Electronic Physician (ISSN: 2008-5842) http://www.ephysician.ir
December 2017, Volume: 9, Issue: 12, Pages: 5877-5884, DOI: http://dx.doi.org/10.19082/5877

Surgical outcome of conjunctival rotational autograft-mitomycin C (MMC) versus free conjunctival autograft-MMC for pterygium removal: A randomized clinical trial

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Type of article: Original

Abstract

Background: Pterygium is a common degenerative eye disease. Despite various surgical methods to treat pterygium, recurrence is the main complication. The main issue is finding a surgical method with the lowest recurrence.

Objective: to compare the complications, recurrence rate and the cosmetic effects of two surgical techniques, namely conjunctival rotation autograft (CRA) and conjunctival autograft (CA), in treating pterygium.

Methods: This randomized clinical trial was conducted at Khalili Hospital in Shiraz, Iran, from January to August 2015. Forty-five eyes from 45 patients were studied. The patients were randomly divided into two groups using the blocking method. The patients of one group were operated on by the CRA technique, while the other group was operated on by the CA method. The patients were checked for the recurrence of pterygium, and other complications at the end of the first, third, and sixth month. Finally, the data were analyzed using SPSS version 21.

Results: The mean age of the patients was 42.5 years. The recurrence of pterygium was not observed in any of the patients 6 months after the surgery. Following 6 months after the operation, graft retraction occurred during the first week for one patient (4.5%) in the CA group, and five patients (21.7%) in the CRA group. The prevalence rate of graft injection among the patients of the CA and CRA groups 6 months after the operation was 9.1% and 65.2%, respectively. There was a significant correlation between injection intensity and the dissatisfaction of the patients with the operation's outcome (p=0.017).

Conclusion: CRA with mitomycin is considered as an effective method to reduce the recurrence of pterygium after operation. This technique can be used as an acceptable method for pterygium operation, especially for patients with insufficient conjunctiva.

Clinical trial registration: The trial was registered at the Iranian Registry of Clinical Trials (http://www.irct.ir) with the Irct ID: IRCT2016092119581N2.

Funding: The study was financially supported by Shiraz University of Medical Sciences (SUMS) (grants No. 8901).

Keywords: Pterygium, Conjunctival rotation autograft (CRA), Conjunctival autograft (CA)

1. Introduction

Pterygium is a common degenerative eye disease resulting from the growth of fibro vascular conjunctiva on the cornea. The prevalence of pterygium has been estimated to be between 7% and 33% according to geographical situation. Pterygium is more prevalent in areas with stronger ultraviolet radiation as well as hot and dry climates (1). Surgery is an optional treatment for pterygium. Indications of Pterygium surgery include vision deterioration as a result of the involvement of visual axis and induction of irregular astigmatism, chronic eye irritation, recrudescent

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Received: October 17, 2016, Accepted: August 17, 2017, Published: December 2017
iThenticate screening: June 12, 2017, English editing: December 01, 2017, Quality control: December 14, 2017

inflammation, limitation of eye movement, and cosmetic purposes. In spite of the presentation of numerous pterygium surgery techniques, recurrence is still an important issue and a major surgical problem, which its prevalence varies from 2% in conjunctival autograft surgery to 89% in the bare sclera method (2, 3). Mitomycin C is an antimetabolite and antiproliferative factor harnessing the synthesis of DNA and RNA. Some studies have reported the recurrence of pterygium by mitomycin C in the rotational method to be equal with free conjunctival graft technique (4, 5). Local application of mitomycin on the operation site will decrease the recurrence risk (6). CRA can be utilized in cases where it is impossible to use the superior bulbar conjunctiva (the most prevalent place for applying graft) or when it is difficult to remove some suitable thin conjunctival tissue from other areas, and also, due to the impossibility of using the conjunctiva of the opposite eye (7). This method was first introduced by Speath et al. (8) in 1926, who grafted the pterygium tissue to the surrounding conjunctiva with a 90° rotation. The CRA method was changed into a 180° rotation of pterygium (7). The recurrence rate is 4% in this report. In 2002, Alp et al. reported that the recurrence rate of this method was 16.6% (9). In another study in 2009, CRA with local mitomycin 0.02% C was used for 5 min during operation while a recurrence rate of 3% was reported in one year (10). In this method, pterygium epithelium is removed from the underlying fibrovascular tissue. Then, it is rotated 180° and mounted on sclera so that the epithelium is positioned at nasal cantus and limbus side. The benefits of this technique include: preserving the conjunctival tissue, creating a coating for the conjunctiva on the surgical site, and decreasing the surgery duration (11). According to the majority of studies carried out in this field, the most significant disorder reported for this method is the undesirable appearance for the patients, caused by the injection of grafted conjunctiva against its surrounding natural tissue (10). The purpose of this study was to compare the complications of conjunctival rotation autograft (CRA) and conjunctival autograft (CA) for the treatment of pterygium considering the appearance results and recurrence possibility.

