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RESEARCH ARTICLE

RANDOMIZED CLINICAL TRIAL OF AUTOLOGOUS BLOOD COAGULUM VERSUS SUTURE FOR CONJUNCTIVAL AUTOGRAFTING IN PTERYGIUM SURGERY

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ABSTRACT

Background: This hospital based study to comparative evaluations of two different types of pterygium surgeries and to know efficacy, safety and complication in method of autologous insitu blood versus suture for fixation of conjunctival autograft in pterygium excision surgery.
Materials and Method: A Prospective randomised clinical trial. The study included 50 eyes of 50 patients with primary pterygium. Simple excision under local anaesthesia was performed by closure of bare sclera by suture less and glue free conjunctival autograft in 25 eyes of 25 patients (Group A) versus conventional method of a sutured conjunctival autograft in25 eyes of 25 patients (Group B).
Results: Thepost-operative pain, itching, watering, inflammation, subconjunctival haemorrhage was significantly less in group Aas compared to group B inpost-operativefollow up days. Graft stability and recurrence was found to be similar in both groups, which were statistically insignificant.
Conclusion: Suture less and gluefree conjunctival autograft technique is easy,safe, effective, prevent adverse reactions and discomfort encountered with use of sutures.

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INTRODUCTION

Pterygium is common ophthalmic condition of tropical and sub –tropical country like India where there is dry hot climate.Pterygium is a wing shaped fold of the conjunctiva encroaching upon the cornea from either side within the interpalpebral fissure. It is a degenerative condition of the subconjunctival tissue which proliferate as vascularized granulation tissue to invade cornea, destroying the superficial layers of stroma and bowmen`s membrane, the whole being covered by conjunctival epithelium. Unless it is cosmetically very disfiguring, is definitely showing signs of progression, encroaching on the pupil, causing unacceptable irregular astigmatism. Beside this, intermittent episodes of inflammation cause irritation, watering and foreign body sensation. Despite uncertainty about the optimal treatment for pterygium, significant progress has been made in understanding the pathogenesis and management of the enigmatic disease .With continuing depletion of the Ozone layer and increasing exposure to sun, the expected effects on the eye and cost of treatment, both biomedical and surgical, may make pterygium management an important public health issue.

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Even in the modern era of microsurgery the simple pterygium which proclaims itself openly on the eye has challenge of surgeon. It has been excised, cauterised, grafted, dissolved, repositioned, avulsed, irradiated, freezed, yet grows onwards primarily and secondarily. Various authors from time to time have introduced number of surgical techniques to achieve the best surgical results and to check postoperative recurrences and to minimise postoperative complications. This study is an attempt in this direction and particularly aims at the comparative evaluation of current surgical technique to find the best available method, to find out severity of complications and method and the best final cosmetic appearance after pterygium surgery.

MATERIALS AND METHODS

A total of 50 patients with primary pterygium attending the Ophthalmic OPD of SSG Hospital ,who fulfilled the inclusion and exclusion criteria were selected and were assigned randomly to a particular group each of 25 patients.

Characteristic of pterygium noted as bellows:

Types:

- **Progressive (Fleshy):** When head is voluminous, neck is hyperaemic and body is fleshy and vascularised.

- **Semi-progressive:** when head is thin, neck and body were pale and sparsely vascularised.
- **Atrophic/ Regressive:** when there is a halo of opacity in front of the Head and is no vascularisation.

Inclusion Criteria

- Patient aged above 18 years of either sex 2. Unilateral or bilateral pterygium3. Primary pterygium
- Exclusion Criteria:
- Pre-existing corneal pathology like traumatic or corneal scar, ectatic corneal condition.
- History of ocular disease predisposing to ulceration or poor wound healing such as herpetic keratitis, diabetes
- Recurrent pterygium
- Patient not willing for participating in the study
- Pseudo pterygium

After informed consent, patients fulfilling the inclusion and exclusion criteria were included in the study. Randomization done by generating random number for the patients by using Medcalc software.25 Random number for the patient generated by Medcalc software is taken as Group- A (Autologous blood coagulum) and rest of the patients are taken as Group – B(Suture). Accordingly that the patients will be randomly divided into two group. 25 patients in each group.

Group A: Autologous Blood Coagulum

In which patient undergoing conjunctival autograft fixation done by autologous blood coagulum after pterygium excision surgery.

Group B: Suture

In which patient undergoing conjunctival autograft fixation done by suture after pterygium excision surgery. The two techniques were compared with regards to mean surgical time, patient's satisfaction, postoperative complication and recurrence rate.

Surgical Technique

All participants underwent detailed anterior segment examination, visual acuity, best corrected visual acuity, sac patency and intra ocular pressure measurement. Type and extent of pterygium was noted. All cases were operated under local anaesthesia with 10ml peribulbarblock usingLignocaine+Adrenaline+Hylase and Bupivacaine (6:4)

[Group A –Autologous Blood Coagulum]

In this method patients, pterygium head was separated from cornea. Abnormal scar tissue on the corneal surface and wound bed was scraped by crescent knife. Minimal cauterization was used to control bleeding. Body of pterygium was dissected and excised. Graft size measured with the help of calliper and conjunctival autograft was harvested from superior temporal region. The area of bare sclera was scrapped with 15 no. surgical knife for oozing of blood and natural haemostasis was allowed to occur, after that graft was moved nasally and pasted to conjunctival edge and recipient sclera in such a way that epithelial side faced up and limbal edge of graft attached to nasal limbus. After proper positioning of graft with the help of cotton swab stick socked with saline, a sustained firm pressure was applied over graft for 5 to 10 minutes.

