

COMPARISON OF RECURRENCE INCIDENCE AFTER PTERYGIUM EXCISION BY USING PEROPRATIVE SUBCONJUNCTIVAL BEVACIZUMAB INJECTION VERSUS CONJUNCTIVAL AUTO GRAFT

By

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ABSTRACT

Background: A pterygium is a fleshy, wing-shaped growth from the conjunctiva, crossing over the limbus onto the cornea. The tissue is fibrovascular and can occur over the nasal or temporal cornea. It can be a bilateral process and asymmetric with one eye affected by a larger pterygium than the other.

Objectives: To compare between Subconjunctival injection of bevacizumab (Avastin) and conjunctival autograft in the treatment of primary pterygium.

Patients and Methods: This study was performed on 40 eyes of 40 patients with primary pterygia of variable durations. The eyes were randomly classified into two equal groups: group A patients to be treated by Subconjunctival Bevacizumab (avastin) 0.2 ml (5 mg) for Primary Pterygium Excision, group B patients treated by conjunctival auto graft. Best corrected visual acuity, occurrence of recurrence, IOP and postoperative complications were compared. Patients were evaluated preoperatively then 1 day, 1 week, 1 month, 3 months after surgery. Eye photography was done before surgery and during the follow up period. This study was conducted at Department of Ophthalmology Al-Azhar University Hospital and Kobry El Kobba Military Hospital, from August 2018 to July 2020.

Results: When the two groups were compared together, we found no statistically significant differences among them in multiple compared items, but the recurrence rate in group A (bevacizumab group) occurred in (10%), while in group B conjunctival auto graft no recurrence occurred and this was statistically insignificant difference among the 2 groups. There were no statistically significant differences regarding improvement in visual acuity, intraocular pressure change and postoperative complications among the two groups.

Conclusion: A single preoperative subconjunctival injection of bevacizumab had decreased the recurrence rate before primary pterygium excision, but did not give a more desirable recurrence rate. On the other hand conjunctival autograft was more effective than bevacizumab in reducing the recurrence rate of primary pterygium after surgical excision.

Keywords: Recurrence Incidence, Pterygium Excision, Peroperative Subconjunctival Bevacizumab Injection, Conjunctival Auto Graft.

INTRODUCTION

Pterygium is a common worldwide eye disease affecting population especially in tropical and subtropical areas. It is a degenerative fibrovascular proliferation of conjunctival tissue over the cornea (from the Greek, pterygos, “little wing”). The tissue is fibrovascular and can occur over the nasal (usually) or temporal cornea (uncommon). It can be a bilateral process and asymmetric with eye affected by a larger pterygium than the other. In addition two pterygia can affect a single eye, one nasally and the other temporally. The pterygium consists of collagen tissue that is hyperplastic and denatured, marked by elastic degeneration (degeneration of collagen fibers) (*Clearfield et al., 2016*).

It often is preceded by a growth of the conjunctiva without extension onto the cornea, known as a pingueculum. It is believed that ultraviolet light is a major contributor in the formation of pterygia, though the finding that a high prevalence of pterygium exists outside inhabitants of equatorial regions strongly suggests that reflected, scattered light is also critical.

Both individual susceptibility and environmental exposure appear to be risk factors responsible for the occurrence of pterygium. Incidence and prevalence; affecting population rates range was from 0.7% to 31%. Pterygium is twice as common in men as in women. It is more prevalent in older age groups, but the incidence is higher in younger individuals. It is uncommon in people younger than 20 years of age and among people who wear glasses. The incidence increases greatly in people between 20 and 40 years of age (*Kuo et al., 2014*).

Pterygia can impair vision through altered tear film, induced astigmatism, photophobia, epiphora, and binocular diplopia due to contraction of the Tenon’s capsule, which limits eye movements. Pterygia can cause symptoms such as eye irritation, foreign body sensation, and dryness. In mild climates, it is unusual for a pterygium to grow over the visual axis, but patients are often concerned about the cosmetic appearance of their eye. In potentially susceptible individuals, the pterygium can grow across the entire corneal surface, impairing vision (*Clearfield et al., 2016*).

For mild cases of pterygium, conservative topical treatment with lubricants or steroids is recommended. For advanced symptomatic pterygium, several surgical techniques have been developed over the past few decades (*Huang et al., 2018*).

