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Efficacy of fibrin glue versus suture in patients undergoing conjunctival autograft for primary pterygium

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Abstract

Purpose: The present study was undertaken to assess the efficacy of fibrin glue versus suture in patients undergoing conjunctival autograft with special reference to operating time, post-operative outcomes and post-operative visual outcomes during follow-up.
Design: Two years prospective randomized controlled trial was conducted for 40 patients who presented to the department of Ophthalmology, who fulfilled inclusion criteria and were willing to enrol in the study.
Method: After taking informed consent, detailed history regarding patients name, age, sex, occupation, address, presenting symptoms, duration, progression, and associated conditions was recorded. Patients were then randomized into two Groups: Conjunctival autograft with suture (Group 1) and Conjunctival autograft with fibrin glue (Group 2). Following parameters were noted in both Groups (1) Operating time in both Groups (2) Post-operative outcomes like pain, foreign body sensation. (3) Visual outcomes in both groups.
Results: The mean operating time in fibrin group was 30.950 minutes (SD= 2.946), whereas in suture group, the mean operating time was 43.40 minutes (SD = 2.703). On post-operative day one, 15 (75%) patients had pain in fibrin group whereas in suture group all 20 (100%) patients had pain. Foreign body sensation was present among 80% patients on post-operative day one, 90% on day three, 25% on day ten, 5% during week three and 0% at the end of the follow up as compared to suture group where all the patients (100%) complained about foreign body sensation on post-operative day one and three which decreased to 90% on post-operative day ten and persisted among 80% at week three and 10% at week six. The mean pre-operative uncorrected log MAR values were 0.390 (SD=0.161) which decreased to 0.190 (SD=0.085) in fibrin group.
Conclusion: There was marked reduction in operating time and post-operative pain and foreign body sensation in fibrin group as compared with suture group.

Keyword: Autograft, Fibrin Glue, Pterygium.

Introduction

Pterygium is a wing shaped encroachment of conjunctival fold on to the cornea with elastostatic degeneration of subconjunctival tissue. Pterygium is a common condition in India due to sunny climate. The incidence of pterygium was found to be 4% in the age group of less than 30 years and maximum of 32% in age group of 30-39 years and then gradually declines. It is more in male (60%) as compared to females (40%). The effect of living surroundings on the occurrence of pterygium showed more cases of rural areas that is 72%, than urban areas which are 28%. It is more in farmers (40%) followed by labourers (20%), office workers (10%) and housewives (10%).[(1)] Anti-inflammatory drugs and lubricants have an important role in minimising the patients' discomfort but do not cure the disease. Hence, surgical removal is the treatment of choice.[(3)] Conjunctival autograft after pterygium excision has been reported to be associated with lower recurrence rate (2% to 9%) and relatively less sight-threatening complications.[(4,5)] The current option for attaching a conjunctival autograft is the use of suture, which is time consuming and increases the operating time. Also, suturing can induce postoperative discomfort and complications such as buttonholes, suture abscesses, granuloma formation, tissue necrosis, and giant papillary conjunctivitis.[(4,6)] Hence it seems reasonable to try to replace the current use of sutures with the use of tissue adhesives that may shorten operating time, improve postoperative comfort and avoid suture-related complications.[(7)] Several studies have considered using commercial fibrin glue in ophthalmic procedures,[(8,9)] but studies about autologous fibrin glueare few.[(10)] The present study was undertaken to assess the efficacy of fibrin glue versus suture in patients undergoing conjunctival autograft with special reference to operating time, post-operative outcomes and post-operative visual outcomes during follow-up.

Aims and Objectives

To compare operating time in patients of primary pterygium (Fig. 1) undergoing pterygium excision and conjunctival autograft apposed with fibrin glue (fibrin group) (Fig. 2) and patients undergoing conjunctival autograft sutured with 10-0 ethilon (suture group) (Fig. 3)and also to compare post-operative and visual outcomes in two groups.