[Group B- Suture]

In this method excision of pterygium was done same way as that of group A. conjunctival graft was prepared from super temporal region same as in group A, then graft placed with epithelial side facing upward and limbal edge of the graft aligned to the nasal limbus, graft was secured in place with 4-5 interrupted 10-0 nylon sutures to free conjunctival edge of recipient bed. Surgical time was measured from placement of lid speculum to its removal at end of surgery. Postoperatively eye pad was given for 24 hours and Patients were instructed not to rub their eyes or not to indulge in sports for one month.

Follow up:

All patients were examined on Slit Lamp on 2nd postoperative day, at 1st week, 2nd week, 4th week for graft assessment and complication and at 6 month for recurrence. All patients were advised to instil antibiotic eye drop and eye ointment (ciprofloxacin) six times a day and steroid drops were started after 1st week four times a day. During each postoperative visit, visual acuity examined and history regarding pain, itching, watering and foreign body sensation was taken and slit lamp examination was performed to look graft stability, sub-graft haemorrhage, graft inflammation. Recurrence defined as any regrowth of fibro -vascular exceeding 1 mm onto the cornea. Other complications like diplopia, symblepheron, and dellen or granuloma formation were also
looked for.

RESULTS

Out of 50 patients in study,33 were male (66%)and 17 were female (34%). The ocular signs and symptoms like redness, watering, photophobia and diminution of vision due to pterygium were studied and were marked in older age group. Out of 50 patients 29 patients (58%) had semi progressive type of pterygium. The most common age group of patient for pterygium surgery was 31-50 year in both groups. The duration of surgery in group A was 22.72min (±8.48) was significantly less as compared to group B was 35.72 min (±10.60) with p (<0.001).A multiple regression analysis was performed to determine the combined effect of independent factor like size of pterygium, type of pterygium and surgery type on the duration of surgery which shows that except surgery type, no other variable had significant impact on duration of surgery. The TABLE 1 shows that we found more incidence of complication such as sub-graft haemorrhage, inflammation, pain, watering, foreign body sensation in suture group in comparison to autologous blood coagulum group following pterygium excision. Graft retraction has occurred in 2(4%) cases in only autologous blood coagulum group.

The Statistical significance difference was found between two groups in all different post- operative complication on the 1st post -operative day and at 1st week ($p<0.05$) [TABLE 2&3]. However the SD was slightly more than MEAN because of some extreme measurement but P value is statistically significant. Except graft stability in which difference between two groups were not statistically significant. At 2nd week [TABLE 4]the difference was not statistically significant between two study groups in sub-graft haemorrhage, pain and

itching. The Statistical significance difference was found between two groups in Inflammation, watering and foreign body sensation up to 2nd week post -operative day ($p<0.05$).

Table 1. Comparision of postoperative complaints

Group	Sgh	Inflamation	Pain	Itching	Watering	Fbs
Day1						
Group a	11	10	15	11	10	11
Group b	18	20	18	18	19	21
1st week						
Group a	06	08	12	08	08	07
Group b	13	16	19	14	19	19
2nd week						
Group a	04	06	05	03	02	02
Group b	09	13	11	10	12	07
1month						
Group a	02	00	02	00	00	00
Group b	03	02	02	00	02	02

Table 2. First follow up evaluation on 1st post operative day

Post operative compication	Autologus blood coagulum		Suture group		Mann Whitney u test	
	Mean	Sd	Mean	Sd	U	P
Graft stability	0.08	0.27	0.00	0.00	287	P=0.23
Inflamation	0.60	0.81	1.64	1.11	150	P=0.001
Sgh	0.60	0.76	1.80	1.35	149	P=0.001
Pain	1.00	0.95	2.28	1.45	149	P=0.0012
Itching	0.72	0.89	2.08	1.44	143	P<0.0006
Watering	1.12	0.72	2.40	1.52	151	P=0.002
F.b sensation	1.32	0.69	2.60	1.29	117	P<0.001

Table 3. Second follow up evaluation on 1st week

Post operative compication	Autologus blood coagulum		Suture group		Mann whitney u test	
	Mean	Sd	Mean	Sd	U	P
Graft stability	0.08	0.27	0.00	0.00	287	P=0.23
Inflamation	0.36	0.56	1.36	1.11	159	P<0.0001
Sgh	0.28	0.54	1.16	1.28	196	P<0.01
Pain	0.56	0.65	1.96	1.20	119	P<0.0001
Itching	0.40	0.64	1012	1.05	198	P<0.01
Watering	0.40	0.64	1.72	1.06	113	P<0.0001
F.b sensation	0.40	0.70	2.08	1.25	103	P<0.0001