Although many surgical approaches have been developed, recurrent pterygium represents a significant surgical problem. Reported rates of recurrence range from 2% to 39% for excision with conjunctival autograft to 89% for bare scleral excision. Differences in study morphology, patient characteristics, nature of pterygium, geographic area, definition of recurrence, duration of follow-up, and loss of follow-up are some of the factors responsible for widely varying rates of recurrence (*Sun et al., 2011*).

Surgical treatment options for pterygium include the following:

1. Bare sclera excision (*Chui et al., 2011*).

2. Bare sclera excision with postoperative beta irradiation (*Said et al., 2013*).
3. Bare sclera excision with perioperative mitomycin C application (*Kinast et al., 2016*).
4. Pterygium excision with conjunctival autograft (free) or rotational flape (*Huang et al., 2018*).
5. Pterygium excision with conjunctival limbal autograft (*Genidy et al., 2017*).
6. Pterygium excision with amniotic membrane graft (*Hussain et al., 2020*).

Despite evolutionary and modification of pterygium excision techniques, recurrence continues to be a limiting factor for success (*Hovanesian et al. 2017*).

The challenge continues to find an adjunctive agent with long-term safety and efficacy (*Razeghinejad et al., 2010*).

In recurrent pterygium, angiogenesis plays a key role in the formation of fibrovascular tissue. In recent years, angiogenesis inhibitors have gained popularity for the management of various neovascular and proliferative ocular diseases. VEGF is one of the key elements in angiogenesis. It exerts its effect binding to vascular endothelial growth factor (VEGF) receptors (VEGF receptor 1 and VEGF receptor 2), which are expressed on vascular endothelial cells. VEGF blockage can lead to inhibition of formation of new vessels. Anti-VEGF may also produce antifibrotic effect (*Ahmed et al, 2019*).

Bevacizumab (Avastin) a recombinant, humanized antiVEGF monoclonal antibody (*Rosenfeld et al., 2016*).

The present work aimed to compare the recurrence rate of the pterygium in the patients treated by Pterygium excision with auto conjunctival graft and the patients treated by Subconjunctival Bevacizumab (avastin) a week preoperative.

PATIENTS AND METHODS

This was a prospective comparative observation study from August 2018 to July 2020.

It included 40 eyes of 40 patients with Primary pterygium of both sexes and of different age groups.

Written informed consent was obtained from every participant or a legally responsible person after approval by the Institutional Ethic Committee.

Patients were divided into two equal groups: **Group A** was treated by Subconjunctival Bevacizumab (avastin) 0.2 ml (5 mg) (100 mg/4 ml Roche) for Primary Pterygium Excision; **Group B** was treated by conjunctival autograft for Primary Pterygium Excision.

Study site: Al- Azhar University Hospital and Kobry El-Kobba Military Hospital.

Inclusion criteria:

- Age 30 years or older.
- Sex both.
- Type of pterygium: Primary.

Exclusion criteria:

- Recurrent pterygium.
- Ocular infection.
- Dry eye syndrome or wound healing problems as ocular cicatricial pemphigoid, immunocompromised patients.

Preoperative evaluated as follow:**History taking:****Personal History:**

- Age, sex, occupation, and residence and immunosuppressive complaints.
- Visual symptoms, diminution of vision, diplopia.
- Irritation, lacrimation, and photophobia.
- Bad cosmetic appearance.

Present history:

- Onset, Course (stationary, regressive, slowly progressive), duration of the complaint.
- Any accompanying general disease
- Measurement IOP.

Past history:

- Similar condition and history of previous ocular operation.

Family history:

- Of any similar conditions

Surgical technique:**Injection technique:**

All injections were performed under microscopy at 10x magnification, after placing topical of Benoxinate HCL 0.4% in the eye, a self-retaining lid retractor was placed and the patient was asked to direct the eye to be injected in extreme horizontal gaze to have adequate exposure of the pterygium, using a 1ml syringe with 30-gauge needle, 5mg (0.2 ml) of bevacizumab was injected in the subconjunctival area of the body of the

pterygium. Two drops of moxifloxacin hydrochloride were subsequently instilled in the eye. The lid retractor was removed and the patient was sent home for one week.

