Comparison of Efficacy and Safety of Sutures Versus Fibrin Glue Versus Glue Free Sutureless for Conjunctival Autograft Fixation in Pterygium Surgery

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Abstract

Introduction: Pterygium is a degenerative condition. Pterygium can induce visually significant astigmatic changes or may grow to occlude the visual axis. In the management of pterygium one of the major problems is the high rate of recurrence. Aims: To study the efficacy and complications of limbal conjunctival autografting using sutures, fibrin glue or autologous blood for graft adhesion after pterygium excision and to compare the results. Materials and methods: A total of 120 patients who underwent limbal conjunctival autografting after pterygium excision. Grafts were secured using autologous blood in 40 eyes, fibrin glue in 40 eyes and sutures in 40 eyes. Study was conducted during a period of 11/2 year in the Department of Ophthalmology, SVS Medical College and Hospital, Mahabubnagar. Results: Of the 120 eyes the grafts were secured in 40 eyes (33.3%) using autologous blood, 40 eyes (33.3%) using sutures and 40 eyes (33.3%) using fibrin glue according to the patient's choice. The mean time taken for surgery in the various groups of this study was compared and found to be highest with sutures (27.7 min) and least with the autologous blood method (15.70 min). No intra op complications were noticed in the three groups. All patients were followed up for a period of 6 months. Postoperative complications were more with the use of sutures and mild enough to subside with treatment in 1 week. Minimal graft displacement was noticed in 1 eye in the autologous blood method group which did not require any revision surgery. In this study single line improvement in postoperative Snellen's visual acuity was noticed in the three eyes with large pterygia unrelated to the method of graft adhesion. Recurrences were noticed in 3 of the 120 eyes over 6 months' follow up. Conclusion: In this study single line improvement in postoperative Snellen's visual acuity was noticed in the three eyes with large pterygia unrelated to the method of graft adhesion.

Keywords: Sutures; Fibrin Glue; Pterygium.

How to cite this article:

KN AnishaDeepti, M Radhika. Comparison of Efficacy and Safety of Sutures Versus Fibrin Glue Versus Glue Free Sutureless for Conjunctival Autograft Fixation in Pterygium Surgery. Ophthalmol Allied Sci. 2019;5(2):171–179.

Introduction

Pterygium is a degenerative condition, characterized by wing shaped overgrowth of bulbar conjunctiva on to the cornea, located in the interpalpebral area. Overall prevalence of the pterygium ranges from 0.7 to 3% [1]. It is common

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Received on 20.04.2019, Accepted on 16.05.2019

in India, where the risk of ultra-violet exposure [1] is more. Pterygium can induce visually significant astigmatic changes or may grow toocclude the visual axis.

In the management of pterygium one of the major problems is the high rate of recurrence. One of the most common methods of surgical management with least rate of recurrence (5%) is pterygium excision with limbal conjunctival autograft. In this context this study is done to compare methods of conjunctival autograft using (1) sutures (2) fibrin glue (3) autologous blood, in terms of efficacy and complications.

Aims

To study the efficacy and complications of limbal conjunctival autografting using sutures, fibrin

glue or autologous blood for graft adhesion after pterygium excision and to compare the results

Materials and Methods

It is a Prospective comparative study conducted during a period of 1.5 years from October 2015 to February 2017, in the Department of Ophthalmology, SVS Medical College and Hospital, Mahabubnagar. The study was conducted according to the principles of the declaration of Helsinki and was approved by the hospital ethics committee. Informed consent was obtained from all patients included in the study. A detailed history followed by clinical examination and routine investigations were done for all patients.

Inclusion Criteria

Patients with pterygium including recurrent pterygium undergoing surgical management with conjunctival autograft

Exclusion Criteria

Bilateral Pterygium, Patients who are unable to come for followup

Procedure

A total of 120 patients who underwent limbal conjunctival autografting after pterygium excision were studied. Patient was given the choice of selecting the method of surgery. Grafts were secured using autologous blood in 40 eyes, fibrin glue in 40 eyes and sutures in 40 eyes.