2. Material and Methods

2.1. Trial design and participants

This randomized clinical trial was conducted at Khalili Hospital in Shiraz, Iran, from January to August 2015. In total, 45 eyes from 45 patients who had visited for pterygium surgery at the Khalili Ophthalmology Center in Shiraz County in southern Iran were studied.

2.2. Sample size

The sample size was calculated to be 45 subjects. This sample size was calculated based on the results of previous studies (10, 22) by assuming the test power of 80% and a confidence level of 95% and using the following formula:
$n= (Z_{1-\alpha/2} + Z_{1-\beta/2})^2 [P1(1-P1) + P2(1-P2)] / (P1-P2)^2$

2.3. Selection criteria

The inclusion criteria were as follows: the presence of primary pterygium (temporal or nasal), having surgical indications (vision deterioration due to involvement of visual axis or induce of irregular astigmatism, chronic eye irritation, recrudescent inflammation, limitation of eye movement, cosmetic problems, and more than 2 mm growth on the cornea), and being younger than 55 years old. Primary pterygium is defined as having no history of pterygium surgery for the target eye. The exclusion criteria of the study were the following: the pterygiums being suspicious of conjunctival intraepithelial neoplasia, the presence of symblepharon, recrudescent pterygiums, double head pterygium, pseudo pterygia, having a history of eye trauma and corneal scar.

2.4. Interventions

All stages of examinations were done by the same ophthalmologist. In cases of bilateral pterygium surgery, the eye was selected based on its severity and complaint of the patient. Also, recurrence of pterygium was defined as growth of the pterygium tissue on the surgery spot more than 1mm. After achieving the informed consent, the patients were randomly divided into two groups (23 and 22 patients in the groups of CRA and CA, respectively) by the blocking method. Before the operation, the demographic information of the patients including occupation, place of living, the conditions of the opposite eye in terms of pterygium, recurrence in the opposite eye, family history of pterygium and history of sun glasses use were recorded. Complete eye examination including vision by Snellen chart, refraction by auto-refractor, and intraocular pressure (IOP) by Goldman tonometry was carried out. The anterior segment was examined by the slit lamp, and fundus was tested using indirect ophthalmoscopy and 20-diopter lens. Also, severity of conjunctiva graft injection was defined as mild (superficial and deep redness of less than half of graft), moderate (superficial and deep redness of more than half but less than total parts of graft) and severe (superficial and deep redness total parts of graft). All stages of operations were done by the same surgeon using local anesthesia and surgery microscope. For both methods, in order to carry out the surgeries, 2% HCL lidocaine mixed with 1/80,000

epinephrine (produced by Daroupakhsh company) were injected into the pterygium tissue by a 25-gauge needle after inserting the speculum. The pterygium was removed from the cornea by blunt method and detached from its base by sharp scissors. Also, the Tenon tissue was removed from a more extensive area than the pterygium tissue. Then, 0.02 mg/ml of mitomycin C was employed beneath the conjunctival tissue and Tenon's capsule for two minutes using a cellulose sponge, without being in contact with sclera and limbus. Then, the mentioned area along with the whole eye were immediately rinsed with 50 cc BSS. In the CRA method (figure 1) with Westcott, the fibrovascular tissue was removed from the pterygium as much as possible and subsequently the pterygium tissue was rotated 180° so that its nasal side was placed near the limbus and sutured to the surrounding conjunctiva by separate nylon 10-0 stitches. In the CA method (figure 2), the superatemporal quadrant was used as the graft. In both methods, bandage contact lens was applied at the end of operation. This lens can be removed on the third day after operation from all the patients' eyes if there is no corneal epithelial defect. All patients under treatment were treated with 0.5% chloramphenicol every 6 hours for two weeks, 1% betamethasone drops (produced by Sina Daru company, Iran) every 6 hours for one month, then, 0.1% FML drops (produced by Sina Daru company, Iran) for 2 months every 8 hours, and artificial tears 4 times a day. The sutures were removed at the end of the third week and the patients were examined at the end of the first, third, and the sixth month.

