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# Clinical application of traditional Chinese medicine eye coating agents in the treatment of hordeola

Клиничка примена средстава за облагање очију традиционалне кинеске медицине у лечењу хордеоле

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**SUMMARY**

**Introduction /Objective** This study aimed to investigate the therapeutic efficacy of combining traditional Chinese medicine (TCM) eye-coating agents with levofloxacin in treating patients with a hordeolum.

**Methods** Using convenience sampling, 110 patients with a hordeolum treated at Tianjin Eye Hospital between March and June 2018 were included in this study. Patients were randomly divided into three groups: a coating agents group (coating agents + levofloxacin, n = 37), a wash group (eyelid wash + levofloxacin, n = 38) and a control group (levofloxacin alone, *n* = 35). Data on nodule size and visual analogue scale (VAS) scores for pain were collected before treatment and at three, five and seven days after treatment. Treatment efficacy was assessed after seven days, and comparisons were made between the three groups regarding nodule size, VAS scores and therapeutic outcomes.

**Results:** Repeated-measures analysis of variance showed significant time effects, group effects and time-group interactions for both nodule size and VAS scores ($p < 0.05$). Over time, all groups exhibited a significant reduction in nodule size and VAS scores compared with the baseline. Pairwise comparisons revealed that on days 3, 5 and 7, the order for nodule size and VAS scores was consistent across the groups: coating agents group = wash group < control group. Treatment efficacy comparisons were statistically significant (94.59% vs. 86.84% vs. 71.43%, $\chi^2 = 7.622$, $p < 0.05$), with the order from highest to lowest efficacy being as follows: coating agents' group = wash group > control group.

**Conclusion:** The combination of TCM eye coating agents with levofloxacin shows promise in treating a hordeolum, effectively reducing eyelid swelling and pain, shortening healing time and improving treatment success rates.

**Keywords:** Traditional Chinese medicine eye coating agents; hordeolum; levofloxacin; clinical outcomes

**САЖЕТАК**

**Увод/Циљ** Истражити ефикасност традиционалне кинеске медицине за очи у комбинацији са левофлоксацином у лечењу грануломе.

**Методе** Ова студија укључивала је 110 пацијената са грануломом који су третирани у Тианьин офталмолошкој болници од марта до јуна 2018. године. Пацијенти су случајно подељени у три групе: група за премазивање (средство за премазивање + левофлоксацин, н = 37), група за испирање (испирање капки + левофлоксацин, н = 38) и контролна група (само левофлоксацин, н = 35). Подаци о величини нодула и болу визуелног аналогног резултата (ВАС) прикупљени су пре и три, пет, и седам дана након лечења. Ефекат лечења је процењен седам дана касније, а упоређена је величина нодула, ВАС резултат и резултати лечења три групе.

**Резултати** Поновљена анализа варијансе показала је значајне временске ефекте, групне ефекте и интеракције временске групе између величине нодула и ВАС резултата ($p < 0,05$). Током времена, величина нодула и ВАС резултати свих група су значајно смањени у поређењу са основном линијом. Парно поређење показало је да је на трећем, петом и седмом дана величина нодула и редослед ВАС резултата биле исте између група: група за премазивање = група за прање < контролна група. Терапеутски ефекат био је статистички значајан (94,59% *vs*. 86,84% *vs*. 71,43%, $\chi^2 = 7,622$, $p < 0,05$), а лекарски ефекат је био од високог до ниског: група премаза = група за чишћење > контролна група.

**Закључак** Кинеска медицина за очи у комбинацији са левофлоксацином у лечењу грануломе може ефикасно смањити оток и бол капка, скратити време зарастања и побољшати стопу успеха лечења.

**Кључне речи:** кинеска медицина за премазивање очију; Слад Левофлоксацин; Клинички исход



## INTRODUCTION

A hordeolum refers to the acute purulent inflammation of the eyelid glands, often caused by

 

*Staphylococcus aureus* infection [1]. This condition is a frequently occurring disease commonly diagnosed in ophthalmology outpatient clinics. A study [2] identifies the presence of *Staphylococcus aureus* in the nasal cavity as a primary etiological factor in the onset of a hordeolum. Clinically, it manifests as localized redness, swelling, heat and pain, with a palpable nodule at the affected area, known as a stye. If the hordeolum is near the external canthus, the pain is often more severe and may lead to reactive conjunctival oedema. It is imperative to avoid self-draining any formed abscess to prevent bacterial backflow into the cranial cavity, which could lead to severe complications, such as cavernous sinus thrombosis, that may be life-threatening.

