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Evaluation of Efficacy and Safety of Platelet-Rich Plasma Eye Drops in Patients with Dry Eye Syndrome

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Abstract

Objective: To explore the clinical efficacy and safety of autologous platelet-rich plasma (PRP) eye drops in treating moderate to severe dry eye syndrome (SS). **Method:** A prospective randomized controlled study was conducted, including 60 patients with SS and moderate to severe dry eye syndrome admitted to the First People's Hospital of Jingzhou from May 2024 to May 2025. The patients were randomly divided into the PRP group (n = 30) and the control group (n = 30). The PRP group received autologous PRP eye drops, while the control group used 0.3% sodium hyaluronate eye drops, both administered three times daily for one month. The primary outcome measures included changes in the Schirmer test, tear film break-up time (BUT), and corneal conjunctival fluorescein staining (CFS) scores before and after treatment, along with recording any adverse reactions. **Results:** After treatment, the PRP group showed significantly better Schirmer test values (6.8 ± 1.5 mm vs 4.5 ± 1.2 mm) and BUT (8.2 ± 1.2s vs 5.0 ± 0.9 s) compared to the control group, with a significant decrease in CFS scores (3.1 ± 0.8 vs 5.2 ± 1.3) (all $P < 0.05$). There was no statistically significant difference in adverse reaction rates between the two groups (13.3% vs 10.0%, $P > 0.05$). **Conclusion:** Autologous PRP eye drops can effectively improve dry eye symptoms in SS patients, promote ocular surface repair, and have good safety and clinical application value.

Keywords

Sjogren's Syndrome, Dry Eye, Platelet-Rich Plasma, Eye Drops, Efficacy

1. Introduction

Sjogren's syndrome (SS) is an autoimmune disease characterized by lymphocytic

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infiltration of exocrine glands such as the lacrimal and salivary glands. Approximately 60% - 80% of patients also have dry eye syndrome [1]. The pathogenesis involves dysfunction of the lacrimal gland and inflammation of the ocular surface, clinically manifesting as dry eyes, foreign body sensation, and decreased vision; severe cases can lead to corneal ulcers [2].

Currently, the primary therapeutic approaches for dry eye in SS patients include artificial tears and immunomodulatory agents. However, these treatments often provide only temporary relief and are associated with limitations such as limited long-term efficacy, potential side effects, and the inability to fundamentally repair ocular surface damage. Specifically, artificial tears primarily lubricate the ocular surface but do not address the underlying inflammation and tissue damage, while immunomodulatory therapies may have systemic side effects and require prolonged use. These limitations underscore the need for innovative therapies that can more effectively target the pathophysiology of SS-related dry eye [3].

In 1977, Harke *et al.* [4] first isolated and prepared platelet-richplasma (platelet-richplasma, PRP) from whole blood and applied it to cardiac surgery patients, achieving good therapeutic effects. PRP is rich in bioactive substances such as platelet-derived growth factor (PDGF) and vascular endothelial growth factor (VEGF), which can promote tissue repair and regulate inflammatory responses [5]. In recent years, PRP has shown potential in ophthalmology, but its application in SS dry eye syndrome still requires more evidence-based medical research. This study systematically evaluates the efficacy and safety of PRP eye drops through a randomized controlled trial, providing new options for clinical use.

2. Data and Methods

2.1. Research Objectives

This study was approved by the Ethics Committee of Jingzhou First People's Hospital, and all participants signed informed consent forms. A total of 60 patients with Sjogren's syndrome who were admitted to our hospital between May 2024 and May 2025 and had moderate to severe dry eye symptoms were selected. Participants were randomized into groups using a computer-generated random number sequence via statistical software (SPSS). A 1:1 allocation ratio to the control group (0.3% sodium hyaluronate) or PRP group (autologous PRP eye drops) was applied. Allocation concealment was ensured by an independent researcher using sealed, opaque envelopes.

Inclusion criteria: 1) meet the 2002 revised International Classification of Sjogren's Syndrome [6]; 2) confirm moderate to severe dry eye syndrome through tear flow rate measurement (Schirmer test), tear film break-up time, and corneal staining tests; 3) blood routine and HB-sAg, anti-HCV, anti-HIV, and anti-TP infection markers related to transfusion are all normal; 4) no associated hematological diseases, no severe cardiovascular disease, no systemic infections or treatment of local severe infections; 5) no recent oral administration of aspirin or other drugs that affect platelets and coagulation function.

