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A randomized control trial comparing the efficacy of fibrin glue with sutures in primary pterygium surgery

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Abstract

Background: Pterygium is one of the most common ophthalmic problems encountered worldwide .Studies have shown reduced recurrence rate following the use of conjunctival autograft in primary pterygium surgery. Our study compares the efficacy of fibrin glue versus suturing in conjunctival auto graft with respect to graft stability, post operative discomfort, surgical time and recurrence.

Methods: A randomized control trial was carried out in 50 patients with primary pterygium and they were randomly divided into two groups. In the first group the autograft was attached using ethilon 10-0 sutures while in second group fibrin glue was used. Surgical duration was recorded and patients were followed up on day 1,7 and 30 . Both the groups were compared for graft stability, post operative discomfort, surgical time and recurrence.

Results: The average surgical time was 50.4 min with suture group and 19.48 min with fibrin glue group. Post operative discomfort was less with the fibrin glue group. At the end of one month, 2 cases (8.6%) from suture group and none from the fibrin glue group had recurrence. There was no significant difference between both the groups with regard to graft stability.

Conclusion: Fibrin glue is effective for attaching conjunctival autograft during primary pterygium surgery. The use of fibrin glue in pterygium surgery with conjunctival autografting significantly improves postoperative patient's comfort, lower recurrence rate and reduces surgical time.

Keywords: Pterygium, Conjunctival autograft, Fibrin glue

Introduction

Pterygium is one of the common problems encountered in ophthalmic practice.(1) Surgical excision is the treatment of choice, but there is a high rate of recurrence after surgery. Various surgical procedures have been tried over the years to reduce the rate of recurrence postoperatively. Anti-metabolites like mitomycin C and beta irradiation have also been tried with unsatisfactory results.(2) Studies have shown reduced recurrence rate following the use of conjunctival autograft in primary pterygium surgery.(3) The existing method of attaching the conjunctival autograft by means of suturing presents with adverse effects, such as extended operating period, postoperative patient discomfort, and possible suture-related complications.(4) Our study compares the efficacy of fibrin glue versus suturing in conjunctival autograft with respect to graft stability, post operative discomfort, surgical time and recurrence.

Objective

To compare the graft stability, post operative discomfort and surgical time, between the fibrin glue and ethilon suture groups in primary pterygium excision conjunctival autograft surgery on Day 1, 7 and 30.

Methods

After obtaining permission from the institution ethics committee, a randomized control trial was carried out in 50 patients with primary pterygium. The patients were divided into two groups randomly. In the first group the conjunctival autograft was attached using ethilon 10-0 sutures while in the second group fibrin glue was used to attach the graft. Surgical duration was recorded and patients were followed up on days 1, 7 and 30. Both the groups were compared for graft stability, post-operative discomfort, surgical time and recurrence. Post- operative discomfort was graded using visual analogue scale.

This study is registered in clinical trial registry – India (REF/ 2014/09/007642).

Inclusion Criteria

All cases of primary pterygium

- Patients above 30 years
- Able to attend the follow up visits for 1 month
- Grades 2 and 3 pterygium

Exclusion Criteria

- Patients with recurrent pterygium
- Pseudopterygium
- All the subjects on anti –coagulants diagnosed with primary pterygium were excluded from this study
- Dry eye

Results

A total of 50 patients underwent primary pterygium surgery with conjunctival autograft. Out of 25 in the suture group, 6 were males and 19 females. The glue group had 7 males and 18 females. Duration of each surgery was noted. The patients were followed up on

day 1, 7 and 30 and assessed for graft stability, foreign body sensation, pain and lacrimation.

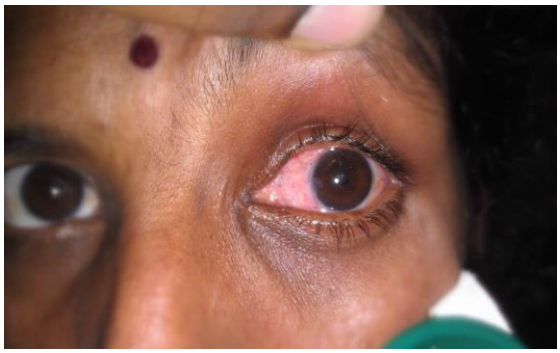

Fig. 1: Pre & post op pictures of a patient who underwent ptergium excision with conjunctival autograft surgery, ethilon sutures in place

Fig. 2: Picture showing pre operative day 0 & post operative day 1 of a patient who underwent pterygium excision with conjunctival auto graft with fibrin glue

Fig. 3: Post operative day 7 & 30th day of the same patient in Fig. 2 who underwent pterygium excision with conjunctival autograft with fibrin glue

The surgical time taken in the suture group was 50.04 minutes. The fibrin glue group took 19.48 minutes. There was significant difference in mean surgical time between both the groups which was proved by 'p' value <0.001.