In clinical practice, the treatment of a hordeolum is predominantly based on Western medicine, which typically involves the use of systemic and topical antibiotics to control inflammation, combined with heat application to facilitate the resolution of the inflammatory process. When an abscess forms, incision and drainage should be performed [3]. Western medicine aims to alleviate symptoms, promote the discharge of pus and prevent spreading. However, the excessive use of Western eye drops can lead to drug resistance in the eyes, thereby reducing their efficacy in treating recurrent conditions, such as herpes zoster ophthalmicus. Moreover, surgery for a hordeolum can cause psychological discomfort in patients and even the formation of eyelid scars [4]. The treatment duration usually lasts 5–10 days, severely disrupting patients' daily activities and occupational commitments. Frequent non-compliance due to work or academic obligations often results in an extended course of the disease and increases the likelihood of requiring surgical drainage [4].

In recent years, traditional Chinese medicine (TCM) has shown promise in treating hordeola and has been receiving increasing attention. Traditional Chinese medicine treats styes based on the etiology and pathogenesis and is safer than Western medicine. Western medicine has



 

relatively large side effects in treating styes, and TCM can make up for the shortcomings of Western medicine with its mild efficacy and good conditioning. A large number of clinical studies have shown that TCM is effective in treating styes; it is safe and quick in effect. Traditional Chinese medicine has mild properties and little gastrointestinal irritation [5, 6, 7]. In TCM, a hordeolum is known by various names such as ‘needle eye’, ‘subcutaneous canker’, ‘soil ulcer’ or ‘stolen needle’. A hordeolum is described as a condition where the eye suddenly develops a vesicular rash and produces pus within 3 to 5 days [1]. The treatment philosophy in TCM has traditionally focused on clearing heat, detoxification and alleviating circulatory stasis [7, 8, 9]. Various methods derived from this philosophy, including herbal fumigation, ultrasonic herbal eye baths, direct current iontophoresis and herbal poultices, have demonstrated efficacy [7, 9, 10, 11]. Traditional Chinese medicine also places a significant emphasis on eyelid hygiene and anti-inflammatory treatment. The TCM eyelid wash has gained widespread usage due to its cost-effectiveness. It functions with the dual capabilities of cleansing and anti-inflammatory effects and exhibits high patient acceptability [10]. A specialized TCM eyelid wash formula has been developed in our institution, comprising key ingredients such as rhubarb, Baikal skullcap root, golden thread and *Phellodendron* bark. This formula has demonstrated efficacy in heat dissipation, swelling reduction, detoxification and blood circulation promotion without any observed adverse reactions [12]. When applied as a wet compress, this eyelid wash can directly treat the affected area by targeting locally produced inflammatory mediators to reduce inflammation and promote blood circulation. This, in turn, alters the local tissue's oxygen supply environment and reduces local inflammatory responses [13].

However, the herbal decoctions in TCM are often cumbersome to prepare and store, leading to poor patient adherence. Therefore, to improve patient compliance without compromising therapeutic efficacy, there is a need for new, more convenient forms of application. Chinese



 

herbal coating agents offer a promising alternative because they maintain effective drug concentrations, are easy to apply and store and can prolong the drug's residence time in the affected area [14]. The objective of this study is to evaluate the clinical effectiveness of a novel TCM topical agent in combination with levofloxacin in comparison with the established treatment protocol that involves the use of TCM eyelid wash and levofloxacin for the management of hordeola.

## METHODS

### Research participants

Using convenience sampling, data were collected from 110 cases of patients with a hordeolum admitted to Tianjin Eye Hospital between March 2018 and June 2018. If both eyes were affected, the more severe eye was studied. The patients were randomly divided into a coating agents group (coating agents + levofloxacin) consisting of 37 cases, a wash group (eyelid wash + levofloxacin) with 38 cases and a control group (levofloxacin only) with 35 cases.

