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COMPARISON OF EFFICACY OF FIBRIN GLUE AND AUTOLOGOUS BLOOD AS ADHESIVES FOR SECURING CONJUNCTIVAL AUTOGRAFT AFTER PTERYGIUMEXCISION.

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Abstract:

Background:
Pterygium is a degenerative disorder of the subconjunctival tissue. Our hospital caters mainly to rural population, in whom the prevalence of pterygium is very high. With this background present study was done to evaluate the efficacy of adhesives in retaining the graft after pterygium excision.

Aim:
This was a study done to compare the efficacy of the adhesives, fibrin glue and autologous blood used for securing conjunctival autograft after pterygium excision.

Materials and methods:
This comparative study was carried over a period of eight months from August 2021 to March 2022 in the Department of Ophthalmology at NRI institute of medical sciences, Visakhapatnam on 200 eyes of 200 patients with primary pterygium. A comprehensive ocular examination was done and the patients were subjected to pterygium excision with conjunctival autograft. The patients were divided into two groups- fibrin glue (FG) and

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autologous blood (AB) group of 100 each based on the adhesive used for affixing the conjunctival autograft.

Results:
In FG and AB groups, female constituted (76%) and (77%) of the patients and (61%) and (64%) of patients were in 40-60 years age group respectively. The frequency of complications observed postoperatively were more in AB group patients (57%) as compared to FG group (39%). Inflammation was noted in (39%) of patients, pyogenic granuloma in (2%), retraction of graft in (8%), complete loss of graft in (3%) in AB group (autologous blood) patients, as compared to inflammation in (23%), pyogenic granuloma in (1%), partial retraction of graft in (6%) and complete loss of graft in (2 %) in FG group (fibrin glue).

Conclusion:
Autologous blood is a promising adhesive for securing conjunctival autograft after pterygium excision. Its effectiveness as an adhesive is comparable to fibrin glue.

Key Words: fibrin glue, autologous blood, conjunctival autograft, graft retraction, granuloma.

Introduction:
"Pterygium is a degenerative condition of subconjunctival tissue which proliferates as vascularized granulation tissue to invade cornea, destroying superficial layers of stroma and Bowman's membrane, the whole being covered by conjunctival epithelium[1]."

In a study done in South Indian population in Andhra Pradesh Eye disease study by Srinivas Marmamula et al [2] prevalence of pterygium was reported to be 11.7% and Asokan R et al[3] reported a prevalence of 9.5% in a study done in South Indian state of Tamil Nadu. Nangia V et al[4] reported prevalence of 8.5+/- 0.3% per eye and 12.9+/- 0.5% per subject in rural central India. The prevalence of pterygium increased with age from 6.7% in 3rd decade to 25% in the 7th decade. The cumulative ultraviolet light exposure due to outdoor occupation is contemplated as a major risk factor besides old age, male gender, genetic predisposition[5] being other risk factors.

In various studies the prevalence of pterygium varied widely ranging from 2% in Greater Beijing in China[6], 3% in Australian[7], 7% in Singapore[8], 23% in blacks in US[9], 30% in Japanese[10], to 48% in Spain[11]. Though it occurs world-wide, its prevalence is high between 30^0 North and 30^0 South of equator[12].

Numerous procedural innovations have taken place over these years to treat pterygium, in order to reduce the recurrence after excision of pterygium. The treatment for pterygium is undisputedly surgical excision. 25% to 45%[13] was the recurrence rate reported after pterygium excision. However pterygium excision coupled with conjunctival autograft which served as a breakthrough solution to prevent the recurrence was spearheaded by Spaeth et al[14] and is now endorsed as the preferred approach.

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The conjunctival autograft can be affixed to the bare sclera in its place with either sutures, fibrin glue or autologous blood. Sutures may cause complications like foreign body sensation, lacrimation, suture related granuloma or abscess. Fibrin glue and autologous blood mitigated all these issues arising from sutures. The usage of fibrin glue for securing autograft by Cohen RA and Mc Donald in 1993[15] was a milestone in pterygium surgery. There is risk of transmission of certain blood related diseases and hypersensitivity reactions with fibrin glue as it is prepared from plasma. Fibrin glue being expensive, autologous blood has evolved as an inexpensive and easily available alternative adhesive.