Graft stability was graded as follows -

Grade 0- All four sides of the graft margin are well apposed.

Grade 1 - gaping of one side of graft bed junction.

Grade 2- gaping of two sides of graft bed junction.

Grade 3- gaping of three sides of graft bed junction

Grade 4 - graft displaced from bed completely

On day1, out of 25 patients in the suture group 20 patients had grade 0 graft stability. There were only 4 patients in grade 1 and a single patient in grade 2. Of 25 patients in glue group 18 patients had grade 0 graft stability and 7 patients had grade 1 graft stability. There was no statistically significant difference in graft stability on day 1 between the two groups (p value 0.74).

On day 7, one patient from each group was lost to follow up.

Out of 24 patients in suture group 19 patients had grade 0 graft stability. 3 patients had grade 1 graft stability and 2 patients had grade 2 graft stability, for the purpose of statistical analysis both the grades were combined. Out of 24 patients in glue group, 21 patients had grade 0 and 3 patients had grade 1.There were no statistical significance in graft stability on day 7 between the two groups p value =0.70

On day 30, 2 patients from suture group and one patient from fibrin glue group were lost to follow up.

Out of 23 patients in suture group, 17 patients had grade 0 graft stability.

As there were only 3 patients in grade 1 graft stability and 2 patients in grade 2 graft stability, for the purpose of statistical analysis both the grades were combined. One patient had grade 4 graft stability. Graft was displaced completely from the bed.

There were 24 patients in glue group, of which22 patients had grade 0 graft stability and 2 patients had grade 2 graft stability. There was no statistically significant difference in graft stability on day 30 between the two groups (p value =0.16)

The results with regard to foreign body sensation, pain and lacrimation are presented in Table 1.

Table 1: Results for post operative foreign body sensation, pain and lacrimation

Outcome measures	Day 1			Day 7			Day 30		
	Suture N =25	Fibrin Glue N =25	P value	Suture N= 24	Fibrin Glue N= 24	P value	Suture N= 23	Fibrin Glue N= 24	P value
Foreign body sensation	17	5	<0.001	4	0	=0.10	1	0	=0.234
Pain	12	4	=0.03	2	0	=0.489	1	0	=0.489
Lacrimation	13	3	=0.005	2	0	=0.489	1	0	=0.489

Discussion

Pterygium is a common ophthalmic condition which is easy to diagnose but difficult to treat.[1] Various modalities of surgical treatment have been described for the management of pterygium. The use of conjunctival autograft to cover the bare sclera has been reported to have less recurrence rate (2-9%).[4] The transplantation of conjunctival autograft helps prevent limbal stem cell deficiency.[4]

In our study, graft stability in both the groups were same and was not statistically significant. Our finding correlates with the study done by Karalezli A, showing conjunctival graft stability with fibrin glue was the same as with sutures over the 3 months course of follow-up (p = 0.258, p = 0.076 and p = 0.6). The intensity of the postoperative pain, foreign-body sensation, and lacrimation were significantly lower in the fibrin glue group than in the suture group on day one post op with the p value 0.03, p =0.001, p= 0.005. However subsequently, on day 7 and 30 were not statistically significant. This findings correlates with the study done in 2008 with statistical significance (p <0.001).[5]

This study had a recurrence rate of (8.6%) 2 patients out of 23 patients in suture group while no recurrence was found in the fibrin glue group at one month follow up. However another study has reported the recurrence of (12%) 3 patients in suture group and (4%) 1 patient in glue group in one year follow up.[4]

The mean surgical time taken in this study for suture group is 50.04 minutes and 19.48 minutes in fibrin glue group with 'p' value <0.001. This finding correlates with the study done in 2012 by Kenyon KR. They have reported duration was 27.71 (5.22) minutes in the fibrin glue group and 43.30 (8.18) minutes in the suture group (p = 0.001).[4] The shorter duration of fibrin glue surgery has made it a more attractive option for busy ophthalmic surgeons.

Conclusions

The use of fibrin glue in pterygium surgery with conjunctival autografting significantly improves postoperative patient's comfort, lower recurrence rate and reduces surgery time compared with suturing. There was no significant difference between both the groups with regard to graft stability.

The limitations of this study could be cost, the small sample size and theoretical risk of virus transmission.

At the end of this study, we recommend that ophthalmologists must consider the use of fibrin glue in pterygium surgery to obtain a superior surgical outcome. The use of fibrin glue makes pterygium surgery easier, enhances patient comfort and is less time-consuming.

Further research should be actually carried out mainly on the cost-effectiveness analysis of fibrin glue and efforts should be dedicated to making fibrin glue available to more patients.

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