

Original Article

Comparison between free limbal based conjunctival autograft and anchored conjunctival rotational flap in primary pterygium surgery in adults; a randomised controlled trial in a tertiary care hospital in North-East part of India

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Pterygium is a benign or noncancerous fibro-vascular growth in conjunctiva which covers part of the cornea and it is not very uncommon in a tropical country like India. Cosmetic and visual problem along with recurrent inflammation are the common chief complaints. Different surgical procedures were compared to reduce its recurrence. In this prospective single blinded randomised controlled trial (with parallel group design), 52 patients (M:F=32:20) with primary progressive pterygium (using inclusion and exclusion criteria) attending ophthalmology outpatient department in North Bengal Medical College were randomized applying appropriate computer generated randomization sequence. Limbal Based Conjunctival Autograft technique and Anchored Conjunctival Rotational Flap technique were performed by single experienced surgeon in the two groups and the outcome was assessed by the same surgeon at regular prefixed intervals upto 18 months. Graft oedema and granuloma formation were significantly reduced in the anchored rotational flap group than limbal based conjunctival autograft group. Though recurrences were more in number in case of anchored flap technique (03.80% to 07.70%) but no statistically significant differences noted ($p=0.50$). The newer technique has shown reduced incidence of early postoperative complications and equally effective to reduce recurrence. Time taken for the surgery compared between the two groups through means and t-test which shows statistically significant less time in ACRF group ($p=0.000$).

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Key words : Pterygium, limbal stem cell, conjunctival autograft, anchored, rotational flap, graft oedema, granuloma, recurrence.

The word pterygium comes from the Greek word “pterygos”, described by Hippocrates, Galen, and others¹ means “wing”, is a common ocular surface disease with multi-factorial association though definite cause is yet to be revealed. Most accepted hypothesis is ultraviolet light induced damage of limbal stem cell². Here the clinical characteristics of pterygium were classified using a modified classification system. The stage (S) of pterygium was rated as stage 1, corneal invasion, 1 mm; stage 2, corneal invasion 1-2 mm; stage 3, corneal invasion 2-3 mm; or stage 4 corneal invasion >3 mm³.

Simple pterygium excision by bare sclera technique has been carried out for many years, because it is simple, less skill demanding and quick procedure. However, the recurrence rate of pterygium with the bare sclera technique were very high, up to 80-90%⁴. Different methodologies have been introduced to lower its recurrence, including

conjunctival flap with or without limbal stem cell (sliding, transposition, bridging, miniflap and mini-SLET⁵, anchored-rotational flap⁶) with or without intraoperative or postoperative mitomycin C, cyclosporine application, beta radiation exposure, and amniotic membrane grafts^{4,7-9}. The application of fibrin glue, and bevacizumab has also been evaluated^{10,11}. However it is very much evident that conjunctivo-limbal autograft is the safe and most cost-effective technique and the recurrences are reduced to a great extent.

In this study we have tried a modified conjunctival auto-graft by rotation of graft anchoring at one point (1 mm diameter). Here after the placement of graft the limbus will not be at the limbus and this procedure is compared with the standard limbal-based conjunctival autograft.

MATERIALS AND METHODS

Patients with primary progressive pterygium are enrolled in our study using following inclusion and exclusion criteria.

- **Inclusion Criteria :** (1) Patients with unilateral

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primary progressive pterygium involving at least 2 mm from limbus between 20 to 50 years of age. (2) Patients of 20 to 50 years of age with bilateral primary progressive pterygium. The eye having pterygium with more corneal involvement from limbus. If both eye having same corneal involvement from limbus, the eye to be selected according to patient's own choice.

• **Exclusion Criteria :** (1) Very early pterygium, (2) Recurrent pterygium, (3) Patients with active ocular infection, (4) Acute or chronic dacryocystitis, (5) Patients with Previously Diagnosed Diabetes Mellitus, (6) Patients with Previously Diagnosed Bleeding or Clotting disorder, (7) Unwilling patients

The study period was 18 months (February 2015 to August 2016) among which first 3 months – sample selection, counselling, randomization and intervention and next 15 months – follow up were done.

The study variables were 'Graft oedema' (>1 central corneal thickness) and 'granuloma formation' (Foreign body granuloma at sutured site, pyogenic granuloma, Tenon's granuloma) and recurrence which will be determined by regrowth of fibro-vascular conjunctiva more than 1 mm into the cornea⁷.