Operative Technique:

Both groups were under surgical excision.

Steps:

1. Sterilization.
2. Anesthesia.
3. Lid speculum is applied.
4. Saline injection under pterygium to facilitate its dissection.
5. Avulsion technique was used for removal as follow.

Postoperative treatment:

Topical combination of corticosteroid and antibiotic eye drops were used and pad was supplied for 24 hours. Antibiotic and steroid were used 4 times a day for a month and the tapered during this period.

Postoperative examination:

- Uncorrected distance visual acuity (UDVA).
- Corrected distance visual acuity (CDVA).
- Full ophthalmic evaluation with slit-lamp examination, IOP and recording of any complication.
- The main outcome measures were the recurrence rate.
- The postoperative complications. Sutures were removed at 3rd week.
- Follow up to 3 months.

Statistical Analysis:

Data were collected, revised, coded and entered to the Statistical Package for Social Sciences (IBM SPSS) version 23. The quantitative data were presented as mean, standard deviations and ranges when their distribution found parametric. Qualitative variables were presented as number and percentages. So, the p-value was considered significant when $P < 0.05$.

The comparison between the studied groups regarding qualitative data was done by using Chi-square test.. The comparison between two independent groups with quantitative data and parametric distribution were done by using Independent t-test while two groups with paired data were compared by using Paired t-test.

RESULTS

There were 16 patients (80%) 30 to 50 years, 4 patients (20%) 50 - 60 years in group A (p-value =0.465) while there were 14 patient (70%) 30- 50 years, 6 patients (30%) 50 – 60 years in group B (p-value = 0.158).There were 18 males (90%) and 2 females (10%) in group A while there were 18 males (90%) and 2 females (10%) in group B (p-value =

1.00).There were 17 patients (85%) working outdoor and 3 patients (15%) working indoor in group A while there were 15 patients (75%) working outdoor and 5 patients (25%) working indoor in group B (p-value = 0.625) . No statistical significant difference (p-value > 0.05) between studied groups as regard main complaints (**Table 1**).

Table (1): Comparison between studied groups as regard demographic data Description the main complaints in the studied patients was variable

Parameters \ Groups		Group A		Group B		P- value
Demographic data		No.= 20		No.= 20		
Age	30 – 50	16 (80.0%)		14 (70.0%)		0.465
	> 50	4 (20.0%)		6 (30.0%)		
	Mean±SD	45.45 ± 5.21		48.15 ± 6.56		
	Range	37 – 56		36 – 60		0.158
Sex	Female	2 (10.0%)		2 (10.0%)		1.000
	Male	18 (90.0%)		18 (90.0%)		
Occupation	Outdoor	17 (85.0%)		15 (75.0%)		0.429
	Indoor	3 (15.0%)		5 (25.0%)		
Main complaints		No.	%	No.	%	
Ocular irritation		6	30.0%	6	30.0%	1.000
Irritation and cosmetic comp		10	50.0%	8	40.0%	0.525
Cosmetic comp		2	10.0%	4	20.0%	0.375
Irritation and visual disturbance		2	10.0%	2	10.0%	1.000

No statistical significant difference between studied groups as regard pre and post-operative best corrected VA, and as

regard post-operative best corrected VA after 1 and 3 months (**Table 2**).

Table (2): Description of pre and post-operative best corrected visual acuity in both groups and visual acuity changes after 1 and 3 months

Parameters	Group A		Group B		P- value
	No.	%	No.	%	
Pre-operative best corrected VA					
6/6	10	50.0%	12	60.0%	0.525
6/9	2	10.0%	2	10.0%	1.000
6/12	4	20.0%	2	10.0%	0.376
6/18	4	20.0%	4	20.0%	1.000
Post-operative best corrected VA (after 1 month)					
6/6	10	50.0%	12	60.0%	0.525
6/9	2	10.0%	6	30.0%	0.114
6/12	6	30.0%	2	10.0%	0.114
6/18	2	10.0%	0	0.0%	0.147
Visual acuity change (after 1 month)					
Improved	2	10.0%	4	20.0%	0.376
Deteriorated	0	0.0%	0	0.0%	
No change	18	90.0%	16	80.0%	
Post-operative best corrected VA (after 3 months)					
6/6	10	50.0%	12	60.0%	0.525
6/9	2	10.0%	6	30.0%	0.114
6/12	6	30.0%	2	10.0%	0.114
6/18	2	10.0%	0	0.0%	0.147