2.5. Outcomes

The primary outcomes of our analyses were the rate of pterygium recurrence. The secondary outcomes from the analyses were the level of graft injection, lost graft, dellen, graft edema, graft retraction, cosmetics, refraction, intraocular pressure (IOP), and best corrected visual acuity (BCVA). Also, the recurrence of pterygium was defined as growth of pterygium tissue on the surgery spot more than 1mm.

2.6. Randomization and blinding

Patients were divided by a non-surgeon examiner into two groups according to the visit. He put the odd numbers in the intervention group and the number of couples in the control group. Surgery, evaluation and recording of the results were done by the same person. All 45 participating patients were present for the 6-month follow-up. No patient withdrew from the study.

2.7. Statistical methods

Finally, the data were analyzed by IBM© SPSS© Statistics version 21 (IBM© Corp., Armonk, NY, USA). Descriptive findings are presented as Mean ± Standard Deviation and percentages. Chi-square test was used for comparison of data. Also, means between differences were compared using t tests. P value of less than 0.05 was considered to be statistically significant.

2.8. Research ethics

The study has been approved by the ethics committee of the Shiraz University of Medical Sciences (Ref. no. 1394-S550). Before surgery, patients were familiarized with the both surgical procedure and their complications and benefits with verbal explanation and written notes. The patients were informed about the duration and frequency of follow-up, then written informed consent was obtained. The patient was reassured that they could exit the study at any time without any question, and they would be assigned to the routine treatment process similar to non-participant patients. Free treatment was assured to patients, in the occurrence of any side effects during the course of treatment.

3. Results

From the 45 examined patients in the present study, 44 cases of the pterygiums were found to be on the nasal side, while in 1 case it was on the temporal side. More than half of the patients (57.8%) were men. The mean age of the patients was 42.5±5 standard deviation (SD). The maximum and minimum ages of patients were 55 and 23 years old, respectively. In all, 40% of the patients were operated on for right eye pterygium. There was no significant difference between using sunglasses or living in a rural area and size of pterygium in the both groups. Difference of best corrected visual acuity (BCVA) ($p=0.02$) and mean astigmatism level ($p=0.04$) was statistically significant before and after operation, but comparison of the items did not show significant difference between the two groups after operation. Also, the average horizontal and vertical extensions of pterygium over the cornea were 2.4 mm and 4.2 mm, respectively. There was significant correlation between horizontal extensions of pterygium with decreasing visual acuity ($p=0.001$). The average IOP of the patients before the operation was 13.5 mmHg and the maximum IOP was measured to be 19 mmHg. Difference of IOP before and after the surgery was not significant in both groups. Table 1 represents the average level of astigmatism, the best modified vision of the patients (BCVA) by Log

MAR method, the average IOP of patients before and after the operation and other important factors have been comparatively illustrated. Epithelialization of the cornea was completed three days after operation in the all patients. Complications such as pyogenic granuloma, symblepharon, dellen of cornea, keratitis, scleral melting, were not observed in any of the patients. The recurrence of pterygium was not observed in any of the patients during the 6-month period after surgery. Six months after surgery, graft retraction occurred in one case of a CA group patient (4.5%) and five patients (21.7%) from the CRA group in the first week. The occurrence rate of graft injection 6 months after the operation was found to be 9.1% and 65.2% for the patients of CA and CRA group, respectively, and the difference was statistically significant. Also, in terms of injection level (figure 3), in the CRA group, 2 mild cases, 3 severe cases, and 10 moderate graft injection cases were found. There was no significant difference between size of pterygium and severity of conjunctiva injection (p=0.1). Also, association between gender and severity of conjunctiva injection was not significant (p=0.08). One patient of the CA group (4.5%) and 8 patients of the CRA group (34.8%) were not satisfied with their eye conditions after surgery. There was a meaningful relationship between the injection intensity and the dissatisfaction of the patients with the surgery (p=0.017). The edema of grafted conjunctiva was observed in 8.7% of the CRA group patients during the first week after surgery. The edema disappeared after 2 weeks. In addition, the lost graft was detected in one of the CRA group patients (4.34%) during the first week after the operation.

Table 1. A comparison between some of the most important indexes studied in the patients of both groups before and after the operation by means ± standard deviation (SD).

