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Application value of pranoprofen eye drops combined with ultrasonic atomization in the treatment of diabetic dry eye

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Abstract: To study the therapeutic effect and clinical application value of pranoprofen eye drops combined with ultrasonic atomization in patients with diabetic dry eye. A total of 100 patients with diabetic dry eye who were admitted to our hospital from October 2018 to March 2020 were randomly selected and divided into control group and experimental group by lotting, with 50 patients in each group. The control group was treated with 0.1% sodium hyaluronate eye drops combined with ultrasonic atomization, while the experimental group received pranoprofen eye drops combined with ultrasonic atomization. SPEED score and SEEQ score in the experimental group were significantly lower than those in the control group, and the differences were statistically significant (P<0.05). The amount of basic tear secretion and tear film break-up time in the experimental group were significantly greater than those in the control group, with statistical significance (P<0.05). The response rate of the experimental group was significantly higher than that of the control group, with statistical difference (P<0.05). Pranoprofen eye drops combined with ultrasonic atomization can significantly improve the response rate of patients with diabetic dry eye, lower SPEED score and SEEQ score and improve the condition of basic tear secretion and tear film break-up.

Keywords: Pranoprofen eye drops, ultrasonic atomization, diabetes mellitus, dry eye, therapeutic efficacy.

INTRODUCTION

Dry eye is a common ocular surface disease, with manifestations of eye dryness and visual loss caused by few secretion of tear. Dry eye may affect patients' daily life, which can lead to irreversible visual loss for patients as it becomes severe (Chen *et al*., 2020; Gong *et al*., 2020; Ogawa *et al*., 2020). The pathogenesis of dry eye generally includes hormone secretion disorder, autoimmune disease and endocrine disease. Diabetes mellitus is an important risk to cause dry eye due to high blood glucose and insufficient insulin secretion in diabetes patients (Li *et al*., 2020; Lin *et al*., 2020). Sodium hyaluronate eye drops are commonly used in clinical treatment of dry eye that is always combined with ultrasonic atomization. It's reported that sodium hyaluronate eye drops may dilute the tear that naturally secreted by human body and stimulate the tear gland. The application of sodium hyaluronate eye drops can temporarily relieve symptoms of dry eye, but the efficacy was not significant (Rongfeng, 2019; Semeraro *et al*., 2019; Zhu *et al*., 2018). Pranoprofen eye drops play antibacteria and anti-allergy effect, with significant action of relieving discomfort symptoms in eyes. To investigate the efficacy of pranoprofen eye drops in the treatment for patients with diabetic dry eye, this paper mainly selected patients with diabetic dry eye as subjects, who were treated with sodium hyaluronate eye drops combined with ultrasonic atomization and pranoprofen eye drops combined with ultrasonic atomization respectively. The response rates, basic tear secretion amounts, tear film break-up time, SPEED score and SEEQ score were compared between the two groups to analyze the therapeutic efficacy of pranoprofen eye drops combined with ultrasonic atomization.

MATERIALS AND METHODS

General information

A total of 100 patients with diabetic dry eye who were received by our hospital from October 2018 to March 2020 were randomly selected and divided into control group and experimental group by lotting, with 50 patients in each group. Patients in the experimental group aged 31-67, while those in control group were at the age of 30-65 years old. By comparing gender, age, history of diabetes mellitus, history of dry eye and other general data between the two groups, the result was not statistically significant (P>0.05). Refer to table 1 for details.

Inclusion/Exclusion criteria

Inclusion criteria

1. Met clinical manifestations of diabetic dry eye;
2. Patient aged ≥18 years old;
3. Patient without history of drug allergy, drug abuse or bad habit;
4. Patient with normal cardiac, pulmonary and renal function, without other organic disease;
5. The study had been approved by hospital Ethics Committee and all patients voluntarily participated in the study and signed Informed Consent Form.

Exclusion criteria

1. Patient without coagulation disorder, no anticoagulant

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taken;
2. Patient with other eye disease, such as cataract, retinal detachment etc.
3. Patient who underwent operation related to eyes, such as myoporthosis operation.

Methods

A comprehensive Keratograph 5M noninvasive ocular surface analyzer (Oculus, Germany) was used to detect manifestations of dry eye for both groups before treatment.