There was a statistically non-significant difference between studied groups as regard recurrence. In group A, recurrence occurred in 2 cases (10%). while in group B it occurred in 0 case after 3 months This table shows description of demographic data of patients with recurrence. As regard age,

the mean age of patients with recurrence was 40.00 ± 4.24 years with minimum age of 37 years and maximum age of 43 years. As regard sex, 2 patients (100%) were males and 0 patient (0.00%) was female. As regard occupation, 2 patients (100%) were working outdoor and 0 patients (0.00%) were working indoor (**Table 3**).

Table (3): Comparison between studied groups as regard recurrence

Parameters		Groups		P- value
		Group A No.= 20	Group B No.= 20	
Recurrence after 3 months	No	18 (90.0%)	20 (100.0%)	0.147
	Yes	2 (10.0%)	0 (0.0%)	
Demographic data			Recurrence after 3 months	
			No.= 2	
Age	Mean±SD	40.00 ± 4.24		
	Range	37 – 43		
Sex	Female	0 (0.0%)		
	Male	2 (100.0%)		
Occupation	Outdoor	2 (100.0%)		
	Indoor	0 (0.0%)		

There was no statistical significant difference between studied groups as regard pre-operative and post-operative IOP. In group A the mean preoperative IOP was 14.2 ± 0.63 , while the mean post-

operative IOP was 13.6 ± 0.96 . In group B, the mean preoperative IOP was 14.1 ± 0.73 , while the mean post-operative IOP was 13.8 ± 0.63 (**Table 4**).

Table (4): Comparison between studied groups as regard preoperative intra-ocular pressure

Parameters		Groups		P- value
		Group A	Group B	
Pre-operative IOP		No.= 20	No.= 20	
13 mmHg		2 (10.0%)	4 (20.0%)	0.654
14 mmHg		12 (60.0%)	10 (50.0%)	
15 mmHg		6 (30.0%)	6 (30.0%)	
Mean±SD		14.20 ± 0.62	14.10 ± 0.72	0.639
Range		13 – 15	13 – 15	
Intra-ocular pressure		No.= 20	No.= 20	
Pre-operative IOP	Mean±SD	14.20 ± 0.62	14.10 ± 0.72	
	Range	13 – 15	13 – 15	
Post-operative IOP	Mean±SD	13.60 ± 0.94	13.85 ± 0.67	
	Range	12 – 15	13 – 15	
P- value		0.001	0.021	

There was a case of right Pterygium before conjunctival auto graft in **Figure 1- A**, post-operative conjunctival auto graft with sutures **Figure 1- B**, after 3 months no recurrence occurred with conjunctival auto graft (**Figure 1- C**). A case of left Pterygium treated by bevacizumab

injection (**Figure 2- A** and after 3 months recurrence occurred with bevacizumab injection (**Figure (2- B)**). A Case of postoperative subconjunctival hemorrhage complication with bevacizumab injection **Figure 3**).

