Comparison of the effects of topical cyclosporine a 0.05% and topical cyclosporine a 0.1% use on recurrence and clinical parameters after pterygium surgery

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Informed consent

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1

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Abstract

Background/Aim: To compare the efficacy of topical 0.05% cyclosporine A (CsA) and 0.1% topical cyclosporine A (CsA) for 6 months after pterygium surgery on postoperative recurrence and clinical parameters.

Material and methods: In this clinical study, 245 patients with pterygium who were operated with the conjunctival autograft technique with Mitomycin C (MMC) were enrolled. Participants were divided into groups as group 1 (CsA 0.05%) (n = 80), group 2 (CsA 0.1%) (n=80) and control group (n = 85). They were examined at postoperative first day, first week, first month and sixth month; best corrected visual acuity (BCVA), intraocular pressure (IOP), presence of inflammation and ptergium recurrence were evaluated and compared.

Results: The mean age of the patients was 63.22 ± 9.39 years and 53.3% were male and 46.7% were female. The three groups were similar in terms of demographic characteristics and pterygium size. Inflammation in surgical area regressed significantly in all groups at 6 months postoperatively ($p<0.05$). Inflammation in the first and sixth months was not different between the groups ($p=0.118$, $p=0.580$ and $p=0.435$, respectively). The recurrence rate was not different between groups ($p=0.890$). There was no statistically significant difference between groups in IOP ($p=0.818$). A significant increase in BCVA after surgery was observed in three groups compared to preoperatively ($p<0.05$).

Conclusion: This study showed that there was no difference between the efficacy of 6 month topical CsA 0.05% and CsA 0.1% application after pterygium surgery with the conjunctival autograft technique with MMC on postoperative outcomes. Including post operative recurrence, IOP changes, BCVA changes and surgical area inflammation.

Keywords: Cyclosporine A 0.05%, cyclosporine A 0.1%, inflammation, pterygium, recurrence

1.Introduction

Pterygium is a degenerative and proliferative ocular surface disease characterized by fibrovascular extension of the conjunctiva onto the cornea. Although the exact etiology is unknown, it is strongly associated with exposure to ultraviolet light. It occurs all over the world, but is more common in dusty, sunny, hot climates and subtropical regions. Its frequency increases between 37 degrees south and north latitudes, also called the pterygium belt[1]. Ultraviolet light, believed to cause pterygium, can induce chronic inflammatory cells in the conjunctiva and damage limbal stem cells. Therefore, chronic inflammation contributes to the formation of pterygium[2,4]. Pterygium can cause non-aesthetic appearance, redness, foreign body sensation, itching and dryness. Sometimes it can spread to the entire corneal surface and close the visual axis, causing vision loss. Involvement of the visual axis, high astigmatism, diplopia due to ocular motility limitation, and cosmetic causes are indications for treatment in pterygium. The treatment of pterygium is surgery. The aim of surgery is to provide ocular surface reconstruction and to prevent recurrence as much as possible[5].

The most important risk of pterygium surgery is the high risk of recurrence, which may vary according to the patients and surgical methods. Surgical methods include bare sclera rotational flap technique, conjunctival autograft technique and amnion membrane transplantation techniques[6,8]. Accordingly, intraoperative and postoperative use of adjuvant agents such as mitomycin C, 5-fluorouracil has been suggested; however, their recurrence reduction efficacy is uncertain and their side effects seem high.[9] Due to the role of inflammation in pterygium formation, attention has also been drawn to anti-inflammatory agents [10].

Cyclosporine A (CsA), one of these anti-inflammatory agents, is a calcineurin inhibitor. It is an anti-inflammatory agent that suppresses T-helper cells, controls interleukin synthesis, and inhibits vascular endothelial growth factor.[11] CsA can also suppress the transition from fibroblast to myofibroblast through inhibition of myofibroblast markers induced by transformed growth factor-beta 2 [12].

In a meta-analysis comparing the recurrence rate, the use of conjunctival autograft and CsA 0.05% eye drops showed low recurrence[13]. Some studies suggested that CsA did not have a significant effect on the recurrence rate [14,16].

We aimed to compare the efficacy of topical application of 0.05% CsA and 1% CsA for six months after pterygium surgery on postoperative recurrence and clinical parameters. Accordingly, we selected pterygium cases who underwent MMC with the conjunctival autograft technique. The efficacy of postoperative treatment was compared between the groups.

2.Materials and methods

Patients who were diagnosed with primary pterygium and had surgery indication in .... City Training and Research Hospital from January 2020 to January 2022 were enrolled in this clinical study. The study protocol was approved by ... University Ethics Committee with the decision numbered (November 28, 2022/185). Patients signed written informed consent. The Declaration of Helsinki was followed in this study.