The control group applied 0.1% sodium hyaluronate eye drops (manufacturer: Qilu Pharmaceutical Co., Ltd., GYZZ: H20103633; specification: 0.1%x5ml) combined with ultrasonic atomization, details including Sodium Hyaluronate Eye Drops, q4h, 0.1 ml/time. 6g of each radix astragali and radix ophiopogonis, 3g of each angelica sinensis, dried rehmannia root and ligusticum chuanxiong hort and 5g of fructus schisandrae chinensis were decocted with water for one hour and 250ml medical solution was obtained after filtering the herbal residue (Rincon *et al*., 2018a; Rincon *et al*., 2018b; Zhang *et al*., 2018). Take 20 ml of medical solution to add in the ultrasonic atomizer (model: VGR-001) with power of AC220V/50Hz-170W to fumigate eyes for 20 minutes and the temperature was maintained at 34°C.

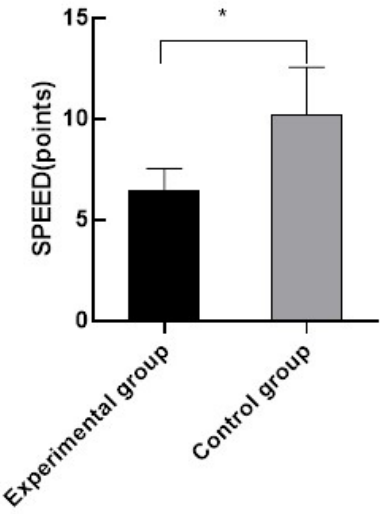
The experimental group received pranoprofen eye drops (manufacturer: Qilu Pharmaceutical Co., Ltd., GYZZ: H20103633; specification: 5ml: 5mg) combined with ultrasonic atomization, details including pranoprofen eye drops, qid, 0.15 ml/time. The ultrasonic atomization was identical with that of control group. A course of treatment lasted for 14 days and both groups received 2 cycles.

Observation indexes

After treatment, SPEED, SEEQ, Scirmer's test result, tear film break-up time and response rate were compared between the two groups.

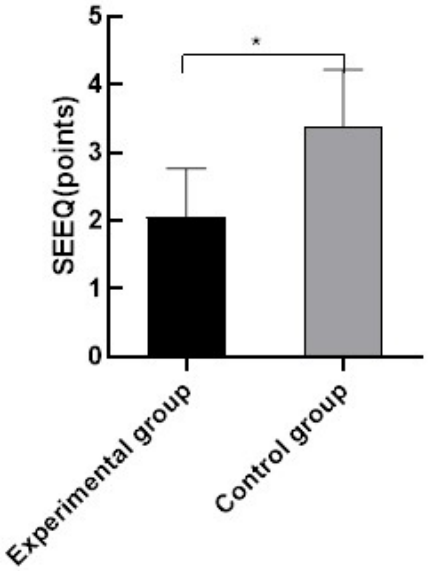
SPEED score is the evaluation criterion to determine the degree of symptoms of dry eye, including dryness sensation, foreign body sensation, pain and lacrimation, with score range of 0-24 points, 1 point and below indicating no dry eye symptoms or disappearance of dry eye symptoms, 2-9 points suggesting mild symptoms of dry eye and 10 points and above presenting severe dry eye (Canadas-Enrich *et al*., 2018).

SEEQ score is to evaluate the symptoms of eye disease in human, mainly including eye soreness and swelling, difficulty in opening eyes, eye dryness, ocular congestion, with score range of 0-4 points. The lower score suggests the less manifestations of eye disease, otherwise the eye disease is severe in patients.



Note: From left to right, the horizontal ordinate successively indicates the experimental group and control group, and the vertical ordinate presents SPEED scores of both groups after treatment.
The symbol * suggests the comparison of post-treatment SPEED score (6.51±1.02 points) of experimental group and that (10.24±2.33 points) of control group, t=4.64, P<0.001, with statistical difference.

Fig. 1: Comparison of SPEED score



Note: From left to right, the horizontal ordinate successively indicates the experimental group and control group, and the vertical ordinate presents SEEQ scores of both groups after treatment.
The symbol * suggests the comparison of post-treatment SEEQ score (2.06±0.71 points) of experimental group and that (3.39±0.83 points) of control group, t=3.85, P=0.001, with statistical difference.