Variables		CRA- MMC (n=23)	CA-MMC (n=22)	p-value
Age (years)		45.2± 4.5	53±3.75	0.07
Gender	Male	12	7	0.05
	Female	11	15	0.08
Side	Right eye	10	8	0.1
	Left eye	13	14	0.1
Log MAR	Pre-operative	0.17±0.01	0.15±0.02	0.06
	Post-operative	0.11±0.03	0.13±0.01	0.07
IOP (mmHg)	Pre-operative	13.2±2	13.72± 3	0.08
	Post-operative	12.3±3	13.7±2	0.08
Astigmatism	Pre-operative	-3.4±0.05	-2.75±0.75	0.07
	Post-operative	-1.7±0.025	-1.45±0.05	0.09
Size#	Horizontal	2.6±1	2.27±2	0.1
	Vertical	3.9±2	4.5±3	0.1

Size of extension of pterygium on cornea.

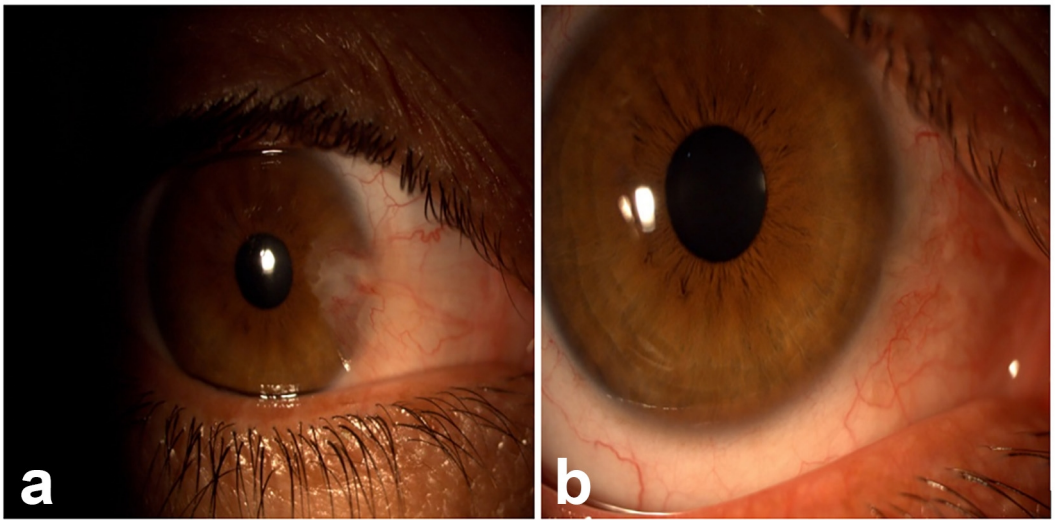

Figure 1. Pterygium surgery with method of conjunctival rotational autograft A) before and B) six months after operation.

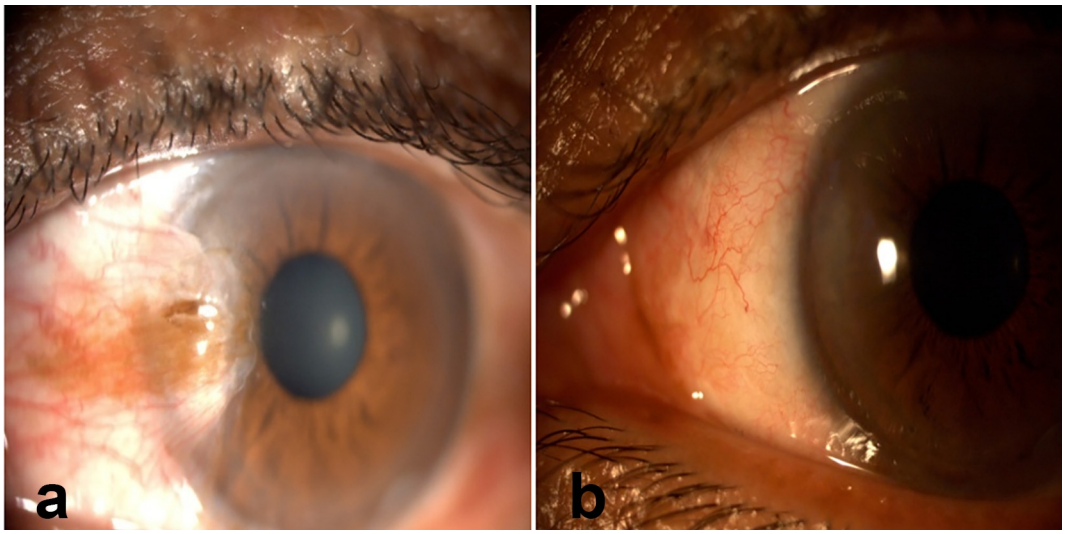

Figure 2. Pterygium surgery with method of conjunctival autograft A) before and B) six months after operation.