Materials & Methods:

This was a prospective study conducted to compare the efficacy of fibrin glue and autologous blood as adhesives for securing conjunctival autograft. It was done over a period of eight months from August 2021 to March 2022 in the Ophthalmology department at NRI institute of medical sciences, Visakhapatnam on 200 eyes of 200 patients with primary pterygium. After NRI Institute of Medical Sciences institutional ethics committee approval (IEC/NRI/26/2021), an informed consent was obtained from all the patients included in the study. A comprehensive evaluation of the patient was done. Using structured questionnaire relevant medical and ocular history was collected. Unaided and best corrected visual acuity was recorded using Snellen's visual acuity chart for all the patients and they were examined under slit lamp, retinal examination was done by 90D lens and IO, intraocular pressure recorded, pterygium was graded according to grading system designed by Tan et al. The **inclusion criteria**of our study were, patients aged above 30 years of both genders, grade 2-3 primary pterygium. The **exclusion criteria**were presence of immune related disease, ocular surface disease, dry eye, eye lid diseases, recurrent pterygium.

The patients were randomly assigned into two groups of 100 each, FG group (Fibrin glue) and AB group (autologous blood). In both the groups pterygium excision with conjunctival autograft was done. In FG group conjunctival autograft was secured with the help of fibrin glue and AB group autologous blood was used as an adhesive.

Surgical procedure for grafting using autologous blood:

All the surgeries were performed by the same surgeon. The surgery was performed under topical anaesthesia using proparacaine 2%. Pterygium was excised using 15 No. blade. Head of the pterygium was grasped with a forceps and pterygium was peeled off the cornea. Superficial keratectomy was done using 15 No blade. Bleeding was controlled using sterile cotton buds. No cautery was done. The conjunctival defect was measured with a callipers and a conjunctival autograft measuring 1mm more than conjunctival defect was retrieved from the superior bulbar conjunctiva near the fornix.

On the scleral bed, a homogenous blood film was allowed to form. The retrieved graft was then oriented into its position. The edges of the graft were tucked into the edges of redundant conjunctiva and pressed gently and left for about 6mts, taking into consideration the normal clotting time as a guide. Subconjunctival dexamethasone 0.1 ml was injected into inferior

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bulbar conjunctiva and moxifloxacin eye ointment was applied in the fornix and the eye was bandaged and left for one day.

Surgical procedure for fibrin glue:

The surgery was performed under topical anaesthesia using proparacaine 2%. After excising pterygium, conjunctival autograft was retrieved from superior bulbar conjunctiva. The conjunctival defect after excision of pterygium was measured with callipers and autograft measuring 1mm more than the defect was retrieved from the superior bulbar conjunctiva. The two components of fibrin sealant were reconstituted according to specified guidelines by the manufacturer. They were loaded separately in two syringes. One drop from each syringe was placed over the recipient bed and the retrieved autograft was oriented onto the recipient bed. Graft adhesion was confirmed. Subconjunctival dexamethasone injection 0.1 ml was given and moxifloxacin eye ointment was applied and pad and bandage applied for a day.

Postoperatively, all patients were prescribed moxifloxacin 0.5% eye drops 6th hourly and prednisolone acetate 1% eye drops every fourth hourly for one week., application of the antibiotic eye ointment at night, artificial tears four times a day for 1 month. The steroid drops were tapered gradually over a period of one month. Patients were assessed on day 1, second week, 1st month, 3rd month by the same reviewer. During each review visual acuity, graft adhesion, graft displacement, graft retraction, recurrence, granuloma and allergic reactions were observed.

Statistical analysis:

The statistical analysis was done using Microsoft excel 2016 and statistical package for social sciences version 21.0 for windows (SPSS21.0). The variables were summarized and expressed as frequencies and percentages. Chi square test was used as the test of significance for categorical data. The independent samples t test is used to compare the means of two independent groups to determine whether there is any statistical evidence. Significance is considered if the p value is <0.05.