Materials and Methods

Two years prospective randomised controlled trial was conducted for patients who presented to the department of Ophthalmology. Adult patients having pterygium were included in the study. Patients with (1) recurrent pterygium (2) history of Ocular surface

infections (3) history of Ocular trauma (4) history of bleeding disorder (5) on anticoagulant therapy and (6) pregnant females were excluded from the study. Ethical comittee aproval was taken. After taking informed consent, detailed history regarding patients name, age, sex, occupation, address, presenting symptoms, duration, progression, and associated conditions was recorded. Patients were then randomized into two Groups (1) Conjunctival autograft with suture (Group 1 and (2) Conjunctival autograft with fibrin glue (Group 2). Patients were posted for pterygium excision with conjunctival autograft (fibrin glue/suture). Uneventful pterygium excision was performed by single operating surgeon at our hospital under local anaesthesia and then patients were followed up on post-operative day one, day three, day ten, week three and week six. The duration of operation was considered as the time from when the lid speculum was placed until its removal at the end of surgery. Eye was patched for 24 hours in both groups. After surgery, all patients were prescribed topical steroids and topical antibiotics and lubricating eye drops 4 times daily for 2 weeks, then tapered off weekly. All the surgeries were done by single operating surgeon, always using the same equipment, technique and materials.10-0 ethicon sutures were used to fix conjunctival autograft on bare sclera in Group 1 and fibrin glue was used to fix the conjunctival autograft on bare sclera in Group 2. Following parameters were noted in both Group (1) Operating time in both Groups (2) Post-operative outcomes like pain, foreign body sensation (3) Visual outcomes in both groups.

Statistical Analysis: The data was coded and compiled on Microsoft Excel spreadsheet and analysed using SPSS 21.0 software. Categorical data was expressed in terms of frequency and percentages. Continuous variables were expressed as mean ± standard deviation (SD).The data was analysed using paired t-test and unpaired t-test. The level of significance was set at 5%.A probability value ('p' value) of < 0.05 was considered as statistically significant.

Observations and Results

The present study was conducted on 40 patients with primary pterygium undergoing pterygium excision with conjunctival autograft fixed with fibrin glue or suture. Based on the computer generated randomization; these patients were divided into two groups. Group1: suture group: n= 20 Group2: fibrin group: n=20. In the suture group there were 9males and 11 females, and in fibrin group there were 11 males and 9 females. The mean age for fixation with suture was 47.100 and for fixation with fibrin glue was 47.900. There was significant difference in the mean operating time of fibrin and suture groups (p<0.001).(Table 1)

Table 1: Mean operating time

	Group	N	Mean	SD	SEM	t-stat	df	p-value
Operating Time	Fibrin	20	30.950	2.946	0.659	13.925	38	<.001**
	Suture	20	43.400	2.703	0.604			

The result indicates the significant difference between post-operative pain in two groups (p<0.05) on post-operative day 10 and week 3 done by Z-test.(Table 2)

Table 2: Assessment of post-operative pain

Follow-up	Pain				Z-stat	p-value
	Fibrin		Suture			
	Number	Percentage	Number	Percentage		
Day 1	15	75.0%	20	100.0%	-2.391	0.016*
Day 3	13	65.0%	20	100.0%	-2.913	0.004*
Day 10	5	25.0%	9	45.0%	-1.326	0.1832
Week 3	2	10.0%	3	15.0%	-0.478	0.6312
Week 6	1	5.0%	1	5.0%	0.000	1.000

The result indicates the significant difference in foreign body sensation between two groups (p <0.05) on post-operative day 1, day 10 and week 3(table 3).

Table 3: Assessment of post-operative foreign body sensation

Follow-up	Foreign body sensation				Z-stat	p-value
	Fibrin		Suture			
	Number	Percentage	Number	Percentage		
Day 1	16	80.0%	20	100.0%	-2.108	0.034*
Day 3	18	90.0%	20	100.0%	-1.451	0.147
Day 10	5	25.0%	18	90.0%	-4.158	< .001*

Week 3	1	5.0%	16	80.0%	-4.798	< .001*
Week 6	0	0.0%	2	10.0%	-1.451	0.147

The result of independent sample t-test showed no difference in pre-operative and post-operative logMAR visual acuity. (Table 4)

Table 4: Comparison of pre-operative and post-operative logMAR visual acuity (uncorrected) between fibrin and suture groups

	Group	Mean	Number	SD	SEM	t-stat	df	p-value
Pre-op	Fibrin	.390	20	.161	.036	0.459	19	0.649, NS
	Suture	.366	20	.170	.038			
Post-op	Fibrin	.190	20	.085	.019	0.229	19	0.82, NS
	Suture	.196	20	.088	.020			