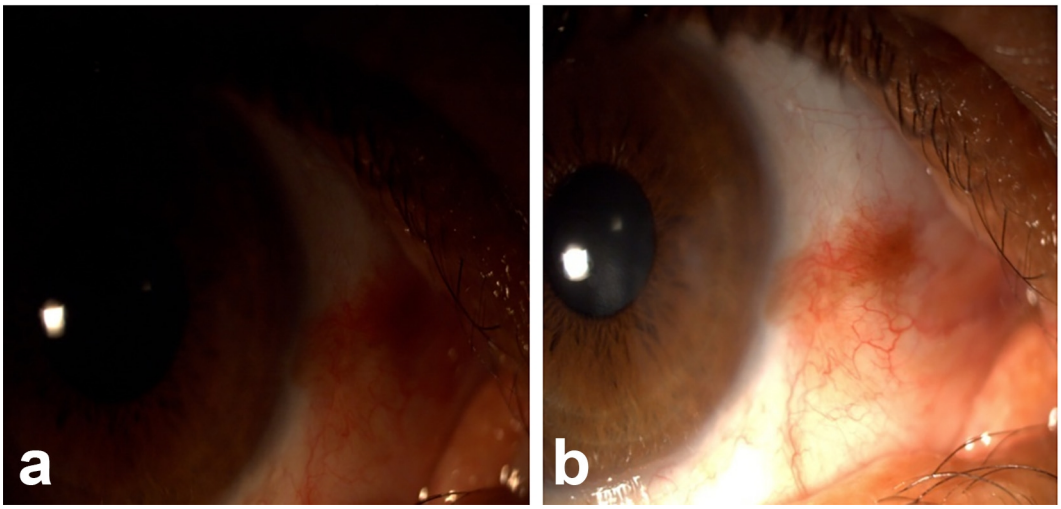

Figure 3. Injection of conjunctiva graft after one month (A) and six (B) months from surgery in the CRA method.

4. Discussion

Although various surgical methods have been introduced to treat pterygium, recurrence has been reported in all these methods (12). However, the recurrence rate varies based on the surgery type, selection conditions of the patient, and geographical situation (13). According to the literature, the recurrence rate in bare sclera and mitomycin C methods has been 24-68% and 4.1-13%, respectively (14). The recurrence rate in the conjunctival autograft was reported to vary between 3.5 and 39 percent (15). According to some reports, the results of the conjunctivolimbal autograft method was similar to those achieved when mitomycin was employed during the operation (intraoperatively) (16). Moreover, according to various published studies, the conjunctivolimbal autograft method has been reported to have a lower recurrence rate than the amniotic membrane placement method or the removal of pterygium by bare sclera excision (17, 18). The combination of conjunctivolimbal autograft excision and the intraoperative mitomycin C has proved to be more effective in reducing the recurrence rate than when the two techniques are separately applied (19, 20). In various studies, the recurrence rate of conjunctival autograft excision with intraoperative mitomycin C has been reported to be 0-2% (21). In the present study, in order to evaluate the benefits, complications, and the recurrence rate of pterygium surgery using conjunctival rotation autograft, it was compared with conjunctival autograft excision with intraoperative mitomycin C. This is the first study in which the two pterygium surgery methods, conjunctival autograft excision and conjunctival rotation autograft using mitomycin C during the operation have been compared. In general, this method is more difficult than the CA method. In the present study, the average surgery duration for both methods has been equal, at around 50 min, which is attributed to