Exclusion criteria: 1) not in line with the revised international classification

standard of Sjogren's syndrome in 2002; 2) accompanied by hematological diseases, severe cardiovascular diseases, and recent use of anticoagulants; 3) Hb, hct, plt and other items do not meet the collection standards; 4) pregnant women and lactating women.

2.2. Research Methods

Patient Grouping

Control group: artificial tears (0.3% sodium hyaluronate eye drops) were given to the eyes on the basis of routine treatment, 3 times/day, for 1 month.

PRP Group: PRP eye drops were prepared by drawing 50 mL venous blood, which was then centrifuged at 1200 rpm (approximately 200 × g RCF) for 10 minutes in a 6K-C low-speed centrifuge (Changsha Xin'ao Instrument & Meter Co., Ltd., equipped with a standard horizontal rotor) to separate platelet-rich plasma; the supernatant was transferred and centrifuged again at 2000 rpm (approximately 400 × g RCF) for 10 minutes to concentrate platelets, after which the supernatant was discarded and approximately 5 mL of PRP was collected, adjusted to a platelet concentration 4 - 6 times that of whole blood using a hemocytometer, aseptically divided into 0.5 mL vials, and stored at 4˚C for up to 72 hours before being administered three times daily for one month.

2.3. Observation Indicators and Testing Methods

Dry eye symptom score: The visual analog scale (VAS) was used to evaluate dry eyes, photophobia and other symptoms, with a score range of 0 to 10.

Objective indicator:

Schirmer Test: The wet length of the filter paper strip was measured within 5 minutes without surface anesthesia.

Tear film rupture time (BUT): The longest time before tear film ruptures after sodium fluorescein staining.

Corneal staining (CFS): After Bengal red staining, the score was graded from 0 to 12 (the higher the score, the more severe the injury).

Safety evaluation: Record ocular irritation, congestion, infection and other adverse reactions.

2.4. Statistical Methods

SPSS 20.0 software was used for analysis, and the measurement data were expressed as ($x \pm s$), and the inter-group comparison was t-test; the count data were expressed as rate (%) and χ^2 test was used. $P < 0.05$ was statistically significant.

3. Results

3.1. Comparison of Baseline Data between the Two Groups

There was no significant difference in gender, age, disease course and dry eye score before treatment between the two groups ($P > 0.05$), and they were comparable (Table 1).

Table 1. Comparison of baseline data between the two groups.

Group	Examples	Sex (male/female)	Age (years)	Duration of Illness (years)	VAS Score (points)
Observation group	30	3/27	45.2 ± 8.5	5.1 ± 2.3	7.8 ± 1.2
Control group	30	2/28	44.8 ± 9.1	4.9 ± 2.5	7.6 ± 1.3

3.2. Comparison of Objective Indicators of Dry Eye before and after Treatment

After 1 month of treatment, the Schirmer test value and BUT of the observation group were significantly higher than that of the control group, and the CFS score was significantly lower than that of the control group ($P < 0.05$) (**Table 2**).

Table 2. Comparison of objective indicators of dry eye before and after treatment.

Group	Time	Schirmer Test (mm/5 min)	BUT (s)	CFS Score (points)
Observation group	pretherapy	3.2 ± 0.8	3.5 ± 0.7	6.5 ± 1.0
	post-treatment	6.8 ± 1.5#	8.2 ± 1.2#	3.1 ± 0.8#
Control group	pretherapy	3.1 ± 0.9	3.4 ± 0.6	6.3 ± 1.1
	post-treatment	4.5 ± 1.2	5.0 ± 0.9	5.2 ± 1.3

Note: #$P < 0.01$ vs control group post-treatment (adjusted for baseline using ANCOVA). Exact P-values: Schirmer Test $P = 0.003$, BUT $P < 0.001$, CFS score $P = 0.002$.

3.3. Safety Analysis

There were 4 cases of transient ocular irritation in the observation group (13.3%) and 3 cases in the control group (10.0%), which did not affect the treatment. There was no significant difference in the incidence of adverse reactions between the two groups ($\chi^2 = 0.22$, $P = 0.64$) (**Table 3**).

Table 3. Comparison of safety analysis between the two groups.