Inclusion criteria: (1) patients with a disease course within 1 week, no self-administered antibiotics, no use of steroid eye drops or ointment, no oral anti-inflammatory medication and no systemic symptoms, such as fever; (2) patients with good compliance, able to return for follow-up within 7 days after the initiation of treatment.

Exclusion criteria: (1) patients with a disease course exceeding 1 week who had used relevant medications; (2) patients with localized pus or hordeolum ulceration; (3) patients with other severe eye diseases, such as glaucoma or retinal diseases; (4) patients allergic to the drug components, pregnant or breastfeeding women and children; (5) patients unable to comply with the treatment schedule or return to the clinic on time.



 

This study was approved by the hospital ethics committee (ethics number TJYYLL-2017-09). All participants or their legal guardians provided informed consent and signed written consent forms. In the case of underage participants, their guardians were ensured to fully understand the content of the study and signed informed consent forms.

**Diagnostic criteria**

The diagnostic criteria for a hordoleum are based on the guidelines outlined in 'Ophthalmology', edited by Loth [15]. The condition is defined by localised redness, swelling, warmth, eyelid skin pain, induration and significant tenderness upon palpation. In all patients, regularity of the eyelid margin, congestion, blockage of meibomian glands and the shifting area where the mucous membrane of the eyelid margin meets the eye skin are observed under slit-lamp microscopy.

**Treatment protocols**

Coating agents' group: 0.5% levofloxacin eye drops are applied to the affected eyelids four times daily, with 1–2 drops per application. Concurrently, a herbal coating agent made from the extracted components of the eyelid wash is used, which is evenly spread over the eyelids with a cotton swab twice daily for 15 minutes per application for a continuous 6-day treatment period, as one course of therapy.

Wash group: 0.5% levofloxacin eye drops are applied to the affected eyelids four times daily, with 1–2 drops per application. Concurrently, a TCM eyelid wash solution is used, applied twice daily for 15 minutes each time over a continuous six-day treatment period to complete



 

one course of therapy.

Control group: 0.5% levofloxacin eye drops are administered to the affected eyelids four times daily with 1–2 drops per application for a continuous six-day treatment period, constituting one course of therapy.

The eyelid wash consists of 10 g each of rhubarb, *Scutellaria*, *Coptis* and *Phellodendron*. The preparation process involves taking 10 doses of herbal pieces, totalling 400 g, and adding 4,800 ml of water. The mixture is soaked for 20 minutes and then decocted using an automated herbal decoction packaging machine for 90 minutes, yielding a total of 3,600 ml of herbal liquid. Each dose is 360 ml and each sachet contains 180 ml. The liquid is stored at temperatures of 0°C–4°C and is applied to the eyes twice daily, with an approximate volume of 90 ml each time.

The herbal coating agent for the eye is prepared by first making a herbal extract concentrate from the eyelid wash using a rotary evaporator. According to the Pharmacopoeia of the People's Republic of China, 1 g of the extract corresponds to 2–5 g of raw material. In this experiment, the prepared extract corresponds to 3.48 g of raw material, which complies with the Pharmacopoeia standards. An appropriate amount of polyvinyl alcohol (PVA) is placed in beaker 1 and dissolved in distilled water at 85°C. An appropriate amount of extract is placed in beaker 2, added to distilled water and stirred until completely dissolved. The fully dissolved medicinal liquid from beaker 2 is poured into beaker 1 and mixed with PVA. Then, 95% ethanol is added dropwise while stirring, followed by the slow addition of acetone while continuing to stir. Finally, a small amount of nitrocellulose and menthol is added, and the mixture is allowed to cool naturally. The final product is stored at temperatures of 0°C–4°C.

The levofloxacin eye drops were purchased from Youfeng Pharmaceuticals (China) Ltd., Batch Number: J20100046.



 

**Data collection**

Before treatment, basic information and clinical characteristics of the patients, such as gender, age and tumour location, were collected. The tumor size and pain visual analogue scale (VAS) scores of the patients were collected before treatment and at three, five and seven days after treatment. The treatment efficacy was evaluated after seven days of treatment.

Lump size measurement (mm): A caliper was used to measure the maximum diameter of the lump.

VAS score: This was utilized to assess the pain conditions before and after treatments for both groups. The score directly correlates with the intensity of the pain. A score of 0 indicates no pain, and the maximum score is 10. A score of ≤ 3 indicates mild pain, 4–6 indicates moderate pain and ≥ 7 indicates severe pain [16].

