ORIGINAL RESEARCH
DOI: 10.17944/interdiscip.1352006
InterdisciplinaryMedicalJournal2023;14(49):126-131.

Comparison of efficacy of Ketorolac %0.4 and Dexamethasone %0.1 in inflamed Pterygium and Pinguecula

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Abstract

Objective: This study investigated the effect of the ketorolac %0.4 and dexamethasone %0.1 on suppressing symptoms in inflamed pterygium and pinguecula.

Methods: 50 patients were included in the study. The patients were divided into two groups, each consisting of 25 patients. Ketorolac %0.4 eye drops were dropped in group 1, and dexamethasone %0.1 eye drops were started in group 2. Groups were compared 3,7,14,30,45. days in terms of total signs and symptoms.

Results: After 14 days of drug administration group 1, scores were reduced %85 for total signs (2.52+1.16, p=0.001), %86 for total symptoms (4.10+2.61, p=0.001) and total scores showed a significant reduction of %86 (6.62+2.91, p=0.001) for the score. After 14 days of drug administration in group 2, scores were reduced %85 for total signs (2.70+1.46, p=0.001), %86 for total symptoms (4.25+2.36, p=0.001), and total scores showed a significant reduction of %86 (7.10+2.99, p=0.001) for the score. The scores for each sign and symptom decreased during the study. However, the statistical evaluation of each sign and symptom was similar in groups 1 and 2. There was no difference between groups 1 and 2 for total signs, total symptoms, and total score on days 3,7 and 14. No significant difference was found between groups 1 and 2 for total signs, total symptoms, and total score on days 14,30 and 45 (p>0.05).

Conclusion: Current study revealed that topical ketorolac %0.4 solutions are as effective as dexamethasone in treating inflammatory pterygium and pinguecula. We suggest that it can be used alone to treat this disease. We need more studies to support our work.

Keywords: Pterygium, Pinguecula, Ketorolac, Dexamethasone

INTRODUCTION

Repetitive microtrauma, solar radiation, chronic irritation, and many other factors are thought to be effective in developing pterygium and pinguecula. (1-3). They consist of newly synthesized elastic fibers, presumably synthesized by actinically damaged fibroblasts of the substantial propria. (4). Some researchers have suggested that the inflammatory mechanism (5,6) may be responsible for the development of pterygium and pinguecula while others have suggested that the immune (7) and angiogenic mechanism (8) may be responsible.

Pterygium and Pinguecula may develop due to dry eye, mechanical irritation, and other tear film anomalies (9). Pinguecula is a yellowish lesion derived from the nasal conjunctiva and located close to the limbus (10). The incidence increases in the presence of male gender, age, UV rays and Diabetes Mellitus (11). Histological studies reported abnormal differentiation and squamous metaplasia of the conjunctival epithelium, exaggeration and distortion in the production of elastic fiber s, and abnormality of their organization in the subepithelial connective tissue (12). The incidence in the population varies between 22.5% and 70.1% (13). This change in prevalence may vary depending on age, ethnicity, geographical location.

Cite this article: Çakmak K, Korkmaz Ş, Yılmaz F. Comparison of efficacy of Ketorolac %0.4 and Dexamethasone %0.1 in inflamed Pterygium and Pinguecula. Interdiscip Med J. 2023;14(49):126-131. https://doi.org/10.17944/interdiscip.1352006

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Received: October 2, 2022
Accepted: August 8, 2023

Inflamed pterygium and pinguecula are primarily seen in chronic eye discomfort, itching, foreign body sensation in the eye, pain, watering, and redness. Topical lubricants and steroid-containing drops are used for highly symptomatic patients. However, the patient's complaints may recur after the treatment is stopped. In addition, continued use of steroids in mildly inflammatory patients may be undesirable due to associated complications (cataracts and increased intraocular pressure) (14).

Topical non-steroidal anti-inflammatory drugs have limited use in ophthalmology (15-18) and have fewer side effects than topical steroids (19). In addition, topical 0.4% ketorolac for two weeks can control the inflamed pterygium and pinguecula (20). Therefore, topical non-steroidal anti-inflammatory drugs may be preferred instead of topical steroids in inflamed pterygium and pinguecula. Consequently, we conducted a study comparing the efficacy of topical ketorolac 0.4% and topical dexamethasone 0.1% in patients with symptomatic pterygium and pinguecula.