All surgeries were performed by a single surgeon to reduce operator bias. After subtenon's block, the apex of the pterygium was scraped off from the cornea and whole pterygium excised. After measurement a limbal conjunctival graft slightly larger than the defect was prepared at the superior limbus of the same eye and moved to the raw area. The graft was held in place maintaining proper orientation, using sutures or fibrin glue or autologous blood.

Sutures used for securing the graft were 6-0 vicryl for conjunctiva and 10-0 nylon at limbus. Commercially available Fibrin glue consist of 4 vials: (1) Sealer Protein Concentrate (Human), Vapor Heated, freeze-dried, (2) Fibrinolysis Inhibitor Solution (Bovine), (3) Thrombin (Human), Vapor Heated, freeze-dried, (4) Calcium Chloride Solution.

Contents of the vials 1 and 2 and vials 3 and 4 were combined which forms a Sealer Protein Solution and Thrombin Solution. The Sealer Protein Solution and Thrombin Solution were then combined (by using the Duploject System, or equivalent delivery device) to form the Fibrin Sealant. It is applied to the raw area and graft is attached maintaining proper limbal orientation.

In the eyes where grafts are secured using autologous blood clot oozing at the excision site was neither cauterised nor washed off with saline. The autograft was secured in place while maintaining proper limbal orientation using the blood over the raw area. Using a non-toothed forceps direct pressure was applied over the graft and with the edges apposed. After securing the graft pad and bandage was applied. Time taken and any intra-operative complications were noted.

Patients were followed up on 1st postoperative day, at the end of first week, and 6 months. At each follow up patients were asked about their symptoms, slit lamp examination was done and visual acuity was checked.

Findings were recorded, tabulated and analysed using statistical software namely SPSS 15.0 and stata 10.1. Microsoft word and Microsoft excel have been used to generate graphs and tables.

Results

A Total of 120 patients were studied of which 70 males and 50 were females. All these patients underwent pterygium excision with limbal conjunctival autograft. These grafts were secured using sutures, autologous blood or fibrin glue as per randomization (Table 1 and Figs. 1 & 2).

Comparisons of Complications Based on Surgery

No intra-op complications were noticed in the three groups. Post-operative complications noted were postoperative pain, watering, congestion, subconjunctival hemorrhage, graft displacement and recurrence. Postoperative pain was graded according to visual analogue scale which ranges from 1 to 10. Postoperative pain of grade more than or equal to 2 was considered significant and was noticed on the first postoperative day and till the end of 1 week after the surgery. On postoperative day 1 all the patients in the suturing group (100%) and 3 in the autologous blood group complained of pain. On the next follow up on the 1st week 5 patients complained of pain in the suturing group

Table 1: Demographic distribution in study

Age in years	Number	Percentage
20 - 29	30	25
30 - 39	35	29.16
40 - 49	46	38.33
>/= 50	9	7.5
Gender		
Male	70	58
Female	50	42
Occupation		
Indoor	54	45
Outdoor	66	55
Site		
Nasal	107	89.1
Temporal	13	10.8
Co-morbidities		
Diabetics mellitus	14	13.33
Hypertension	16	15
Others	6	5.8

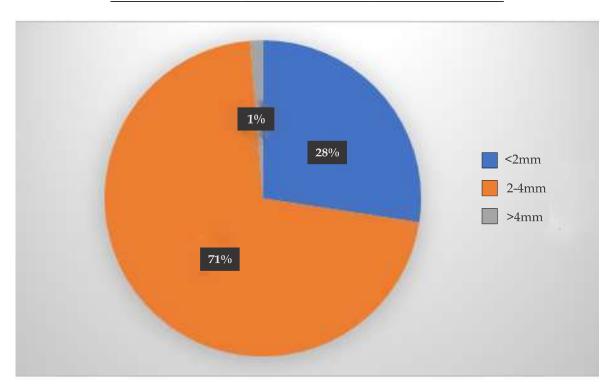


Fig.1: Distribution of the sample according to the corneal extension

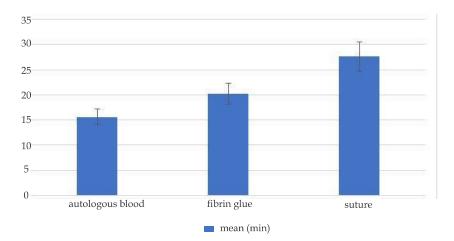


Fig. 2: Distribution of the sample according to time taken for the surgery.