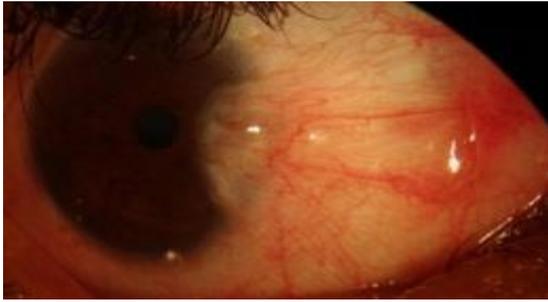


Figure (1-A): Pterygium before conjunctival autograft

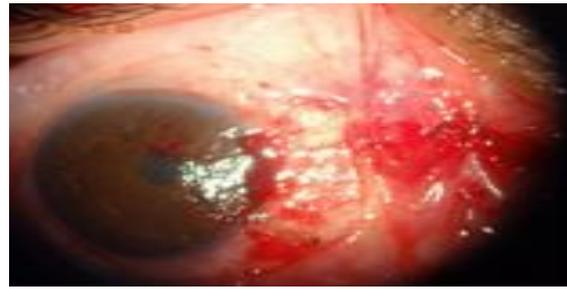


Figure (1-B): Pterygium post conjunctival autograft

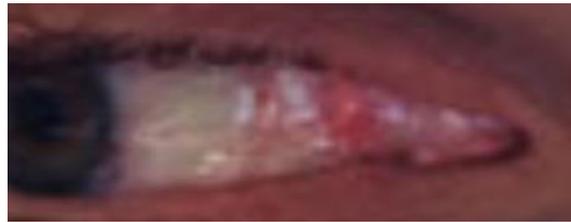


Figure (1-C): No recurrence case with conjunctival autograft after 3 months



Figure (2-A) :Pterygium before bevacizumab injection



Figure (2-B): Postoperative with recurrence case with bevacizumab injection after 3 months



Figure (3):Case of postoperative subconjunctival hemorrhage complication

DISCUSSION

Regarding the age of the patients of our present study, it ranged from 30-60 years. The higher incidence was found to be in the age group of 30-50 years 75%. This may be due to maximum exposure to sun light and various irritants in this age, as

pterygium is one of the sun related condition. This finding was in agreement with that was recorded by some previous studies *Bunga and Kotipalli, (2016)* observed that the incidence of pterygium is higher in 3rd and 4th decades. The incidence is lower in 5th decade which

was 10 %, and the highest incidence 65.5% in the age group 40-49 years.

Regarding the sex of the patients of our present study, it was found that primary pterygia were common in males (90%) than females (10%) and the recurrence was more in males (100%). These results were parallel to that of *Bunga and Kotipalli (2016)* found that 70% of the affected patients were males, and 30% were females. Also, *Shenasi et al. (2011)* stated that males were 81.8%, and females were 18.2% in the study group.

Regarding the occupation in our study, pterygia 100% were working outdoors. *Bunga and Kotipalli (2016)*, found that 76% of the affected patients were in outdoor group, who are more exposed to sunny and dusty climate, while 24% were indoor group.

Regarding the site of pterygium, in our study, all patients presented with nasal pterygium which was explained by the role of sun light. These findings were parallel to that of *Bunga and Kotipalli (2016)* found that 96.4 presented with nasal pterygia, and 3.6% presented with temporal pterygia.

Regarding the recurrence rate, in our study, the pterygium recurred in 5%. The recurrence in bevacizumab group occurred in 10% out of cases. In conjunctival autograft no recurrence occurred. Recurrence was considered when a fibrovascular growth had occurred in the position of the previously excised pterygium, *Kocabora et al. (2013)* stated that recurrence occurred in 66.7% of cases of bevacizumab group.

Rashid et al. (2012) found that sub-conjunctival bevacizumab injection was

useful in management of patients with primary pterygium with local or systemic adverse effects. There was a significant difference in the mean surface area of pterygium and the size of pterygium was reduced. *Han et al. (2016)* studied the clinical effect of subconjunctival administration of bevacizumab in patient primary and recurrent pterygium. They received subconjunctival bevacizumab (0.02cc). Pterygium vascularity and thickness were graded. The size of the pterygium (measured by surface area in cm^2) was recorded from baseline to 12 weeks after injection. Treatments related complications and adverse events were reported. The main outcome of measurements was a decrease in size, vascularity, thickness and color intensity, so sub-conjunctival bevacizumab injection is useful in management of patients with primary and recurrent pterygium without significant local or systemic adverse effects.

Razeghineja et al. (2010) evaluated the efficacy of subconjunctival bevacizumab as an adjunctive therapy for primary pterygium surgery. After pterygium excision and accomplishing a rotational conjunctival flap, patients received 1.25ml bevacizumab. The recurrence rate was 13.4% during the follow up period of 8 months, so a single intraoperative injection had no effect on pterygium recurrent rate.

Dos Santos Martins et al. (2016) studied patients with primary and recurrent pterygium who were treated by excision and conjunctival auto-graft. At the end of follow up period (6-12months), the recurrence rate was found to be 5.7 %.

Regarding postoperative complications, in our study, this was 2.5 % that showed postoperative complications. Complications observed in the bevacizumab group included 5% that developed subconjunctival hemorrhage. This case improved within 2 weeks.