METHODS

The study was conducted in Düzce Atatürk State Hospital in a prospective, double-masked and controlled manner with ketorolac 0.4% and dexamethasone 0.1% topical eye drops between January 2021 and April 2021 on the signs and symptoms of patients with inflammatory pterygium and pinguecula. 50 (25 male, 25 female) patients were included in the study. The age range of the patients ranged from 25 to 78. Sixteen of the patients had pterygium, and 34 of them had pinguecula. Photophobia, eye pain, watering, eye discomfort, and foreign body sensation in the eye were accompanied by sudden eye redness in all patients. All patients had inflammation in one eye. Exclusion criteria from the study were those with a Schirmer test less than 10 mm, who took systemic analgesic or immunosuppressive agents, who had previous keratitis, those who used contact lenses, and those with a last inflammatory conjunctival disease.

All patients underwent a complete ophthalmologic examination, including visual acuity, slit-lamp examination, intraocular pressure measurement, fundoscopic examination, and Schirmer test. Objective symptoms included corneal or conjunctival staining, conjunctival congestion or edema, and flushing. All these objective findings were evaluated on a scale (0=no findings, 1=mild, 2=moderate, 3=severe), and each patient was given a score. The sum of this scoring was called the total objective finding score. Subjective symptoms were Photophobia, eye pain, burning, foreign body sensation, discomfort in the eye, and watering. Each patient scored all subjective symptoms on a scale (0=no symptoms, 1=mild, 2=moderate, 3=severe), and this total was subjective and constituted the symptom score. The sum of total objective symptom scores and total subjective symptom scores were called the total score.

All patients were numbered from 1 to 50. Odd numbers constituted group 1. There were 16 female and nine male patients in group 1, and the mean age was 47. Topical ketorolac 0.4% eye drops were dropped. Ketorolac 0.4% eye drops were instilled six times daily for the first four days. Between 5-14 days, it was applied as a drop four times a day, the drug was discontinued on the 14th day, and the follow-up of the patients continued until the 45th day.

The even numbered patient group constituted group 2. Group 2 included nine female and 16 male patients. In Group 2, the mean age was 43 years. Dexamethasone 0.1% topical eye drops were started in group 2. Dexamethasone eye drops were instilled six times daily for the first four days. Then, between 5-14 days, it was applied as one drop four times a day, the drug was discontinued on the 14th day, and the follow-up of the patients continued until the 45th day.

Statistical analysis

SPSS 11.5 program was used in the analysis of the data. Mean ± standard deviation and median (minimum-maximum) were used as descriptors for quantitative variables, and the number of patients (percentage) for the qualitative variable. The Mann-Whitney U test was used to determine whether there was a difference between the qualitative variable and the two categories of quantitative variables since the assumptions of normal distribution were not met. When the relationship between two quantitative dependent variables was wanted to be examined, the Wilcoxon Signed Rank test was used since the assumptions of normal distribution were not met. The statistical significance level was taken as 0.05.

RESULTS

One patient from each group of 50 patients left the follow-up on the 14th and 30th days of the treatment.

At enrollment, 46 of 50 patients had conjunctival congestion, 46 had redness, and 6 had punctate staining. In addition, photophobia was present in 9 patients, pain in 17 patients, foreign body sensation in 30 patients, eye discomfort and burning sensation in 41 patients, and watering in 9 patients.

Before treatment, none of the signs and symptoms studied differed in the two groups (p=0.809, p=0.990, and p=0.927, respectively). In Group 1, mean prior to treatment scores were 5.57±1.57 for total signs, 9.90±4.35 for total symptoms, and 15.62±5.07 for total scores. İn Group 2, mean scores before treatment were 5.52±1.59 for total signs, 9.85±4.25 for total symptoms, and 15.55±5.24 for total scores (Table 1).

Table 1. Scores before medical treatment in inflammatory pterygium and pinguecula group 1 (ketorolac 0.4%) and group 2 (dexamethasone 0.1%)

Variables	Group 1		Group 2		
	Mean±SD	Median (Min-Max)	Mean±SD	Median (Min-Max)	p-value
Total Signs	5.57±1.57	5.00 (2.00-9.00)	5.52±1.59	5.00 (2.00-9.00)	0.809
Total Symptoms	9,90±4,35	9,00 (5.00-18.00)	9.85±4.25	8.50 (4.00-18.00)	0.990
Total Score	15.62±5.07	15.00 (9.00-27.00)	15.55±5.24	14.00 (9.00-27.00)	0.927

SD: Standard Deviation, Min: Minimum, Max: Maximum

After 14 days of drug administration in group 2, scores were reduced 85% for total signs (2.70+1.46, p=0.001), 86% for total symptoms (4.25±2.36, p= 0.001) and total scores showed a significant reduction of 86% (7.10+2.99, p= 0.001) for the score. (Table 2).

The scores for each sign and symptom decreased during the study. However, the statistical evaluation of each sign and symptom was similar in groups 1 and 2. There was no difference between groups 1 and 2 for total signs, total symptoms, and total scores on days 3, 7, and 14 (p>0.05) (Table 2).