and none in the group that had graft adhesion using autologous blood. No postoperative pain was noticed in the fibrin glue group. Watering was noticed in all 40 patients on the 1st postoperative day where sutures were used, in 7 patients where autologous blood was used and 8 patients where fibrin glue was used for graft adhesion. On the first follow up visit there was watering in 15 patients with suture. 7 with fibrin glue and none with

autologous blood (Table 2).

Foreign body sensation was noticed on 1st postoperative day in all patients with suture, 36 patients with fibrin glue and 1 patient with autologous blood. On the next follow up it came down to 17 patients with sutures and 6 patients with the fibrin glue method (Table 3).

Table 2: Comparision of post operative pain on post operative day 1 and at the end of 1 week based on surgery

Carronar	Post operative pain (NO)		Post operative pain (YES)	
Surgery —	Count	Percentage	Count	Percent
	Post operative p	ain on post operative day 1 b	ased on surgery	
Autologous blood	37	92.5	3	7.5
Fibrin glue	37	92.5	3	7.5
Suture	0	0	40	100
	Post op pai	in at the end of 1 week based	on surgery	
Autologous blood	40	100	0	0
Fibrin glue	39	97.5	1	2.5
Suture	35	87.5	5	12.5

Table 3: Comparision of foreign body sensation on post operative day 1 and at the end of 1 week based on surgery

C	No (Foreign body sensation)		Yes (foreign body sensation)	
Surgery —	Count	Percentage	Count	Percentage
	Foreign body sens	ation on post operative day1 ba	ased on surgery	
Autologous blood	39	97.5	1	2.5
Fibrin glue	4	10	36	90
Suture	0	0	40	100
	Foreign body ser	nsation at the end of 1 week bas	ed on surgery	
Autologous blood	40	100	0	0
Fibrin glue	34	85	6	15
Suture	23	57.5	17	42.5

Table 4: Comparision of watering on post operative day 1 and at the end of 1 week based on surgery

C	Watering (NO)		Watering (YES)	
Surgery —	Count	Percent	Count	Percent
	Watering on	post operative day 1 based	l on surgery	
Autologous blood	33	82.5	7	17.5
Fibrin glue	32	80	8	20
Suture	0	0	40	100
	Watering a	t the end of 1 week based o	on surgery	
Autologous blood	40	100	0	0
Fibrin glue	33	82.5	7	17.5
suture	25	62.5	15	

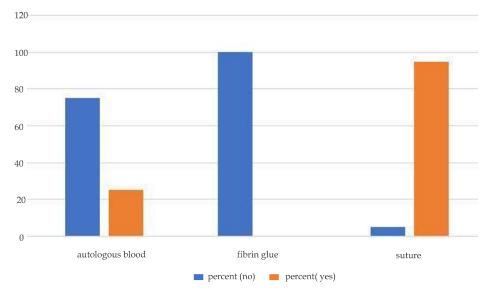


Fig. 3: Comparison of congestion on first postoperative day

Table 5: Comparison of SCH on first postoperative day

Cumanu	SCH (NO)		SCH (YES)	
Surgery —	Count	Percent	Count	Percent
Autologous blood	40	100	0	0
Fibrin glue	40	100	0	0
Suture	32	80	8	20

Table 6: Comparison of graft displacement

C	Displacement (NO)		Displacement (YES)	
Surgery —	Count	Percent	Count	Percent
Autologous blood	38	95	2	5
Fibrin glue	40	100	0	0
Suture	40	100	0	0

Table 7: Comparison of recurrence at 6 month post op based on surgery :

Comment	Recurrence at 6 month (NO)		Recurrence at 6 month (YES)	
Surgery —	Count	Percent	Count	Percent
Autologous blood	39	97.5	1	2.5
Fibrin glue	39	97.5	1	2.5
suture	39	97.5	1	2.5