the difficulty of separating the fibrovascular tissue from a small graft, the smaller size of the graft compared with bare sclera and a need for more sutures to hold the graft in the CRA method. Nevertheless, Subbash et al. have reported the CRA duration to be shorter than the CA method by 20 min (22). In the present study, no recurrence was observed after 6 months of the patients' follow-up. In a study, the recurrence rate in CRA and CA groups were reported to be 5.58% and 5.55%, respectively (22). Moreover, in a study carried out by Wu et al. (11) in 2007 on the CRA method, the recurrence rate was reported to be 35%. Jap et al. (7) employed the CRA method when CA was contraindicated, and recorded a recurrent rate of 4% with an average follow-up of 12 months. In another study which was carried out in 2009, the combination of CRA and the 0.02% mitomycin C for 5 min was used to treat pterygium, reaching a recurrence rate of 3% after one year (10). All these data indicate that the CRA operation method is similar to the CA method and the lower recurrence rate in this study is most likely the result of applying mitomycin C during the operation, more effective separation of the fibrovascular tissue, longer employment of anti-inflammation factors after operation and shorter follow-up time. The injection was related to the dissatisfaction level of the patients so that 8 out of 9 patients attributed their dissatisfaction to injection. The graft injection level in the present study for CA and CRA groups was 9.1% and 65.2%, respectively (7, 10, 11). Currently, no standard classification has been mentioned to describe the injection level. In the present study, injection has been classified based on the percentage of graft congestion. Since the applied method was the same in both groups, except for the graft, and considering the fact that similar dosages and durations of mitomycin were employed in both groups, mitomycin and the amount of anti-inflammation drugs do not possibly affect either the occurrence or prevention of injection. Thus, the higher injection level of CRA may be due to the presence of more fibrovascular tissue, variations of pterygium epithelium due to long-term sunlight exposure, the larger number of sutures and the resulting inflammation in the CRA method. According to some reports, the injection level in large pterygiums is higher, which is attributed to the higher amount of the attaching fibrovascular tissue (11). However, in the present study, no relationship was found between the pterygium size and the injection level. In the present study, the retraction graft in the CRA group was 5 times higher than that in the CA group; which can be related to the small graft size, edema and chemosis in the graft and the fibrous tissue attached to the graft (23). Figueira et al. (23) showed that retraction can be inhibited as the fibrous tissue of the graft, being a few millimeters larger than the sclera defect, is completely removed. In the present study, one case of lost graft was observed in the CRA group in the first week, which is most likely attributed to rubbing the eyes, small size of the graft, and the inadequate number of sutures. Shaaban et al. (24) have mentioned the graft dehiscence caused by eye trauma because of harsh rubbing of the eyes and the wrong technique. In fact, fibrin glue has been employed to attach the graft in the mentioned study. In this study, the prevalence of pterygium was higher in men. The role of sex in the pterygium prevalence is a controversial issue having been interchangeably higher among men and women (25, 26). Doing outdoor activities is one of the possible reasons why the prevalence of pterygium is greater among men. In addition, the prevalence of pterygium has increased among the women who worked outdoors. It has been revealed by several epidemiologic studies that the prevalence of pterygium among men is intensified by older age, working outdoors, and avoiding using sun glasses. The synergistic effect of dust and UV light on the interpalpebral conjunctival tissue is among the probable causes of this phenomenon (26, 27). In the present study, only 4.4% of patients used sun glasses. According to the study of Peter et al. (2014), genetics is essential for the occurrence of pterygium and is considered as a basic factor; which may interfere with the propagation of the fibrovascular tissue, and the sunlight is only a stimulating factor which may result in the propagation of the chronic inflammatory fibrovascular tissue in susceptible people. It would finally lead to extension of pterygium (28). Various studies have evaluated the relationship between pterygium and astigmatism using topography, keratometry, and refraction. The results totally reveal that the astigmatism of the cornea has been reduced by the removal of the pterygium. This reduction in the size of the cornea is in accordance with the pterygium size and would finally improve the BCVA after the operation (29, 30). Some important limitations of the study were including these notes: pre-and postoperative assessment of patients were not blinded which may result in bias especially for subjective signs such as injection; also, sample size and duration time of the study seems to be insufficient for comparison of all items between the two groups. Also, it was better that pterygium severity was defined, and evaluates its association with different complications of the surgery.

5. Conclusions

Based on the results of this study, it can be concluded that CRA with mitomycin C and the CA method with mitomycin C can be equally effective in reducing recurrence in the pterygium surgery. Since the other complications are more than in the CA method, it is better to employ this type of surgery for the patients with a suitable or sufficient conjunctiva for surgery, but we think that further studies with more samples and longer follow up duration are needed to compare the two methods.

Trial registration:
The trial was registered at the Iranian Registry of Clinical Trials (http://www.irct.ir) with the Irct ID: IRCT2016092119581N2.

Funding:
The study was financially supported by Shiraz University of Medical Sciences (SUMS) (grants No. 8901).

Acknowledgments:
The present article was extracted from the thesis written by Dr Shamsi Kooshki Anis. The author thanks all participants of the study, and the research center of Poostchi Ophthalmology in Shiraz city.

Conflict of Interest:
There is no conflict of interest to be declared.

Authors' contributions:
All authors contributed to this project and article equally. All authors read and approved the final manuscript.

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