TST (mm/5 min)	Test	4.45 (0.90)	9.48 (2.23)	113.1	<0.001**
	Control	4.34 (1.07)	6.96 (2.90)	60.1	<0.001**
	P	0.468	<0.001*		
BUT (s)	Test	5.44 (1.12)	9.51 (1.53)	74.9	<0.001**
	Control	5.46 (1.27)	8.30 (1.39)	52.1	<0.001**
	P	0.924	<0.001*		
FS (score)	Test	1.92 (0.59)	0.65 (0.54)	−66.0	<0.001**
	Control	2.03 (0.57)	1.07 (0.86)	−47.5	<0.001**
	P	0.175	<0.001*		
TNF-α (pg/mL)	Test	47.65 (4.61)	30.04 (4.14)	−37.0	<0.001**
	Control	46.53 (5.02)	34.02 (4.94)	−26.9	<0.001**
	P	0.112	<0.001*		
IL-6 (pg/mL)	Test	28.65 (3.95)	15.52 (3.39)	−45.8	<0.001**
	Control	27.80 (4.42)	17.68 (3.77)	−36.4	<0.001**
	P	0.164	<0.001*		

All clinical variables were compared before and 1 month after treatment in the test group and the control group. For intra-group analysis, continuous variables are displayed as mean (±SD) and compared using a two-tailed independent samples *t*-test; *P*<0.05 is considered statistically significant*. For inter-group analysis, continuous variables are displayed as mean (±SD) and compared using a two-tailed paired sample *t*-test; *P*<0.05 is considered statistically significant**. % change indicates the difference in mean values before and one month after treatment

Table 5: Comparison of the frequency of effective scores among cases between the test group and the control group

	Test group (*n*=98)	Control group (*n*=90)	χ^2	*P*
Effective score				
Cured	36 (36.7)	20 (22.2)	13.444	0.004*
Highly effective	58 (59.2)	53 (58.9)		
Moderately effective	3 (3.1)	7 (7.8)		
Ineffective	1 (1.0)	10 (11.1)		
Effective‡	97 (99.0)	80 (88.9)	8.672	0.003*
Cured†	36 (36.7)	20 (22.2)	4.724	0.030*

Effective scores are compared between cases in the test group and cases in the control group, with *P*<0.05 considered statistically significant*. Effective score frequencies are displayed as *n* (%) for each category and compared using a Chi-square test. ‡The effective category includes cases rated as cured, highly effective, and moderately effective as compared to ineffective. †The cured category includes cases rated as cured as compared to all other cases

Table 6: Prediction of clinical variables 1 month after treatment based on study group (test vs. control) and age

	Independent variables	Coefficient	*P*
TST (mm/5 min)	Group (test vs. control)	2.970	<0.001*
	Age	-0.168	<0.001*
BUT (s)	Group (test vs. control)	1.366	<0.001*
	Age	−0.058	<0.001*
FS (score)	Group (test vs. control)	−0.527	<0.001*
	Age	0.043	<0.001*
TNF-α (pg/mL)	Group (test vs. control)	−4.186	<0.001*
	Age	0.077	0.037*
IL-6 (pg/mL)	Group (test vs. control)	−2.331	<0.001*
	Age	0.065	0.025*

Study group as an independent variable adjusted for age in the prediction of clinical variables one month after treatment. Coefficients are calculated using linear regression, with *P*<0.05* considered statistically significant

Table 7: Prediction of effective score based on study group (test vs. control) and age

Regression model	OR (95% CI)	Coefficient	*P*
Study group	2.61 (1.45-4.79)	0.960	0.002*
Study group	5.58 (2.86-11.36)	1.719	<0.001*
Age	0.86 (0.82-0.90)	−0.149	<0.001*

Study group as an independent variable unadjusted (model 1) and adjusted for age (model 2) in the prediction of effective score 1 month after treatment. Coefficients and odds ratios are calculated using ordinal logistic regression, with *P*<0.05* considered statistically significant

dry eyes after phacoemulsification. We found that this scheme was associated with a significantly improved effective rate and curative effect. The addition of sodium hyaluronate to the standard treatment regimen resulted in a reduced corneal FS score, markedly improved TST and BUT indexes, and reduced inflammation as compared to the treatment with tobramycin dexamethasone and pranoprofen eye drops.

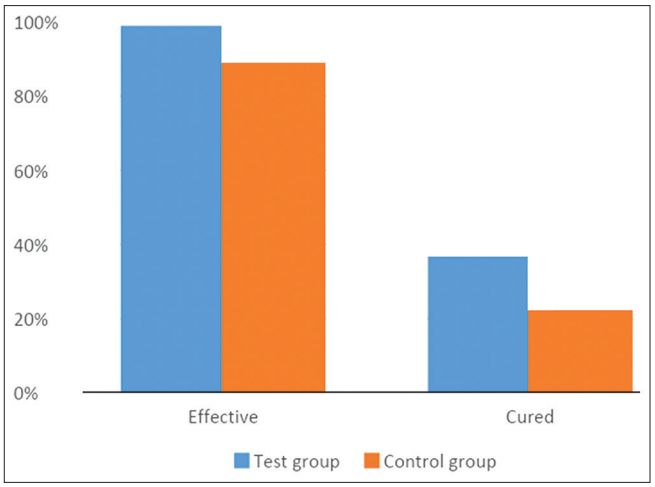

Figure 1: Comparison of percentages of effective scores and cured scores between study groups. Effective includes cases with cured, highly effective, or moderately effective scores as a % of total cases. Cured indicates cured cases as a % of total cases