Results:

Patients characteristics:

Analysis was done on 200 eyes of 200 patients and they were all followed up for a period of 3 months. The demographic profile of the patients in this study is summarized in table (1)

In FG group, 24(24%) patients were male and 76 patients (76%) were female(table-1). The age ranged from 26-79 years. The mean age was 53.29 years and median age 52.5 years. Majority of patients (61%) were in 40-60 years age group (table -1), 93 patients (93%) had nasal pterygium, 3 patients (3%) had temporal pterygium and 4 patients (4%) had bipolar pterygium. 53 eyes (53%) had grade 3 pterygium.

In AB group, 23 patients (23%) were male and 77 patients (77%) were female(table-1). The age ranged from 33-81 years, the mean age was 53.52 years and median age was 53 years. Majority of patients (64%) belonged to 40- 60 years age group(table-1) (73%) of patients

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were rural patients (table- 2). pterygium was of grade 3 in 61 eyes (61%).95 patients (95%) had nasal pterygium, 2 patients (2%) had temporal pterygium, 3 patients (3%) had bipolar pterygium.

Age	**FG Group (fibrin glue group)**		**AB Group (autologous blood group)**	
	Female	Male	Female	Male
<40 years	9(11.8%)	3(12.5%)	8(10.4%)	1(4.3%)
41-50 years	26(34.2%)	5(20.8%)	28(36.4%)	4(17.4%)
51-60 years	25(32.9%)	520.8%)	25(32.5%)	7(30.4%)
61-70 years	12(15.8%)	8(33.3%)	12(15.6%)	9(39.1%)
>71 years	4(5.3%)	3(12.5%)	4(5.2%)	2(8.7%)
Total	76(100.0%)	24(100.0%)	77(100.0%)	23(100.0%)
Table 1: Demographic profile				

The prevalence of pterygium was more in patients belonging to rural area.In FG group 79(79%) (table-2) patients were from rural area while 24(24%) (table-2) patients belonged to urban area. In AB group 73(73%) (table-2) patients were from rural area and 27(27%) (table-2) were from urban area.

Geographic distribution	**FG group (fibrin glue group)**	**AB group (autologous blood group)**
Rural	79(79%)	73 (73%)
Urban	21(21%)	27(27%)
Table 2: Geographic distribution		

The preponderance of pterygium in females was found to be statistically significant x2=0.543 and (P=0.461). Though the pterygium was more prevalent in 40-60 years age group in our study, it was not statistically significant, because we did not randomize patients according to age.

23 patients (23%) were symptomatic for about 2 weeks in FG group as compared to 39 patients (39%) in AB group (table *3*). Graft edema was noted on 1st postoperative day in 10 eyes (10%) of FG group as compared to 23 eyes (23%) in AB group(table-3). All the grafts showed good adherence in both the groups except for complete graft loss noted in 2 eyes in FG group and 3 eyes in AB group(table-3). In FG group out of 2 eyes in whom complete graft loss was observed(table-3), graft had to be retrieved from another site of the same eye and sutured with 8-0 vicryl in one eye. In the other patient the graft got displaced completely from its original site wherein, the same graft was relocated to its original position and secured using fibrin glue.

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In AB group, of the 3 eyes with complete graft loss(table -3), in 2 eyes, graft had to be retrieved from another site of the same eye and was sutured with 8- 0 vicryl while in one eye fibrin glue was used to re fix the graft to the recipient bed.