Fig. 2: Comparison of SEEQ between the two groups

Response rate includes significant response, response and non-response, with basic disappearance or significant remission of symptoms of dry eye as significant response;

Table 1: Statistical comparison of general data

Group	Experimental group	Control group	t/X^2	P
Gender (M/F)	29/21	26/24	0.36	0.55
Age (Y)	48.33±6.92	48.60±6.55	0.09	0.93
Height (cm)	163.18±5.88	163.56±5.73	0.15	0.89
Weight (kg)	63.61±5.00	63.17±5.24	0.19	0.85
History of diabetes (Y)	8.37±1.16	8.65±1.21	0.53	0.60
History of dry eye (Y)	1.03±0.22	1.08±0.17	0.57	0.58
Smoking history (Y)	9.94±3.06	10.00±3.51	0.04	0.97
Drinking history (Y)	16.82±5.44	16.77±5.09	0.02	0.98
Hypertension (n)	10	11	0.06	0.81
Hyperlipidemia (n)	5	6	0.10	0.75

Table 2: Comparison of response rate between the two groups

Group	Significant response	Response	Non-response	Overall response rate (%)
Experimental group	31	15	4	92%
Control group	15	20	15	70%
X^2				7.86
P				0.005

remission of dry eye as response; no remission, even aggravation of dry eye as non-response.

STATISTICAL ANALYSIS

The study selected SPSS20.0 software to process data and GraphPad Prism 7 (GraphPad Software, San Diego, USA) was used to plot pictures against the study data. The study included enumeration data and measurement data, the former was expressed with (x±s) and t test was conducted, while the latter was indicated with [n %)] and X^2 test was conducted. The difference was of statistical significance as $P<0.05$.

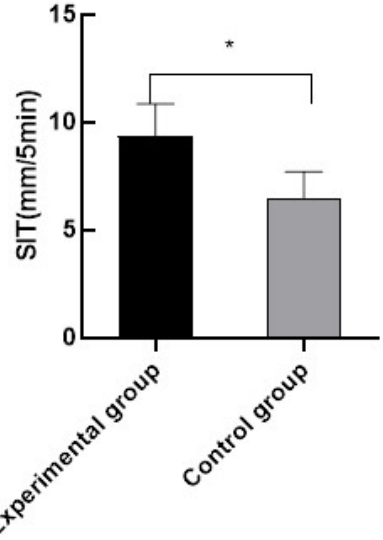
RESULTS

Comparison of SPEED score and SEEQ score between the two groups

After treatment, SPEED and SEEQ score were compared between the two groups and result indicated that SPEED score and SEEQ score of experimental group were significantly lower than those of control group, with statistical difference ($P<0.05$). The lower SPEED score and SEEQ score suggested milder manifestations of dry eye and eye disease in patients. The result demonstrated that pranoprofen eye drops combined with ultrasonic atomization can significantly relieve symptoms of diabetic dry eye. Refer to fig and fig. 2 for details.

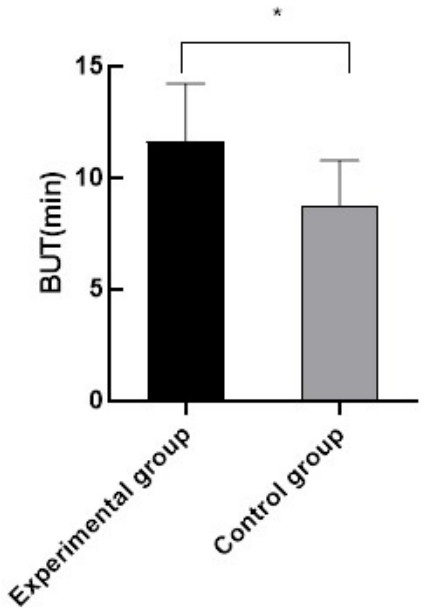
Comparison of basic tear secretion amount between the two groups

Scirmer's test was conducted for patients in both groups after treatment and the basic tear secretion amount was compared between the two groups. The result demonstrated that the basic tear secretion amount of experimental group was significantly greater than control group and the difference was significant ($P<0.05$), indicating that Pranoprofen Eye Drops combined with ultrasonic atomization can significantly relieve eye dryness. Refer to fig. 3 for specific comparison.



Note: From left to right, the horizontal ordinate successively indicates the experimental group and control group, and the vertical ordinate presents tear secretion amounts (SIT, mm/5min) of both groups after treatment.
The symbol * suggests the comparison of basic tear secretion amount (9.38±1.47 mm/5min) of the experimental group and that (6.48±1.22 mm/5min) of control group after treatment, t=4.80, $P<0.001$ and the difference was significant.