Postoperative dry eye after cataract surgery remains one of the main obstacles to patient satisfaction.[15,16] The study by Asbell *et al*.[17] showed that dry eye after phacoemulsification is caused both by corneal and conjunctival damage and by inflammatory factors that are secreted during the surgical procedure. After phacoemulsification, the number of tears and the lactoferrin content are reduced, resulting in lymphocyte infiltration of the conjunctival tissues and lacrimal gland and increased production of inflammatory factors. These factors can directly cause irritating damage to the ocular surface, causing excessive evaporation of the tear film and dry eye. Therefore, when treating dry eye after phacoemulsification, there is a need for artificial tear supplement treatment and an anti-inflammatory agent to promote incision healing, improve the curative effect and the symptoms related to the dry eye, and promote the effective recovery of the eye function. In patients after phacoemulsification, the standard treatment scheme routinely includes a combination of tobramycin dexamethasone teardrops and pranoprofen. Tobramycin dexamethasone tear drops contain mostly tobramycin (an antibiotic) and dexamethasone (a glucocorticoid). This combination has good anti-inflammatory effects that accelerate incision healing. Pranoprofen is a non-steroidal anti-inflammatory agent available as eye drops. It can reduce inflammatory reactions and prolong the tear film rupture time, thereby alleviating dry eye-related symptoms. Sodium hyaluronate eye drops are artificial tears that can supplement the endogenous tears to form an artificial protective film on the surface of the eye, wet the eyes, and promote tear film repair.[18]

TST and BUT are the main indexes used to detect tear secretion function during ophthalmological eye examinations. They reflect the tear secretion function and tear film stability[19,20] Corneal fluorescence staining (FS) is a common test to check the integrity of the corneal epithelial cell layer and can identify dry eye lesions.[21] Levels of TNF-α and IL-6 are commonly used as markers of inflammation control.[22,23] Gao *et al*.[24] evaluated the effectiveness of the postoperative treatment of phacoemulsification dry eye using the combination of tobramycin and dexamethasone and found that TST, BUT,

Table 8: Prediction of effective and cured categories based on study group (test vs. control) and age

	Independent variables	OR (95% CI)	Coefficient	*P*
Effective‡	Group (test vs. control)	15.20 (2.59-291.12)	2.721	0.013*
	Age	0.78 (0.65-0.89)	−0.248	0.002*
Cured†	Group (test vs. control)	3.92 (1.82-9.04)	1.365	0.001*
	Age	0.88 (0.84-0.92	−0.127	<0.001*

Study group as an independent variable adjusted for age in the prediction of effective and cured categories. Odds ratios and coefficients are calculated using logistic regression, with $P<0.05$* considered statistically significant. ‡The effective category includes cases rated as cured, highly effective, and moderately effective as compared to ineffective. †The cured category includes cases rated as cured as compared to all other cases

and FS scores significantly improved after the treatment. Meta-analysis by Wen *et al*.[25] showed that for the patients with dry eye after the cataract surgery, the addition of sodium hyaluronate to the conventional treatment regimen was highly effective in improving the dry eye symptom scores and BUT and FS indexes. These results are in agreement with our observations that the addition of sodium hyaluronate to the treatment regimen significantly improves TST and BUT indexes and reduces FS scores in postoperative patients. Moreover, higher coefficients and more significant *P* values of the age-adjusted TST, BUT, and FS scores in our study indicate that the treatment effect becomes even more pronounced when accounting for the effects of age. Similarly, when corrected for age, the effect of sodium hyaluronate becomes markedly stronger in terms of reducing inflammation in postoperative patients with dry eye. Studies show that when combined, sodium hyaluronate, tobramycin, dexamethasone, and pranoprofen act synergistically to reduce the ocular inflammatory response and shorten the incision healing time, thus keeping the eyes moist, promoting corneal and conjunctival repairs, and improving the ocular circulation, to achieve an optimal curative effect.[26,27] Consistently with these observations, we found that the addition of sodium hyaluronate to the post-phacoemulsification treatment regimen was associated with a markedly improved effective rate in patients with postoperative dry eye. Moreover, it resulted in an over 1.8-fold increase in the rate of complete cure as compared to patients who received the conventional treatment with tobramycin, dexamethasone, and pranoprofen only. The results of logistic regression analysis showed that the effect of sodium hyaluronate becomes more pronounced when the effective rate and the curative effect of both groups are adjusted for age.

Limitation of the study

This study was retrospective. We only analyzed data from 188 patients, and the follow-up period was short. This may introduce a bias that may render our conclusion one-sided. Further studies with larger sample sizes and longer follow-ups are needed.

Conclusion

Combined treatment with sodium hyaluronate, tobramycin, dexamethasone, and pranoprofen eye drops is effective for the treatment of dry eye after phacoemulsification. TST, BUT, and FS scores, the inflammatory factor levels, and the total effective and curative rates are improved after the treatment. Our results may provide information that can be used to improve the treatment of dry eye after phacoemulsification.

Ethics

The Medical Ethics Association of our college approved this study (no. 2021KY308, date: 2021-11-25).

The procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional or regional) and with the Helsinki Declaration of 1975, as revised in 2000.

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Conflicts of interest

There are no conflicts of interest.

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