Patients with primary pterygium of 3 mm or above on the horizontal axis were included in this study. Recurrent pterygium, pseudoptergium, complicated pterygium surgery, keratitis, conjunctivitis and severe dry eye disease, ocular surgery within the last six months, diabetes mellitus and cardiac disease, history of hypersensitivity to CsA, pregnant and breastfeeding women were excluded. The patients were divided into groups as group 1 (CsA 0.05%), group 2 (CsA 0.1%) and control group (CsA not used group)

All patients underwent a complete ophthalmological examination with a slit lamp biomicroscopy. All preoperative and postoperative examinations were performed by a same surgeon. Demographic and preoperative data of the participants, such as age, gender were recorded and best corrected visual acuity (BCVA) and intraocular pressure (IOP) were measured preoperatively. Slit lamp examination was performed for the measurement and grading of the pterygium size. Pterygium size was considered as the distance from the corneal limbus to the head of the pterygium. Pterygium were graded according to the Tan classification[17] .Tan staging is a classification based on the visibility of episcleral vessels under the pterygium tissue, according to which stage 1: atrophic, clearly visible episcleral vessels are present, stage 2: moderate, partially

visible, presence of episcleral vessels stage 3: opaque episcleral vessels cannot be distinguished.

All patients underwent pterygium surgery using the conjunctival autograft technique with MMC. All surgeries were performed by a same surgeon. The surgical procedure was performed under local anesthesia. Topical propacaine 0.5% (Alcaine, Alcon, USA) were initially instilled. An speculum was placed and 0.5 ml of local anesthetic lidocaine hydrochloride 20 mg/ml was injected into the pterygium body with a 27 gauge needle. The pterygium body was grasped with the tenon capsule and cut with the help of scissors. Hemostasis was achieved by thermal cautery. A sterile cotton-tipped applicator moistened with 0.02% MMC (Kyowa, Seoul, Korea) was applied to the scleral bed for 90 seconds. Abundant irrigation was done with 200 ml of normal saline solution. A conjunctival autograft was prepared from the superotemporal bulbar conjunctiva under the upper eyelid. Graft were attached with tissue adhesive (Tisseel, Baxter, USA) and fixed to the conjunctiva and sclera. In some patients with poor compliance, the graft was supported with 8/0 polyglactin 910 absorbable and synthetic suture. Suture removal was performed one month later.

All groups received Moxifloxacin 0.5% (Moxai, Abdi Ibrahim, Turkey) four times a day for two weeks, dexamethasone 0.1% (Maxidex, Novartis, Switzerland) four times a day for one month and preservative-free artificial tear drops (Eyestil, SIFI, Italy) four times a day for one month. In addition to these medications, group 1 (0.05% CsA, Depores, Deva, Turkey) were given twice a day for six months and group 2 (0.1%, Depores X, Deva, Turkey) were given twice a day for six months. Cyclosporine A was not used in the control group. Patients were examined on the postoperative first day, first week, first month and sixth month. Slit lamp examination was performed at each

visit, and signs on inflammation in the surgical area, BCVA, IOP, and postoperative recurrence were recorded.

Postoperative inflammation is considered as hyperemia of the surgical area. Inflammation degrees and recurrences of the cases were graded using the classification proposed by Prabhasawat. This classification is as follows. Absence of inflammation is graded as G0, mild inflammation as G1, moderate inflammation as G2, and severe inflammation as G3. Grade 2 and Grade 3 inflammation is considered as recurrence [18].

All statistical analyzes were performed using the statistical software IBM SPSS Statistics for Windows version 21.0 (IBM Corp. Armonk, NY, USA). The normal distribution was tested with the Kolmogorov-Smirnov test, and according to its result, the mean ± standard deviation or median range was used for the definition of variables with and without normal distribution, respectively. Frequency (percentage) was used for categorical variables. Comparisons between the three groups were made using Student's t-test and Mann-Whitney U for normally distributed numerical variables. Chi-square or Fisher's precision test was used according to the sample size in the comparison of categorical variables. Wilcoxon signed-rank test or paired-sample t-test was used to compare the differences in each study group for normally distributed and non-normally distributed variables, respectively. In all tests, $p<0.05$ was considered statistically significant.

3.Results

There were 80 patients in group 1, 80 patients in group 2 and 85 subjects in the control group. As stated in Table 1, there was no difference between the groups in terms of age, gender, pre-operative pterygium size and UV exposure ($p>0.05$ for all).