Table 8: Effectiveness	of autologous blood	procedure on vision

	Post - op BCVA					
Pre-op BCVA	6/6-	6-6/18 6/18-6/60		-6/60	>6/60	
	Count	Percent	Count	Percent	Count	percent
		Effectiveness of au	itologous blood pro	cedure on vision		
6/6-6/18	34	100	0	0	0	0
6/18-6/60	0	0	4	100	0	0
>6/60	0	0	0	0	2	100
		Effectiveness o	f fibrin glue proced	ure on vision		
6/6-6/18	32	100	0	0	0	0
6/18-6/60	0	0	6	100	0	0
>6/60	0	0	0	0	1	100
		Effectiveness	of suture procedu	e on vision		
6/6-6/18	38	100	0	0	0	0
6/18-6/60	0	0	1	100	0	0
>6/60	0	0	0	0	1	100

Congestion was noticed in 10 patients with autologous blood method, none with the fibrin glue method and 38 patients with suture. Subconjunctival hemorrhage was noticed only in 8 patients with sutures (Tables 4–8).

Discussion

A total of 120 patients who underwent pterygium excision with limbal conjunctival autograft were studied, of which 70 were males and 50 were females. 120 patients with 120 eyes underwent surgery. All are unilateral. In this study, most patients (38.3%) were more than 40 years old. Previous studies on Asian populations [2,3,4] have shown that prevalence of pterygium increases with age. The Beijing eye study [2] which was a population based prevalence study on a population of 4439 subjects showed that prevalence of pterygium is higher in people over 40 years of age(p>0.001). The Tanjong Pagar Survey [3] results showed that pterygium prevalence increases linearly with age (p<0.001) and age is an independent risk factor with an Odds Ratio of 7.8 (95% CI) in those in the age group 70-81 years. The Tehran Eye study [4] on 4564 people observed an age standardized prevalence of 1.3% (95% CI).

A male preponderance was noticed in this study. The above mentioned studies [2,3,4] have also shown that the prevalence of pterygium is significantly higher in males. The Beijing eye study [2] observed that pterygium is significantly associated with male sex (p = 0.04). The Tanjong Pagar Survey [3] showed that prevalence of pterygium is more among men than women (age

adjusted Odds Ratio 4.2, 95% CI) with the highest overall prevalence of 25.4% in men aged more than 70 years. In the Tehran Eye study [4] which was a cross-sectional population study pterygium prevalence was found to be more in males (1.4%) compared to females (1.1%), but no significant difference in the prevalence of pterygium were observed in a study by Bueno-Gimeno I *et al.* [5] where out of the 238 subjects with pterygium, 139 (58.4%) were males and 99 (41.6%) were females. A population based prevalence study of 1210 people aged 21 years and above conducted in Indonesia [6] showed slightly higher prevalence rate among females (17.6%) than males (16.1%).

In this study, the distribution of pterygium was found to be slightly higher in those working outdoors (55%) as compared to those working indoors (45%). Many studies have shown that pterygium is more prevalent in outdoor workers. Joan Khoo [7] *et al.* in their study on 38 outdoor workers and 148 indoor workers observed an increased prevalence of pterygium among the outdoor workers with an odds ratio of 7.0. A study in Jordanian population [8] showed a strong positive association of pterygium in those who worked outdoors with an odds ratio of 5.47.

A study by Rashima A *et al.* [9] has shown an increased prevalence of pterygium in rural population of South India which is due to their higher life time UV exposure. Though most of our patients are not working outdoors, the increased prevalence of pterygium in them can therefore be related to their high life time UV exposure. Of the total 120 pterygia, 107 were nasal (89.1%) and 13 were temporal (10.8%). Previous studies support this finding of increased incidence of nasal

pterygium compared to temporal. In a study by V. Dolezalova [10] on 1388 patients temporal pterygia were seen in only 33 cases. In another study by C SH Tan *et al.* [11], majority had nasal pterygia (69 out of 81) of which 12 had both nasal and temporal pterygia.