Discussion

Our study was conducted to assess and compare the mean surgical time, post-operative outcomes and visual outcomes among patients undergoing pterygium excision with conjunctival autograft using fibrin glue and 10-0 ethicon suture. In our study, the mean operating time in fibrin group was 30.950 minutes (SD= 2.946), whereas in suture group, the mean operating time was 43.40 minutes (SD = 2.703). The mean surgical time in fibrin group was thus found to be significantly less as compared to suture group. Longer operating time is considered to be closely associated with enhanced postoperative reaction and increased risk of infection and thus reduction of operating time has important implications. Another study done in India reported significantly less mean surgical time in fibrin glue group (22.72 ± 3.69 minutes vs 41.0 ± 3.53 minutes) as compared to suture group.[11] A similar Indian study reported average surgical time as 21 minutes in the fibrin glue group as compared to 38 minutes in the suture group.[12] In our study, on post-operative day one, 15 (75%) patients had pain in fibrin group whereas in suture group all 20 (100%) patients had pain. On post-operative day three, in fibrin group, 13 (65%) patients reported pain whereas in suture group all 20 (100%) patients reported pain. ($p<0.05$) However, during the follow up on day ten, at week three and six the pain reported by patients was not significant in both the groups. A study from Sweden found significantly lower pain in the glue group both on day zero and at each point of time during the first postoperative week and concluded that the use of a fibrin tissue adhesive when securing the autologous conjunctival graft in pterygium surgery causes significantly less pain than using sutures.[2] In the present study, foreign body sensation was present among 80% patients on post-operative day one, 90% on day three, 25% on day ten, 5% during week three and 0% at the end of the follow up as compared to suture group where all the patients (100%) complained about foreign body sensation on post-operative day one and three which decreased to 90% on post-operative day ten and persisted among 80% at week three and 10% at week six. Hence, there was significant difference in foreign body sensation between both the groups on post-operative day one, day ten and at week three. ($p<0.05$) Foreign body sensation present in most of the patients on 1st post-operative day may be due to superficial keratectomy done during surgery. However, on subsequent days patient in fibrin group were more comfortable than those in suture group. These observations are comparable to other studies evaluating this parameters. Similar study from India reported that, in fibrin glue patients, post-operative foreign body sensation of mild and moderate grade was seen in 54.54% and 36.36% of eyes respectively. At the end of 1 month, 90.91% patients had no foreign body sensation and 9.09% had mild sensation. Compare to this in suture group, 100% patients had severe foreign body sensation on day 1 ($p<0.001$).[10] A study from Philippines concluded that subjective symptoms of foreign body sensation were fewer and disappeared more rapidly in the fibrin glue group than the suture group. The intensity of symptoms was significantly lower in the fibrin glue group than the suture group on all follow-up days ($P>0.001$) and all patients treated with fibrin glue were asymptomatic after 2 weeks.[6] In the present study almost all the post-operative symptoms and signs of the conjunctival auto graft were compared between the two groups, along with the analyses of the operating time and complications. This being a prospective, randomized clinical trial with a minimum of 6 week follow-up strengthens the credibility of the results.In our study, the mean pre-operative uncorrected logMAR values were 0.390 (SD=0.161) which decreased to 0.190 (SD=0.085) in fibrin group. This post-operative improvement in visual acuity was statistically significant ($p<0.05$). In suture group, the mean pre-operative uncorrected logMAR values were 0.366 (SD=0.170) which decreased to 0.196 (SD=0.088). It was statistically significant ($p<0.001$). The improvement in vision may be due to reduction in astigmatism and removal of pterygium from visual axis.There were some concerns regarding the safety of fibrin glue use, including potential for anaphylactic reaction and disease transmission which was not considered in this study. Long-term studies are needed to determine whether the rate of pterygium

recurrence is affected by the use of fibrin glue instead of suture material.

Conclusion

Our study concluded that there was marked reduction in operating time, post-operative pain and foreign body sensation in patients with conjunctival autograft apposed with fibrin glue compared with patients undergoing conjunctival autograft sutured with 10-0 ethicon.

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