The efficacy evaluation was performed based on the criteria for blepharitis outlined in 'Practical Ophthalmology' [17], as follows: (1) cured – redness, swelling, heat and pain symptoms disappear, conjunctiva shows no signs of oedema or congestion and there is no tenderness upon palpation. Recovery is complete; (2) improved – reduced redness and swelling and alleviation of heat and pain symptoms. Mild discomfort still present; (3) ineffective – no alleviation of symptoms or worsening conditions, resulting in suppuration, rupture or the need for incision and drainage. In severe cases, cellulitis of the eyelid may occur, presenting systemic symptoms such as fever, chills and headaches.

The overall effectiveness rate was calculated as Total Effective Cases = (Cured + Improved) Cases / Total Cases × 100%



 

### Statistical analysis

Statistical analyses were performed using SPSS 26.00 software. Data with normal distribution were expressed as x ± s. One-way analysis of variance (ANOVA) was used for comparing group means. Repeated measures ANOVA was used for repeated measures data. The least significant difference method was employed for pairwise comparisons between groups. Count data were represented by frequency or rate and analysed using the $\chi^2$ test. Pairwise comparisons for count data were performed using the $\chi^2$ partitioning method. A $p$-value of <0.05 was considered statistically significant.

**Ethics:** This study was conducted in accordance with the declaration of Helsinki, and with approval from the Ethics Committee of Tianjin Eye Hospital (NO.: TJYYLL-2017-09).

## RESULTS

### General patient information

A total of 110 patients were included in this study. The coating agents group consisted of 37 patients (16 men and 21 women) with an average age of 28.31 ± 10.32 years. The wash group had 38 patients (17 men and 21 women) with an average age of 29.76 ± 8.43 years. The control group had 35 patients (15 men and 20 women) with an average age of 28.44 ± 9.39 years. There were no statistically significant differences among the three groups in terms of gender ratio, age, lump size, VAS scores or lump location before the treatment ($p > 0.05$). The comparability among the groups was satisfactory (Table 1).



 

**Comparison of lump size and visual analogue scale scores within seven days post-treatment**

A one-way repeated-measures ANOVA was employed to explore the effects of different treatment methods on lump size and VAS scores within 7 days following treatment. According to the Shapiro–Wilk test, the data for each group followed an approximately normal distribution ($p > 0.05$). Mauchly's sphericity test showed that the covariance matrices of each group were equal ($p > 0.05$). Data are represented as x ± s (Table 2).

In terms of lump size, the interaction between time and treatment was significant across the three groups ($F_{interaction} = 343.142$, $p < 0.001$). This finding suggests that the individual effects of different treatments on lump size varied at four different time points. Furthermore, lump size in all three groups decreased over time ($F_{time} = 129.532$, $p < 0.001$). Different treatments had various effects on lump size ($F_{treatment} = 352.532$, $p < 0.001$). Pairwise comparisons on days 3, 5 and 7 showed that the sequence of lump sizes remained consistent across the three groups: coating agents group = wash group < control group.

In terms of VAS scores, there was a significant interaction between time and treatment in the three groups ($F_{interaction} = 232.322$, $p < 0.001$). This finding shows that the impact of different treatment methods on VAS scores is different at different time points. As treatment progressed, the VAS scores of all groups decreased significantly ($F_{time} = 241.253$, $p < 0.001$), reflecting the positive effect of treatment on pain relief. In addition, the effects of different treatment measures on VAS scores also showed significant differences ($F_{treatment} = 263.132$, $p < 0.001$). Pairwise comparisons conducted on days 3, 5 and 7 after treatment showed that the order of VAS scores among the three groups was consistent: coating agents group = wash group < control group.



 

**Comparison of efficacy rates among the three groups**

The results indicated that in the coating agents group, six patients were cured, 29 were effective and two were ineffective; in the wash group, two were cured, 31 were effective and five were ineffective; and in the control group, one was cured, 24 were effective and 10 were ineffective. A statistically significant difference was observed in the efficacy rates among the three groups (94.59% *vs*. 86.84% *vs.* 71.43%, $\chi^2 = 7.622$, $p < 0.05$). Further pairwise comparisons revealed that the efficacy rates among the three groups were ranked as follows: coating agents' group = wash group > control group (Table 3).