Fig. 3: Comparison of basic tear secretion amount between the two groups



Note: From left to right, the horizontal ordinate successively indicates the experimental group and control group, and the vertical ordinate presents tear film break-up time of both groups after treatment (BUT, min).
The symbol * suggests the comparison of tear film break-up time (11.65±2.58 min) of experimental group and that (8.77±2.01 min) of control group after treatment, t=2.78, P=0.01, and the difference was significant.

Fig. 4: Comparison of tear film break-up time between the two groups

Comparison of tear film break-up time between the two groups

The tear film break-up time of experimental group was significantly longer than that of control group after treatment, and the comparison was statistical (P<0.05). See figure 4.

Comparison of response rate between the two groups

The response rate was compared between the two groups, and the result showed the response rate was 92%, significantly higher than 70% of control group, with statistical difference (P<0.05), suggesting that Pranoprofen Eye Drops combined with ultrasonic atomization can significantly improve the onset manifestations of diabetic dry eye in patients, further to enhance the response rate. See table 2.

DISCUSSION

The diabetes mellitus patients may experience severe complications if they cannot control the blood glucose in the normal range and the common diabetic complications include cardiovascular and cerebrovascular complications, severe nephropathy, eye diseases, diabetic foot and others (Qiu *et al*., 2018; Zhang *et al*., 2018; Zhu *et al*., 2018). Dry eye is a common diabetic complication, with dryness sensation, swelling pain sensation in eyes due to insufficient secretion of tear. Treatment of dry eye applies eye drops combined with other medication. The combination of 0.1% sodium hyaluronate eye drops with ultrasonic atomization is commonly used in clinical treatment of dry eye for now, however sodium hyaluronate eye drops can only relieve eye dryness temporarily and application of sodium hyaluronate for long term may further worsen the symptoms of dry eyes (Chen *et al*., 2018; Wang *et al*., 2018). In consequence, application of pranoprofen eye drops is more and more popular in clinical settings, and as an anti-bacteria and anti-allergy drug, Pranoprofen eye drops are used to treat dry eye with minor side effect. It's reported that pranoprofen eye drops can significantly improve symptoms for patients with diabetic dry eye, further to enhance therapeutic effect. The study selected patients with diabetic dry eyes as subjects to analyze the therapeutic effect and application value of pranoprofen eye drops combined with ultrasonic atomization.The study result showed that SPEED score and SEEQ score of patients in experimental group that used pranoprofen eye drops combined with ultrasonic atomization for treatment of diabetic dry eyes were significantly lower than those of control group that applied sodium hyaluronate eye drops, with significant difference (P<0.05). The SPEED score and SEEQ score are the criteria to evaluate the dry eye and manifestations of eye diseases, with low score as dominance. As a result, the result demonstrated that the therapeutic effect of pranoprofen eye drops combined with ultrasonic atomization was significantly superior to that of sodium hyaluronate eye drops combined with atomization. After two cycles of treatment, Scirmer's test was conducted for all patients to observe their tear film break-up time, and the test result proved that basic tear secretion amount and tear film break-up time of experimental group were significantly greater than control group and the difference was significant (P<0.05). The study conducted by scholar Yao (Yao, 2020) proposed that pranoprofen eye drops can significantly improve symptoms of dry eye for patients and the basic tear secretion amount and tear film break-up time were obviously increased after treatment. This conclusion was identical with that of this study, i.e. pranoprofen eye drops combined with ultrasonic atomization can increase the basic tear secretion amount and tear film break-up time in patients with diabetic dry eye, completely demonstrating the reliability of this study. In addition, the response rate of experiment group was significantly superior to that of control group, with significant difference (P<0.05), indicating that pranoprofen eye drops combined with ultrasonic atomization can significantly improve the manifestations in patients with diabetic dry eyes. They are similar to the previous study which argued that pranoprofen eye drops yielded excellent results in terms of effectiveness and safety (Zhang *et al*., 2018; Zhu *et al*., 2018).

CONCLUSION

In conclusion, pranoprofen eye drops combined with ultrasonic atomization can significantly enhance the response rate in patients with diabetic dry eyes, lower SPEED score and SEEQ score and improve basic tear secretion and tear film break-up condition. Therefore such combination in the treatment of diabetic dry eye has high value in clinical treatment, worthy of clinical promotion and application.

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