On the 14th, 30th, and 45th days, it was checked whether each of the signs and symptoms differed between groups 1 and 2. No significant difference was found between groups 1 and 2 for total signs, total symptoms, and total score on the 14th, 30th, and 45th days (p>0.05) (Table 3). Each sign on the 14th, 30th, and 45th days and whether the symptom differed between groups 1 and 2. No significant difference was found between groups 1 and 2 for total signs, total symptoms, and total score on days 14, 30, and 45 (p>0.05) (Table 3)

All-time descriptors for the total score in groups 1 and 2 are given in Figure 1.

In the study, one patient had a headache (group 1), and one patient had eyelid swelling that disappeared despite the continuous use of drops. No other complication related to drug use occurred.

Table 2. Post-medical treatment scores, 3-, 7-, and 14-days group 1 and group 2

Variables		Group 1		Group 2		
		Mean±SD	Median (Min-Max)	Mean±SD	Median (Min-Max)	p-value
Total Signs	Day 3	4.65±1.72	4.00 (1.00-9.00)	4.57±1.53	5.00 (1.00-7.00)	0.750
	Day 7	3.48±1.56	3.00 (1.00-8.00)	3.70±1.36	4.00 (1.00-8.00)	0.246
	Day 14	3.04±1.07	3.00 (1.00-5.00)	2.83±1.15	3,00 (1.00-5.00)	0.524
Total Symptoms	Day 3	8.10±3.81	7.00 (3.00-17.00)	7.75±3.46	7.00 (2.00-15.00)	0.864
	Day 7	6.62±3.09	6.00 (2.00-14.00)	6.45±3.19	6.00 (2.00-14.00)	0.864
	Day 14	5.81±2.84	5.00 (2.00-13.00)	5.60±2.54	5.00 (2.00-11.00)	0.958
Total Score	Day 3	12.90±4.81	11.00 (7.00-26.00)	12.50±4.22	12.00 (7.00-22.00)	0.948
	Day 7	10.24±4.07	9.00 (5,00-21.00)	10.30±3.83	10.00 (5.00-19.00)	0.792
	Day 14	9.00±3.21	8.00 (6.00-17.00)	8.45±2.96	7.50 (4.00-15.00)	0.680

SD: Standard Deviation, Min: Minimum, Max: Maximum

DISCUSSION

Inflammation is joint among advanced pterygium and pinguecula ocular surface diseases. Although this inflammatory process is self-limiting mainly (20), most patients require medical treatment to alleviate symptoms and signs. Most patients with provocative eyes use vasoconstrictors or topical steroids intermittently or continuously. Inflamed pterygium and pinguecula, we determined the efficacy of topical ketorolac 0.4% solution and the natural history of this disease. Since we examined the same patient population living in the same environment and treated by the same ophthalmologists, the use of topical ketorolac 0.4% with 0.1% topical dexamethasone was not included in patients treated with placebo patients we compared.

Table 3. Posttreatment Scores, Days 14, 30, and 45, in Patients in Group 1 and Group 2

Variables		Group 1		Group 2		
		Mean±SD	Median (Min-Max)	Mean±SD	Median (Min-Max)	p value
Total Signs	Day 14	3.04±1.07	3.00 (1.00-5.00)	2.83±1.15	3.00 (1.00-5.00)	0.524
	Day 30	0.70±0.77	1.00 (0.00-2.00)	0.83±0.98	0.00 (0.00-3.00)	0.802
	Day 45	0.04±0.21	0.00 (0.00-1.00)	0.22±0.52	0.00 (0.00-2.00)	0.154
Total Symptoms	Day 14	5.81±2.84	5.00 (2.00-13.00)	5.60±2.54	5.00 (2.00-11.00)	0.958
	Day 30	0.90±1.22	1.00 (0.00-4.00)	1.15±1.09	1.00 (0.00-3.00)	0.324
	Day 45	0.20±051	0,00 (0.00-2.00)	0.25±0.72	0.00 (0.00-3.00)	0.932
Total Score	Day 14	9.00±3.21	8.00 (6.00-17.00)	8.45±2.96	7.50 (4.00-15.00)	0.680
	Day 30	1.67±1.68	1.00 (0.00-6.00)	2.10±1,68	2.00 (0,00-5,00)	0.365
	Day 45	0.24±0,54	0.00 (0.00-2.00)	0.50±1.00	0.00 (0.00-4.00)	0.394