Group	Examples	Eye Irritation [n (%)]	χ^2 Price	P Price
Observation group	30	4 (13.3)	0.22	0.64
Control group	30	3 (10.0)		

4. Discussion

The pathological mechanism of dry eye syndrome (SS)-related dry eye involves a vicious cycle of tear gland tissue destruction and ocular surface inflammation, which traditional artificial tears struggle to fundamentally repair. The results of this study show that autologous platelet-rich plasma (PRP) eye drops exert multiple effects through their rich bioactive factors (such as PDGF, TGF-β), signifi-

cantly improving the dry-eye symptoms and objective indicators of patients. One month after treatment, the patient's Schirmer test value increased from baseline 3.2 ± 0.8 mm to 6.8 ± 1.5 mm ($P < 0.01$), indicating a significant recovery in tear secretion function, possibly due to PDGF activating the MAPK signaling pathway in PRP, promoting the proliferation of tear gland epithelial cells, and duct repair [7]. Additionally, the tear film break-up time (BUT) extended from 3.5 ± 0.7 s to 8.2 ± 1.2 s ($P < 0.01$), and the corneal conjunctival fluorescein staining (CFS) score decreased from 6.5 ± 1.0 to 3.1 ± 0.8 ($P < 0.01$), suggesting that PRP inhibits ocular surface inflammatory factors (such as IL-6, TNF-α levels reduced by 40 - 60%) through TGF-β and promotes corneal epithelial cell proliferation (in vitro experiments showed an increase in proliferation rate of 65.2 ± 8.7%), thereby repairing corneal epithelial defects and stabilizing tear film structure [8].

The autologous nature of PRP avoids the risk of immune rejection from allogeneic materials. This study adopted a closed preparation system and sterile operation procedure [9] that meet ISO 13485 standards, further ensuring safety. Although 13.3% of patients in the observation group experienced transient ocular irritation, there was no statistically significant difference compared to the control group (10.0%) ($P = 0.64$), and all symptoms were mild, with no severe complications observed, suggesting that the safety of PRP is comparable to that of artificial tears. Notably, PRP does not require the addition of preservatives, avoiding the potential risk of ocular surface toxicity caused by preservatives in traditional artificial tears [10], making it more suitable for long-term use.

This study provides initial evidence for the potential of PRP eye drops in treating SS-related dry eye syndrome, but several limitations warrant consideration. First, the 1-month follow-up period was insufficient to fully assess long-term efficacy and safety, including the durability of observed improvements and risks of delayed adverse events (e.g., fibrosis or chronic inflammation) linked to growth factor accumulation. Second, the small sample size ($n = 30$/group) may have limited statistical power and generalizability, increasing the risk of Type II errors and masking subgroup-specific responses. Third, reliance on subjective outcome measures, such as the Visual Analog Scale (VAS) for ocular discomfort, introduces potential bias due to individual variability in pain perception and placebo effects, despite the inclusion of objective assessments. Finally, the study did not explore dose-dependent effects of PRP, leaving the optimal therapeutic concentration undefined. Future research should incorporate longer-term, multicenter trials with objective biomarkers (e.g., cytokine levels, corneal nerve density) and dose-ranging studies to validate efficacy, optimize safety, and clarify the mechanisms of PRP-mediated ocular surface repair. Despite these limitations, PRP eye drops show promise as a targeted, safe, and novel treatment option for SS dry eye syndrome, meriting further investigation to support clinical translation.

5. Conclusion

This study confirms that autologous PRP eye drops can effectively improve dry

eye symptoms in patients with Sjogren's syndrome, significantly increase tear secretion and tear film stability, and promote ocular surface repair. The treatment is safe, with only a few patients experiencing brief ocular irritation. PRP offers a safe and effective biological therapy for SS dry eye syndrome, making it worthy of clinical promotion. Further larger sample sizes and longer follow-up studies are needed to verify its long-term efficacy.

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Availability of Data and Materials

The datasets used and/or analyzed during the present study are available from the corresponding author on reasonable request.

Authors' Contributions

LH and XQL designed and managed the whole study. MW wrote the manuscript and performed the all figures and tables.BW and LPP helped to revise the manuscript. All the authors have read and approved the final manuscript.

Ethics Approval and Consent to Participate

The study was approved by the Ethics Committee of the First Affiliated Hospital of Yangtze University.

Patient Consent for Publication

Consent for publication.

Conflicts of Interest

The authors declare that they have no competing interests.

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