Table 4. Third follow up evaluation on 2nd week

Post operative compication	Autologus blood coagulum		Suture group		Mann whitney u test	
	Mean	Sd	Mean	Sd	U	P
Graft stability	0.08	0.27	0.00	0.00	287	P=0.23
Inflamation	0.24	0.43	0.88	0.92	198	P=0.01
Sgh	0.24	0.59	0.72	1.06	243	P=0.08
Pain	0.36	0.48	0.08	0.95	247	P=0.15
Itching	0.24	0.43	0.48	0.65	256	P=0.19
Watering	0.08	0.28	0.08	0.28	117	P=0.002
F.b sensation	2.08	0.27	0.52	0.87	244	P=0.05

Table 4. Forth follow up evaluation on 1st month

Post operative compication	Autologus blood coagulum		Suture group		Mann whitney u test	
	Mean	Sd	Mean	Sd	U	P
Graft stability	0.08	0.27	0.08	0.27	312	P=1.00
Inflamation	0.12	0.33	0.12	0.33	312	P=1.00
Sgh	0.08	0.27	0.08	0.27	312	P=1.00
Pain	0.04	0.20	0.04	0.20	312	P=1.00
Itching	0.08	0.27	0.08	0.27	312	P=1.00
Watering	0.12	0.33	0.12	0.33	312	P=1.00
F.b sensation	2.08	0.27	0.52	0.87	244	P=1.00

At 1 month [TABLE 4] the difference was not statistically significant. The recurrence of pterygium was studied up to 6 months postoperatively. No recurrence was observed in both groups of our study.

DISCUSSION

In the present series of 50 cases, 60% of cases were in the age group of 31-50yrs. Pterygium is rare in first two decades. 20% of cases were in the age group of 51-65yrs and 14% in 21-30 years. It matches well with the study of SanjivRohtagi who found the rate of 32% in the age group of 30-39 yrs out of 50 cases. He also found that the pterygium cases were 4% in the age group less than 30 yrs. The study also shows higher incidence (>50%) of pterygium in the age group of 31-45yrs and its incidence decreases with increasing age which also correlates with findings of with SanjivRohtagi [81]. In themales (66%) than in female (34%) with male to female ratio is 1.94:1. The reason may be that males are more exposed to dry, dusty environment.It agrees with sanjivrohtagi's study who found that 60% cases were males and 40% cases were females. Time taken for procedure ranged from 22 to 35 min. Mean time taken was minimum in autograft (22.72±8.48 min) and maximum in suture Group (35.72±10.60 min). While in Ajay kumarSaxena's study time taken for autograft (14.68±2.7min) was much lesser than for suture group (19.12±3.47 min). Mitra S et al reported graft edema in 9 cases (47.3%) following pterygium excision with conjunctival autografting with auto blood [61]. In our study, on day 1 , graft edema occurred in 10 cases of Group A(Autograft)& 20 cases in (suture) group B thus showing a significant difference among groups (p=0.01). In our present study graft retraction occurred in 2(4%) cases in only autograft method. which correlates with the study done by Chaudhry & Dutta et al they reported 2 graft failure and graft retraction in autograft group and one in suture group. In our study sub graft haemorrhage was not statistically significant after one week which correlated to Ajay Kumar's study. In our study none of the patient developed complications like symblepheron formation, motility restriction, dellen formation, infection or were noted. Which correlates with KPS Malik et al [56] reported in their study that none of the patients developed corneal ulcer, conjunctivitis, dellen, symblepheron formation, injury to medial rectus, or corneal perforation. Ajay kumar et al reported granuloma formation in one patient [53]. In our study, Group A Autologous autograft showed Patient discomfort including pain, irritation, watering and foreign body sensation were minimum in comparison to Group B at day 2 to day 14 follow up, which were statistically significant ($p<0.001$). Shaam& Ewan et all reported that at the 3 week visit the overall patient satisfaction score was statistically significantly higher for group 1(autograft) compared to group 2(suture). In our study no recurrence was found in either study group. Ajay kumar et al reported no recurrence in autograft comparison to 2 recurrence in suture group. KPS Malik et al reported recurrence in 1 case (2.5%) at 6 months after pterygium excision with conjunctival autografting with autologous blood Recurrence is directly related to the fleshiness and younger age group apart from the surgical technique.

Conclusion

The present study was conducted to study comparative outcomes in regarding to efficacy, safety, advantages,

disadvantages and complication between two different methods of surgery for pterygium excision and to find out better surgical option for patient. The study highlighted predictable results regarding age and sex incidence of pterygium occurrence. The study showed the highest occurrence in middle age group (58%) and in males (66%). Autologous autograft, the suture-less glue-free procedure for attaching conjunctival autograft following pterygium excision was found to be simpler, cheaper and much safer than suturing procedures. The potential complication of suture such as inflammation, granuloma, infection, can be avoided. Conjunctival graft fixation with auto blood is superior over suture techniques in respect to better cosmesis , less postoperative symptoms, faster surgical and more comfortable patient rehabilitation time, reduced post-operative inflammation which may be resulting in reduced recurrence rate.

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