The degree of inflammation was not different between the groups at the first month and sixth months after surgery ($p=0.208$ and $p=0.428$, respectively). In the inter-group comparison, a significant decrease in inflammation was observed between first month and sixth months in all three groups ($p<0.05$). (Table 2)

There was no difference between the groups in terms of preoperative BCVA. A significant increase in postoperative BCVA was observed in all three groups compared to preoperative period ($p<0.05$). (Table 3)

Postoperative recurrence rates are shown in Table 4. The recurrence rate was determined by groups, gender and preoperative pterygium size. There was no statistically significant difference between groups in terms of recurrence ($p=0.899$).

Recurrence was seen in 3 females and 3 males in group 1 (7.5%), 2 females and 3 males in group 2 (6.25%) and 4 females and 4 males in the control group (9.4%). There was no significant difference between the groups in terms of recurrence.

Patients under 40 years of age had the highest recurrence rate. This was not statistically significant ($p>0.05$). The number of recurrences decreased with advanced age. This situation was similar in all groups.

There was no statistically significant difference between groups in IOP levels. However, slight increases in IOP levels were observed in the groups between preoperative and postoperative sixth month follow-up measurements ($p=0.132$ for group 1, $p=0.350$ for group 2 and $p=0.142$ for group 3 respectively), was not statistically significant between

time and groups (p=0.818). It was observed that the increasing trend in IOP was parallel in the groups during the measurement periods.

Cases that developed complications were not included in this study. The inclusion and exclusion criteria were explained above. However, postoperatively, patients experienced burning, stinging, dryness and persistent epithelial defect was observed in 8 patients. These symptoms regressed in all patients after 6 months of follow-up.

4.Discussion

In this study, we investigated the effects of 6 months of additional treatment with 0.05% CsA and 0.1% CsA on the postoperative outcomes of patients with primary pterygium. Postoperative inflammation, BCVA, IOP, and recurrence rates were compared between the groups. There was no statistically significant difference. These results show that there is no difference in reducing postoperative pterygium recurrence between different forms of CsA.

When we look at the literature, there are studies stating that the surgical technique we apply is the most successful pterygium surgical method with postoperative results [19]. The low recurrence rate and reduction in inflammation in the study groups confirmed the suitability of the conjunctival autograft technique. Moreover, previous studies have found promising the application of MMC in pterygium surgery with conjunctival autografts.[20,21] For these reasons, these two methods were used in our study for optimal outcomes.

MMC causes a decrease in cell proliferation and migration. In addition to pterygium surgery, it has applications in ocular surface tumors, refractive surgery, glaucoma surgery, oculoplastic and strabismus surgery. Although promising in treatments, MMC has potential complications such as endothelial cell loss, corneal perforation, scleral

melting, secondary glaucoma, iritis, and endophthalmitis. No side effects or complications were observed in any of our patients due to the use of MMC. The reason why we did not observe any complications may be that the mitomycin C applied for three minutes during the surgery was washed off abundantly with at least 200 ml serum irrigation.

The symptoms of pterygium are similar to dry eye disease and meibomian gland dysfunction (MGD), including dryness and irritation. Janson et al. [20] found a significant relationship between pterygium size and dry eye symptoms. Pterygium has an negative correlation with tear film break-up time (TBUT) and Schirmer test result, but positive correlation with corneal staining. It has been shown that pterygium can cause compression under the meibomian glands due to its contact with the palpebral conjunctiva. There are studies in the literature showing that ocular surface disease index score (OSDI), tear film break-up time test (TBUT), and Schirmer test results of the patients treated with cyclosporine A improved significantly [21]. Cyclosporine has also been beneficial for complaints of dryness, stinging, itching and burning.

Considering the effects of CsA on postoperative results, although the sample size is small compared to the calculated value. The number of 19 recurrence patients in our study was low. It was thought that it would not be correct to draw definite conclusions about recurrence.

In the study conducted by Ozulken et al., observed that the use of cyclosporine A showed a significant decrease in the recurrance rate on 56 patients [14]. Similar to our study, patients were given cyclosporine A for 6 months after surgery. Unlikely, MMC was not applied and a different surgical technique was used. The overall recurrence rate in their study (14.2%) was higher than in our study's recurrence rate (7.7 %) which may

be due to the effect of MMC adjunctive therapy and operation technique. There was a lower recurrence rate in our study, but we did not see a statistically significant decrease. Meneghim et al. showed that 0.05% CsA plus 5-fluorouracil application 10 days before and 10 days after the rotational conjunctival flap technique did not differ between the 6 month recurrence rates in the control and case groups, and the recurrence rate was higher than our study.[22] Although these results are consistent with the general result of our study, the fact that they used 5-fluorouracil instead of MMC and the duration of CsA administration was different and shorter than our study may be the reason for the higher recurrence rate. Dhar et al. reported that CsA 0.05% administered 4 weeks before and after surgery had no effect on the recurrence rate [23]. Other investigators who reported no effect for CsA also used different inclusion criteria, such as bilateral pterygium with >2 mm corneal invasion.