## DISCUSSION

In this study, both the coating agent and wash groups demonstrated superior effectiveness in treating the hordeolum size and alleviating pain compared with the control group. Moreover, patients in the coating agent and wash groups also exhibited quicker recovery rates than those in the control group. The overall effectiveness was also higher in the coating agent and wash groups compared with the control group. These findings indicate that the integration of TCM with levofloxacin-based treatment can significantly enhance therapeutic outcomes for hordeola. These results are consistent with previous studies, as many have shown that the combination of TCM and Western medicine in treating hordeola is more effective than using antibiotics or TCM alone [18, 19, 20]. For instance, one study [18] applied a topical formula combined with heat steaming and ofloxacin ointment for early-stage hordeola and found that it reduced the rupture rate, showing better efficacy than antibiotics alone. In another study, Ji et al. [19] used a combination of levofloxacin eye drops and Wu Wei Xiao Du Yin (a TCM formula) to treat hordeola, which not only showed significant therapeutic effects but also reduced the recurrence rate. These findings further confirm our study's conclusion that the



 

integration of TCM and Western medicine can significantly enhance the treatment efficacy of hordeola.

The prescription used in this study consisted of rhubarb, *Scutellaria baicalensis* (Huang Qin), *Coptis* (Huang Lian) and *Phellodendron* (Huang Bai), which are collectively known for their therapeutic effects of properties for heat-clearing, dispelling dampness, aiding detoxification, promoting blood circulation and reducing swelling. These characteristics are crucial for explaining the superior outcomes observed in the coating agents' group and wash group compared with the control group. All four herbal ingredients inherently exhibit bitter and cold properties, predominantly used for treating various overheating syndromes. Rhubarb is recognized for its heat-clearing, analgesic, blood-cooling and detoxifying properties. Its major components include both bound and free anthraquinones and anthrones. Modern pharmacological studies indicate that rhubarb possesses antibacterial activity [21, 22] and anti-inflammatory and antipyretic effects [23]. Research by Cheng et al. [11] found that topical application of rhubarb vinegar could rapidly control inflammation and shorten the disease duration for a hordeolum. This is consistent with the study's observation of significant reductions in lump size and VAS scores in the coating agent group and wash group, indicating effective control of inflammation and pain. *Scutellaria baicalensis* is associated with the lung and stomach meridians and is particularly effective at clearing 'real fire', a term in TCM that refers to acute inflammation or infection. Its decoction has been found to have a broad-spectrum antibacterial effect [25]. Further pharmacological investigations into the primary components of *Scutellaria* revealed that baicalein may exert its antipyretic effect by reducing levels of tumour necrosis factor and interleukins [26]. Additionally, baicalein inhibits the expression of the cyclooxygenase-2 gene and prevents the binding of the transcription factor CCAAT/enhancer-binding protein beta to deoxyribonucleic acid (DNA], thereby interfering with arachidonic acid metabolism and exerting an anti-inflammatory effect [27]. *Coptis* also



 

displays a broad-spectrum antibacterial activity and significantly inhibits gram-positive bacteria, such as *Staphylococcus aureus* [25]. This is associated with the rapid alleviation of symptoms in the treatment groups. The primary medicinal components of *Coptis* and *Phellodendron* are alkaloids [28]. Specifically, berberine in *Coptis* can bind with single-stranded or double-stranded DNA to form complexes that impact DNA function [29]. Moreover, *Phellodendron* is known for its antimicrobial and bacteriostatic effects. In vitro studies have shown that it is most effective against *Chlamydia trachomatis* and *Pseudomonas aeruginosa* [30]. Leveraging the significant antimicrobial properties of these two ingredients, the coating agent can swiftly eliminate bacteria at the site of infection, thereby effectively alleviating the associated symptoms.