COMPLICATIONS	**FG Group (fibrin glue group)**	**AB Group (autologous blood group)**	**TOTAL**
Inflammation	23(23%)	39(39%)	62(31%)
Recurrence	3(3%)	5(5%)	8(12%)
Pyogenic granuloma	1(1%)	2(2%)	3(1.5%)
Partial retraction of graft	6(%)	8(8%)	14(7%)
Complete loss of graft	2(2%)	3(3%)	5(2.5%)
Total	35(35%)	57(57%)	92(46%)

Table 3: Summary of the complications

Partial retraction of the graft was observed in 6 eyes in FG group, 8 eyes in AB group (table-3). Retraction of the graft was noted towards conjunctival side with the limbal end being intact. Of these 6 eyes, partial retraction was observed on 1st post-operative day in 4 eyes, and in other 2 eyes at 1 week. In AB group, 7 eyes showed retraction of graft on post-operative day 1 and at one week in one eye. This complication was managed conservatively and no surgical intervention was required. Complete re-epithelization was noted at 1 month review uneventfully in all the eyes. Neither the incidence of this complication nor the difference in incidence of this complication between the two adhesives is statistically significant.

Pyogenic granuloma was observed in one eye in FG group and 2 eyes in AB group at one month follow up(table-3). In all the eyes in both the groups we had to excise the granuloma and start the patient on immunomodulator cyclosporine 0.05% eye drops twice a day for one month and hourly instillation of topical steroids post operatively for one week followed by tapering of the steroids over a period of one month.

Recurrence was observed in 3 eyes in FG group as compared to 5 eyes in AB group(table-3). The recurrence was observed in patients with pterygium of grade 3 with both the procedures. In AB group recurrence was observed as early as one month in 4 eyes and in one eye at the end of 3 months. In FG group, recurrence was observed in all the 3 eyes at the end of one month. We re-excised the pterygium and applied intraoperative mitomycin-c prepared in the concentration of 0.02% for 3mts and secured the conjunctival autograft with fibrin glue. Postoperatively we advised cyclosporine 0.05% eye drops twice a day for one month and prednisolone acetate 1% eye drops applied four times a day for two weeks and tapered gradually over a period of one month. These patients are being followed monthly since the time of surgery and no recurrence was observed.

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Discussion:

Amongst the spectrum of treatment options available for pterygium, pterygium excision followed by conjunctival autograft has been advocated as the best option to prevent recurrence[16].The graft can be secured in its place either with sutures, fibrin glue or autologous blood.

Fibrin glue is a biological tissue adhesive, which has a fibrinogen and thrombin component prepared from plasma where in human fibrinogen is activated by thrombin as in final stage of coagulation cascade. The possible adhesion with higher tensile strength is because of formation of a smooth veal along the wound edge. Anaphylactic reactions have been reported with fibrin glue which has been advocated due to the presence of bovine aprotinin[17]. The possibility of transmission of diseases from pooled and single blood donors is a substantive issue. Using patients own blood to prepare fibrin glue to avoid these problems would be a viable option but is time consuming and expensive.

Fibrin glue has vivid range of applications in ophthalmology which include conjunctival wound closure, pterygium surgery, strabismus surgery, for perforated corneal ulcer, ulcers with impending perforation, descemetocele, treating recalcitrant cases of epithelial in growth, treating post- operative leaking bleb post trabeculectomy. In spite of wide range of applications of fibrin glue, usage of fibrin sealants in ophthalmology is not US Food and Drug administration approved, and is therefore considered "off label".

In our study, majority of patients belonged to 40-60 years age group (64%)(table-1) which correlates with all other studies where it is proven without dissent that prevalence of pterygium increases with age. Pterygium was more preponderant in females (76.5%) as compared to males (23.5%) in our study(table-1). There was a disparity in this observation with other studies. Kurian et al[18] reported preponderance of pterygium more in males (53%) as compared to females (47%/), Gaayathri et al[19] reported the male preponderance to be 55.9% and female preponderance to be 44.1%. It was a similar observation by Kodavoor SK et al[20] who reported male to female preponderance ratio of 1.7:1. This discrepancy could be explained by the fact that majority of patients our hospital caters are from agricultural background where both males and females are involved equally in outdoor activity.

Patients experienced more discomfort in the first post-operative week in AB group (39%) as compared to 23% in FG group (table-3)). This was a similar observation in other studies. Kumar S et al[21] reported signs of inflammation in 55% in AB group as compared to 20% in FG group. KodavoorSK et al[20] reported signs of inflammation like graft edema in AB group (43.02%) as compared to 88.53% in FG group Kurian et al[18] reported no signs of inflammation in any of the patients included in the study subjected to both the procedures.