The percentage distribution of pterygia was found to be similar in both right (18, 51.4%) and left (17, 48.6%) eyes. Similar results were observed in another study by C S H Tan *et al.* [11], where both eyes were affected equally (Right 85.2% 69/81 subjects, Left 86.4% 70/81 subjects). Considerable variation in bilaterality of pterygium had been observed among different studies. In the study by C S H Tan *et al.* [11] most of the subjects had involvement of both eyes (58 out of 81 subjects) while in another study G Gazzard *et al.* [12] bilateral pterygia were found in just 4.1% of their subjects.

This study graded the size of the pterygium based on its extension on to the corneal surface. Out of the 120 pterygia, 30 (27%) were small (< 2 mm), 12 (1%) were large (> 4mm) and 78 were medium sized (2–4 mm) ranging from 1 to 6mm and a mean of 2.61 mm (SD: 1.0). In a study by Mohammad-Salih *et al.* [13], pterygium extension ranged from 0.25mm to 6.5 mm and the mean extension was 2.0mm (SD: 1.2). Another study by Lin *et al.* [14] showed that corneal extension to within 3.2 mm of visual axis induces significant astigmatism, and therefore requires surgical management.

All these patients underwent pterygium excision with limbal conjunctival autografting and the grafts were secured using sutures or fibrin glue or autologous blood according to the patient's choice. Of the 120 eyes that underwent pterygium excision with limbal conjunctival autografting, the grafts were secured in 40 eyes (33.3%) using autologous blood, 40 eyes (33.3%) using sutures and 40 eyes (33.3%) using fibrin glue. The mean time taken for surgery in the various groups of this study was compared and found to be highest with sutures and least with the autologous blood method. The mean time taken for the fibrin glue group was 20.33 minutes (SD: 2.08). The mean time taken for the suture group was 27.7 min (SD: 2.93). The mean time taken for autologous blood method group was 15.70 min (SD: 1.54) which was less compared to other two groups.

A prospective randomized control trial on 50 patients comparing sutures and fibrin glue for graft adhesion by Reece C Hall Franzco *et al.* [15] showed shorter time for surgery in the fibrin glue group (12 minutes) compared to sutures (22 minutes).

One of the early randomized clinical trials comparing efficacies of fibrin glue and sutures for conjunctival graft adhesion by G Koranyi *et al.* [16] on 53 patients showed that the average time taken for the surgery is significantly higher for sutures (18.5 min) compared to fibrin glue (9.7 min).In the study of 15 eyes by D de Wit *et al.* [17] where autologous blood was used for graft adhesion the mean surgical time was 14 minutes (SD: 1.4).

A prospective randomized case control study by Singh PK *et al.* [18] compared the outcomes of conjunctival autograft adhesion using fibrin glue to that using blood clot in two groups of 10 patients each after pterygium excision. The mean duration of surgery in the fibrin glue group was 14.74 min (2.35) min which was less than that of the autologous blood group which was 17.45 (2.89) min. Increased mean surgical time in fibrin glue group of this study was due to the technical difficulties encountered during mixing of the glue in two of the three surgeries.

In this study no intraoperative complications were noticed. The significant postoperative complications noticed were postoperative pain, foreign body sensation, watering, congestion, subconjunctival hemorrhage and graft displacement. All the postoperative complications were noticed within 1 week of the surgery and they were fewer with fibrin glue and autologous blood compared to sutures. A randomized clinical trial by G Koranyi et al. [16] comparing efficacies of fibrin glue and sutures for conjunctival graft adhesion on 53 patients showed that postoperative pain was significantly higher for sutures but there was no correlation between postoperative pain and size of the pterygium.

Another comparative study of the efficacy and complications of fibrin glue and sutures by Harvey S et al. [19] showed similar results. They also found that postoperative complaints like pain, watering and foreign body sensation were less for fibrin glue compared to sutures. The same study found that 9% experienced subconjunctival hemorrhage while in this study there were 8.6% cases of SCH. There were no intraoperative or postoperative complications noted in the study by D de Wit et al. [17] of 15 eyes which underwent pterygium excision with graft adhesion using autologous blood. Minimal graft displacement was noticed in 1 eye in the autologous blood method group which did not require any revision surgery.