SD: Standard Deviation, Min: Minimum, Max: Maximum

Application of topical ketorolac 0.4% solution (group 1) in patients with inflammatory pterygium and pinguecula reduction is 85% for total signs (2.52+1.16, p=0.001) and 86% for total symptoms (4.10±2.61, p= 0.001) and 86% (6.62+2.91, p= 0.001) for the total score. A 14-day application of topical dexamethasone 0.1% similarly resulted in a similar reduction in total signs, total symptoms, and total score. In addition, the efficacy of topical dexamethasone was not different from the

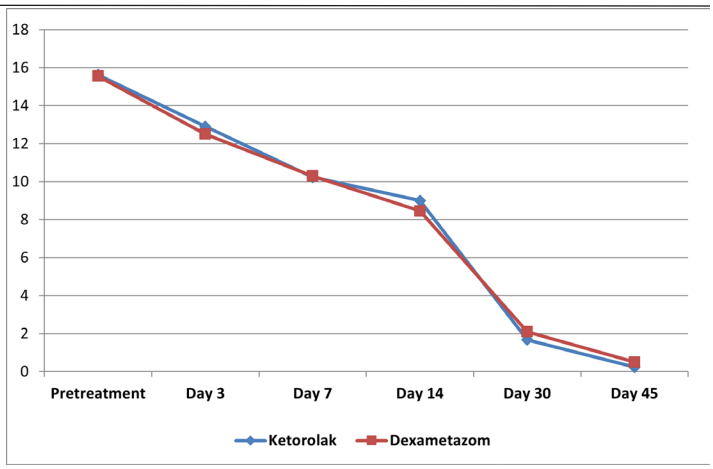

Figure 1. Identifiers oftwo groups for total score

efficacy of topical ketorolac. Patients in both groups stated that they were satisfied with the treatment. In addition, the lubricant (3) properties of instillation of the drops may have had some beneficial effects on our patients.

In a study conducted by Frucht-Pery J et al., as a result of using indomethacin 0.1% for 14 days, they found an 85% decrease in total sings, an 86% decrease in total symptoms, and an 86% decrease in total score. İn the same study, after 14 days of dexamethasone 0.1% use, they found a 91% decrease in total sings, a 95% decrease in total symptoms, and a 93% decrease in total score (30).

Another study conducted by Karlok bh et al., found that the length of the pterygium decreased from 1.5 mm to 1.00 mm as a result of 12-month use of dipyridamole in patients with inflamed pterygium.it was found that the height of the pterygium decreased to 0.3 mm per 1.00 mm. It was observed that hyperemia and vascularization in the conjunctiva completely regressed.

In a study conducted by J Frucht-Pery et al., in inflamed pterygium, a significant decrease in total symptoms, total score and total signs was observed after 14 days of topical indomethacin 0.1% use (19).

Although inflammation is suppressed in treated patients, the ocular surface lesion and primary pathology remain, and signs and symptoms may recur. The analgesic effects of topical indomethacin (18) and diclofenac (21,22) have been reported. Anti-inflammatory (17,24-29) activities are used in cataract surgery and trabeculoplasty operations. These reports show that topical non-steroidal anti-inflammatory drugs are at least as effective as topical steroids in treating ocular surface inflammation (17,28,29).

Most importantly, although topical non-steroidal anti-inflammatory drugs are safer than the uncontrolled use of topical steroids, which can cause many complications, non-steroidal anti-inflammatory drugs have some side effects.

Our findings showed that topical dexamethasone 0.1% had no superiority over topical 0.4% ketorolac solution in treating inflamed pterygium and pinguecula. Our study revealed that a topical 0.4% ketorolac solution is as effective as 0.1% dexamethasone in treating inflammatory pterygium and pinguecula.

CONCLUSION

Inflamed pterygium and pinguecula are frequently encountered in the clinic. Our studies showed us that the efficacy of ketorolac %0.4 and dexamethasone %0.1 in reducing total symptoms and total signs in inflammatory pterygium and pinguecula is not superior to each other. This study showed that ketorolac %0.4 alone can be used in this disease. More comprehensive and prospective studies are needed to support current study.

ACKNOWLEDGEMENT

Conflict of Interest

The authors declare that they have no conflict of interests regarding content of this article..

Financial Support

The Authors report no financial support regarding content of this article.

Ethical Declaration

Ethical permission was obtained from the Duzce University, Medical Faculty Clinical Research Ethics Committee for this study with date 25-07-2022 and number 2022/139, and Helsinki Declaration rules were followed to conduct this study.

Authorship Contributions

Concept:K.Ç Design: K.Ç, Ş.K, Supervising: K.Ç,Ş.K Financing and equipment: K.Ç,Ş.K Data collection and entry:Ş.K Analysis and interpretation: K.Ç,Ş.K, Literature search:Ş.K, Writing: K.Ç, Critical review: Ş.K

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