Partial retraction of graft was observed in 6% in FG group and 8% in AB group(table-3). This was a similar observation by Kurian et al[18] who reported partial retraction in 10.4% in AB group as compared 8.16% in FG group. Gaayathri et al[19] reported partial retraction in 11.3% in AB group as compared to 1.7% in FG group. KodavoorSK et al[20] reported incidence of graft retraction to be more in AB group (35.67%) as compared to 2.85% in FG group. Kumar S et al[21] reported graft retraction in 5% in AB group and nil in FG group. Dong Min Cha et al[22] reported dehiscence of graft in 21.87% in FG group. This

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incidence of retraction observed was more with AB groupcan be explained by the fact that it was difficult to standardize graft with autologous blood as it is difficult to control the amount of sub graft blood. When more blood oozes the clot formed would be larger which on contraction would cause dislodgement of graft. When glue is used, it is applied to the graft bed uniformly which would result in better adherence of graft. This could be the reason for occurrence of partial retraction to be more common when autologous blood is used as an adhesive in comparison with fibrin glue.

A single case of anaphylactic reaction was reported in FG group. Such episodes of anaphylactic reaction have been reported in literature with fibrin glue which was attributed to bovine aprotinin.

Complete loss of graft was reported in 2% FG group and 3% in AB group(table-3). This observation was similar to other studies done by Kurian et al[18] who reported this complication in 3.13% in AB group and 2.04% in FG group Kodavoor SK et al[20] reported loss of graft in 1.14% in FG group and 3.82% in AB group. Gaayathri et al[19] reported complete dislodgement of graft in 24.2% in AB group and nil in FG group. The occurrence of complete loss of graft being more common with AB group as compared to FG group could be due to non-standardization of amount of sub-graft blood.

The occurrence of pyogenic granuloma was negligible in both the groups in our study. The exact mechanism involved in the formation of tenon's granuloma is not known, but associations with abnormal VEGF, cytokine abnormalities and fibroblasts activation has been postulated. In our patients incomplete adaptation between the autograft and recipient conjunctiva could have activated the fibroblasts Kodavoor SK et al[20] reported granuloma in 0.64% in AB group and nil in FG group. Gaayathri et al[19] reported granuloma in 4.88% in AB group.

The recurrence rates in FG group was 3% and 5% in AB group(table-3). Recurrence was more with autologous blood in our study which was similar to all the other studies though the rate of recurrence in various studies differed. Kurian et al[18] reported recurrence of 6.25% in AB group and 8.16% in FG group. Kodavoor SK et al[20] reported recurrence of 1.99% in FG group and 5.10% in AB group, Kumar S et al[21] reported recurrence of 5% in AB group and nil in FG group.

Dong Min Cha et al[22] reported a recurrence rate of 4.55% in FG group, Gaayathri et al[19] reported recurrence of 10.6% in AB group as compared to 3.4% in FG group. There was a discrepancy in the observations between various studies. But most of the studies showed lower recurrence with FG than AB. The fact that lesser inflammation in the early post-operative period is related to lesser chances of recurrence.

The main limitation of our study was duration of post-operative follow up which was 3 months.It would have been ideal if it was for 6 months.

Conclusions:

Autologous blood and fibrin glue are equally good alternatives for securing conjunctival autograft in its place. Autologous blood cause lesser postoperative inflammation and is cost effective. Recurrence rates with both the adhesives being similar, autologous blood can be

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used as an adhesive for securing conjunctival autograft in pterygium surgery. Feasibility of adherence of graft with autologous blood in pterygium surgery is promising and its efficacy is comparable with fibrin glue in terms of inflammation, adhesion, retraction and recurrence. The patient's own blood usage eliminates the risk of disease transmission. The autoimmune reactions or hypersensitivity reaction are also drastically reduced, thereby avoiding the expenditure of glue, the burden of preparation and suspicion of sterilization status. These pose the major reasons for adopting autologous blood as sealant in future.

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