Nonetheless, this study has some limitations. First and foremost, the cases examined were exclusively sourced from outpatients of Tianjin Ophthalmology Hospital. The narrow scope of the patient pool may introduce certain biases in statistical interpretation due to the limited sample size. Second, due to time constraints inherent in the research process, the follow-up duration for patients was abbreviated, thus potentially compromising the assessment of long-term clinical efficacy. Additionally, our study did not employ a blinding method, which may have introduced performance and detection biases, as both patients and researchers were aware of the specific treatment assignments. This awareness could have influenced the reporting and interpretation of the results. Finally, the study falls short in its investigation into the mechanisms of treatment, especially in the context of TCM categorizations and theoretical elaborations. Accordingly, future research is called for, with an expanded sample size, scientifically rigorous and effective clinical efficacy studies and well-designed randomized controlled trials. Further exploration into the scientific rationale and clinical evidence of treating styes using this methodology is warranted. Establishing stable animal models and deepening experimental and mechanistic research, especially in neurology, humoral biology



 

and histopathology, could be beneficial.

## CONCLUSION

The combined application of topical TCM and levofloxacin demonstrated commendable effectiveness in treating styes. It successfully mitigated eyelid swelling and pain, expedited the healing process and increased the overall rate of effective treatment. Additionally, the established preparation methods for the eye wash contribute to its user-friendly nature, which is likely to enhance patient compliance.



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Qi-Miao Wang and Yi-Ping Ma have contributed equally to this study.

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**Table 1.** Comparison of general patient characteristics

| Variable | | Coating agents Group (n = 37) | Wash Group (n = 38) | Control Group (n = 35) | $\chi^2/F$ value | p-value |
|---|---|---|---|---|---|---|
| Gender (Male/Female) | | 16/21 | 17/21 | 15/20 | 0.030 | 0.985 |
| Age (years, x ± s) | | 28.31 ± 10.32 | 29.76 ± 8.43 | 28.44 ± 9.39 | 2.312 | 0.212 |
| Lump Size (mm, x ± s) | | 9.13 ± 5.08 | 7.88 ± 4.47 | 8.58 ± 5.17 | 1.897 | 0.321 |
| VAS Score (points, x ± s) | | 6.82 ± 2.01 | 7.02 ± 2.43 | 6.92 ± 1.83 | 2.110 | 0.254 |
| Lump Location | Right Eye | 20 | 20 | 15 | 1.063 | 0.588 |
| | Left Eye | 17 | 18 | 20 | | |

VAS – visual analog scale for pain



 

**Table 2**. Comparison of mass size and VAS score within seven days post-treatment

| Variable | Time | Coating agents Group (n = 37) | Wash Group (n = 38) | Control Group (n = 35) | $F_{interaction}/P_{interaction}$ | $F_{time}/P_{time}$ | $F_{treatment}/P_{treatment}$ |
|---|---|---|---|---|---|---|---|
| Lump Size (mm, x ± s) | Baseline | 9.13 ± 5.08 | 7.88 ± 4.47 | 8.58 ± 5.17 | 343.142/0.001 | 129.532/0.001 | 352.532/0.001 |
| | 3d[a] | 5.23 ± 3.11 | 5.11 ± 2.89 | 6.10 ± 3.56 | | | |
| | 5d[a] | 2.31 ± 1.28 | 2.28 ± 1.16 | 3.56 ± 2.19 | | | |
| | 7d[a] | 1.02 ± 0.34 | 1.13 ± 0.28 | 2.34 ± 1.03 | | | |
| VAS Score (points, x ± s) | Baseline | 6.82 ± 2.01 | 7.02 ± 2.43 | 6.92 ± 1.83 | 232.322/0.001 | 241.253/0.001 | 263.132/0.001 |
| | 3d[a] | 3.51 ± 1.96 | 3.61 ± 2.13 | 4.78 ± 2.11 | | | |
| | 5d[a] | 1.31 ± 0.93 | 1.45 ± 1.11 | 3.14 ± 1.22 | | | |
| | 7d[a] | 0.43 ± 0.11 | 0.52 ± 0.12 | 2.11 ± 1.41 | | | |

VAS – visual analog scale for pain

[a] statistically significant inter-group difference



 

**Table 3.** comparison of efficacy rates among the three groups

| Group | Cured | Effective | Ineffective | Efficacy Rate |
|---|---|---|---|---|
| Coating agents Group (n = 37) | 6 | 29 | 2 | 94.59% |
| Wash group (n = 38) | 2 | 31 | 5 | 86.84% |
| Control group (n = 35) | 1 | 24 | 10 | 71.43% |
| $\chi^2$ value | 7.622 | | | |
| p-value | 0.022 | | | |



 