A prospective randomized control trial on 50 patients comparing sutures and dehiscence at first week in 1 patient in the glue group that required

revision of the graft. Harvey S et al. [19] in their study comparing efficacy and complications of sutures and fibrin glue observed partial graft dehiscence in 1 patient (9%) from the suture group. A prospective interventional case series by Malik KP et al. [20] in 40 eyes with primary nasal pterygium excision and graft adhesion using autologous blood showed graft dehiscence in 2 eyes, graft retraction in 3 eyes. A Karalezli et al. [21] in their prospective study comparing fibrin glue and sutures for graft adhesion in 50 eyes with primary pterygium noticed 2 partial graft dehiscence in fibrin glue group.

Singh PK *et al.* [22] in their study noticed graft retraction and graft displacement in 10% of the eyes that underwent graft adhesion with autologous blood compared to those with fibrin glue.

In this study no significant vision improvement was noticed irrespective of the method of graft adhesion. Effect of pterygium excision on visual acuity was studied on 36 patients by S Maheshwari [23] and observed visual improvement in 15 eyes (41.67%). The improvement was directly related to the size of the pterygium. Fong KS *et al.* [24] studied the refractive changes following pterygium surgery in 123 eyes and observed postoperative reversal of pterygium-induced astigmatism and the improvement correlated to the pterygium size as well.

Out of 120 eyes operated, only 3 eyes showed recurrence for the first 6 months after surgery in this study could be a significant finding as many previous studies have observed recurrences within 6 months time period.

G Koranyi *et al.* [16] in their randomized control trial observed 2 recurrences in the glue group (8%) and 4 in the suture group (20%). All of the recurrences were within 6 months' follow up and they occurred after 2–3 months. A prospective randomized control trial on 50 patients comparing sutures and fibrin glue for graft adhesion by Reece C Hall Franzco *et al.* [15] showed no recurrences in the glue group (0/24) and two recurrences in the suture group (2/23) after 3 months follow up. No further recurrences were noticed on the 6th month and 12months' follow ups.

M Fernandez *et al.* [25] studied the outcomes of different methods of pterygium surgery over 14 years and observed that recurrences after surgery were noted on an average of 6.0 (SD: 8.2) months for primary pterygia and an average of 3.1 (SD: 3.1) months for recurrent pterygia. However, they have found recurrences as late as 59.9 months. Prospective study comparing fibrin glue and sutures for graft

adhesion in 50 eyes with primary pterygium by A Karalezli *et al.* [21] showed recurrence in 1 eye in fibrin glue group and 3 eyes with sutures after a follow up period of 12 months.

A prospective randomized case control study by Singh PK *et al.* [22] compared the outcomes of conjunctival autograft adhesion after pterygium excision using fibrin glue to that using blood clot in two groups of 10 patients each who were followed up for 12 months. However, the recurrence rates were identical (10%) in both groups. The study by D de Wit *et al.* [17] of 15 eyes which underwent pterygium excision with graft adhesion using autologous blood with a mean follow-up period of 9.2 (SD: 2.2) months, there were no recurrence.

A prospective interventional case series in 40 eyes with primary nasal pterygium using autologous blood for graft adhesion by Malik KP *et al.* [20] showed recurrence in 1 eye over a 12 month follow-up period.

Conclusion

The mean time taken for surgery in the various groups of this study was compared and found to be highest with sutures (27.7 min) and least with the autologous blood method (15.70 min). No intra op complications were noticed in the three groups. All patients were followed up for a period of 6 months. Postoperative complications were more with the use of sutures and mild enough to subside with treatment in 1 week.

Minimal graft displacement was noticed in 1 eye in the autologous blood method group which did not require any revision surgery. In this study single line improvement in postoperative Snellen's visual acuity was noticed in the three eyes with large pterygia unrelated to the method of graft adhesion. Recurrences were noticed in 3 of the 120 eyes over 6 months' follow up.

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