Mak et al. (2017) found that the most commonly detected complication with bevacizumab was subconjunctival hemorrhage which was self-limited and may be related to the subconjunctival injection only.

Mak et al. (2017) concluded that anti-VEGF is safe and no systemic complications were detected. There were no complications observed in conjunctival auto graft regarding the visual acuity. Improvement occurred in 30%. This improvement may be due to reduced astigmatism and relieved pterygial interruption of visual axis by its surgical removal, irrespective to the adjunctive treatment used.

Regarding intraocular pressure (IOP) changes in the present study, the mean preoperative IOP was 14.20 ± 0.62 , while the mean postoperative IOP was 13.60 ± 0.94 in bevacizumab group, and the mean preoperative IOP was 14.10 ± 0.72 while the mean post-operative IOP was 13.85 ± 0.67 in conjunctival autograft groups. But these changes were statistically insignificant.

CONCLUSION

Patients treated by conjunctival auto graft were the best method with low recurrence rate and high safety, but has longer duration, and associated with patient discomfort.

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دراسة مقارنة لمعدلات إرتجاع الظفرة بعد إزالتها بحقن البيفاسيزوماب مع إزالتها بعمل رقعة ذاتية من ملتحمة نفس العين

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خلفية البحث: الظفرة عبارة عن نمو لحمى على شكل جناح ينمو من الملتحمة ويعبر فوق اللم (الحواف) إلى القرنية. وهي عبارة عن أنسيجة ليفية وعائية، ويمكن تحدث للجانب الأنفي أو الصدغى للقرنية العين. وقد تكون بالعينين وغير متماثلة حيث تكون تتأثر إحدى العينين بظفرة أكبر من العين الأخرى.

الهدف من البحث: مقارنة نسبة إرتجاع الظفرة بعد حقن البيفاسيزوماب (الأفاسيتين) تحت ملتحمة العين قبل إستئصال الظفرة أو إستئصال الظفرة وعمل رقعة ذاتية من الملتحمة من نفس العين.

المرضى وطرق البحث: اشتملت هذه الدراسة على 40 عينا" فى 40 مريضا يعانون من ظفرة أولية لفترات مختلفة، و تم تقسيمهم عشوائيا الى مجموعتين متساويتين: مجموعة أ من المرضى تم علاجهم باستخدام حقن تحت الملتحمة بمادة البيفاسيزوماب (الأفاسيتين) 0.2 مل (5 مجم) قبل عملية إستئصال الظفرة بأسبوع ومجموعة ب تم فيها إستئصال الظفرة وعمل رقعة ذاتية. وتم قياس قوة الابصار، وعمل مقارنة بين نسبة ارتجاع الظفرة، والفحص الاكليينيكى المجهرى للعين، ومتابعة أى مضاعفات و قياس ضغط العين، وتم تقييم المرضى قبل العملية ثم بعدها بيوم، اسبوع وشهر، وثلاثة شهور بعد العملية وتم تصوير العيون قبل واثناء وبعد العملية، وأجريت هذه الدراسة بقسم العيون بمستشفى جامعة الأزهر ومستشفى كوبرى القبة العسكرى فى الفترة من أغسطس 2018 الى يوليو 2020.

نتائج البحث: لا يوجد فرق معتد به إحصائياً بين عديد من عناصر المقارنة، ولكن كان معدل الإرتجاع للظفرة فى المجموعة أ (حقن البيفاسيزوماب) 10 % بينما فى المجموعة ب (رقعة ذاتية للملحمة) كان لا يوجد حالات إرتجاع للظفرة وكما انه ليس هناك فرق معتد به إحصائياً بين المجموعتين فى تحسن قوة الابصار والتغير فى ضغط العين والمضاعافات بين المجموعتين.

الاستنتاج: حقن جرعة واحدة من عقار البيفاسيزوماب (الأفاستين) تحت ملتحة العين قبل إستئصال الظفرة الأولية بأسبوع قللت معدل تكرار نمو الظفرة ولكن إستئصال ظفرة العين مع عمل رقعة ذاتية للملحمة من نفس العين هى الافضل نسبياً لمنع تكرار نمو الظفرة.