On the other hand, Tok et al. reported a significantly lower recurrence rate with 0.05% CsA [24]. Ahmed et al. again showed low recurrence rates in the control groups versus 0.05% CsA[25]. These two studies showed statistically lower recurrence rates in the group treated with CsA 0.05%. This difference may be due to the cyclosporine A dose used and the follow-up period. Therefore, differences between studies prevent proper comparison of results. When the results of 408 patients were evaluated in a meta-analysis of seven studies. Confirmed that the adjuvant use of CsA significantly reduces recurrence compared to the bare sclera technique alone. However, this meta-analysis indicated that there was no difference in the recurrence rate of pterygium between the conjunctival autograft technique with and without CsA and the rotational conjunctival flap technique [26]. This result is consistent with our study. Patients with complications were not included in this study. Therefore, complications were not evaluated. In a meta-

analysis of 408 patients, the CsA group showed a significantly lower incidence of complications compared to the control group [27]. In our study, subgroup analysis showed that the recurrence rate was not related to the age, gender, and preoperative pterygium size of the patients. Looking at the literature, Han et al. applied the same surgical technique as our study and reported that gender and age were not significant in the one year recurrence evaluation. Anguria et al found that age had no effect on recurrence [27]. This is consistent with our results. However, they reported pterygium size as an important marker. Other studies in the literature suggested that larger pterygium size or grade before surgery is an important indicator of postoperative recurrence [26]. The differences in pterygium recurrence reported in studies can be attributed to the different surgical techniques used. Low recurrence in our study. It can be attributed to the fact that it is used simultaneously with conjunctival autograft and the small number of samples.

Our study has some limitations. Due to the retrospective nature of the study, the accuracy of the information obtained from the records can be questioned. The limited number of samples, 6 month follow-up and sampling from a single center were among the factors limiting the generalizability of the results to the whole population.

The results of this study demonstrated that primary pterygium surgery with conjunctival autograft technique and the use of MMC is a successful surgical procedure in the treatment of primary pterygium, resulting in low recurrence rate after surgery. However, the main hypothesis of this study was rejected and observed that the addition of two different concentrations of 0.05% CsA and 0.1% CsA administered 6 months after surgery did not reduce the risk of postoperative pterygium recurrence. In the light of this information, the ineffectiveness of cyclosporins at different doses may have been

observed because the use of appropriate surgical technique and adjuvant MMC caused a low recurrence rate. More comprehensive studies in the future may find the answer to this question.

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Table 1. Comparison of demographic and preoperative data of the groups

	Group 1	Group 2	Control	p
	n=80	n=80	n=85	
Age (years)	53.87±11.35	54.67±10.85	54.32±10.99	0.684
Gender (n) Male/Female	42/38	44/36	45/40	0.717
Average UV exposure (hours)	3.0 - 3.5	4	3.5 - 4.0	0.224
Mean pterygium size (mm)	3.5 (3-4)	3.4 (3-4)	3.6 (3-4)	0.185

Table 2. Comparison of inflammation results between groups

Inflammation	Group 1	Group 2	Control	p	
	n= 80	n= 80	n=85	Inter-group	Intra-group
G0 (first month)	15	17	20	0.208	p<0.05
G1 (first month)	31	29	25		
G2 (first month)	25	24	30		
G3 (first month)	9	10	10		
G0 (sixth month)	70	72	72	0.428	
G1 (sixth month)	6	4	6		
G2 (sixth month)	3	4	5		
G3 (sixth month)	1	0	2		

Table 3. Comparison of BCVA results between groups

BCVA	Group 1	Group 2	Control	p

	n=80	n=80	n=85	Intergroup	Intragroup
Preoperative	0.27±0.19	0.26 ±0.18	0.27 ± 0.19	0.657	<0.05
Postoperative	0.26 ±0.19	0.24 ±0.18	0.26 ± 0.19	0.724	

BCVA (logMAR mean ± standard deviation)

Table 4. Comparison of recurrence rates between groups

	Age (years)	Group 1 n=80	Group 2 n=80	Group 3 n=80	Control n=85	p Inter-groups	p Intra-group
Recurrence (n)		6	5	8	3	0.899	
According to pre-operative pterygium size (n)	under 40 (n)	3	4	3			
	40-49 (n)	2	1	3			>0.05
	50-59 (n)	1	0	1			
	55 and above (n)	0	0	1		0.999	> 0.05
	3 mm	2	1	3			
	3.5 mm	3	2	2			
	4.5 mm	1	2	3			
Gender (n)	Female	3	2	4		> 0.05	
	Male	3	3	4			

Table 5. Recurrence distribution of groups by age