In this prospective comparative study, 52 patients with primary progressive pterygium (using inclusion and exclusion criteria) will be randomized applying appropriate computer generated randomization sequence. Limbal Based Conjunctival Autograft (LBC Autograft) technique and Anchored Conjunctival Rotational Flap (ACR Flap) technique were performed by single experienced surgeon in the two groups and the outcome was assessed by the same surgeon at regular prefixed intervals.

Following anti-septic dressing and draping topical anaesthetic (pro-paracaine hydrochloride 0.5%) was given. Pterygium mass along with Tenon's fascia (on the adjacent sclera) were excised with crescent knife and conjunctival scissors and a bare sclera area was made. LBC Autograft was taken from superior limbal conjunctival area with the help of Vanna's scissors after measurement of bare sclera area. Graft was taken 0.5 mm larger than measured reading. Graft was placed in the bare area and sutured at

four corners with 8-0 'polyglactin 910' absorbable suture. ACR Flap was taken from adjacent superior conjunctiva (0.5 mm larger than the bare sclera area) but keeping 1 mm area attached (centre of rotation) at limbus in the pterygium side after measuring the bare sclera area. Now the flap is rotated keeping the attached 1 mm area at the centre of rotation, to cover the bare sclera (limbal conjunctiva of the graft will not be on the limbal side after rotation) and sutured at three corners with 8-0 'polyglactin 910' absorbable suture.

Topical antibiotic-steroid (Moxifloxacin hydrochloride 0.5% and Dexamethasone 0.1%) eye drop with artificial tear substitute (0.5% Carboxy-methyl cellulose) were given to all the patients from first postoperative day to two postoperative weeks (Topical antibiotic-steroid eye drop 1 drop QID for 1 week followed by BID in the next week and artificial tear substitute QID for two weeks) in the operated eye.

Then patients of each group will be examined, after surgery, at 1 week, 2 week, 4 week and then monthly upto 16 months (from intervention) by slit-lamp by the same surgeon. Time period for assessment of early complications will be upto 2 months and for recurrence upto 18 months.

Ethical approval : The protocol and both the patient information sheet and the consent form were submitted to the Institutional Ethics Committee of NBMCH for approval and the same was taken and Clinical Trial Registry of India (CTRI). (CTRI/2015/02/005533)

Confidentiality and Anonymity were maintained.

Funded : No

Statistical analysis : After collection of data, using Microsoft Excel data sheet and SPSS Version 20 appropriate statistical tests (student –t test and chi-square test) are applied to test the significance and a p value <0.05 is considered significant (Fig 1).

OBSERVATION

The pre-operative parameters: few socio-demographic variables eg, age, gender, occupation were compared between two groups along with pterygium size, and the groups were found to be comparable (Tables 1-4).

As graft oedema is a result of graft handling and it depends upon absorption of intra-graft or infra-graft fluid

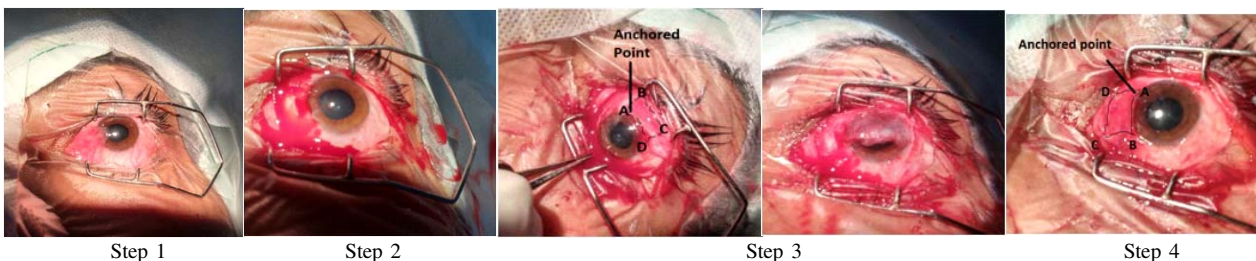


Fig 1 — Anchored conjunctival rotation flap technique [Step 1 : Preparation of pterygium before surgery. Step 2: Blunt dissection of the head and the body of pterygium and cutting of the same to make bare sclera. Step 3: Measurement of the bare area and according to the measurement harvesting of the graft preserving the inferior limbal anchoring point (A) (1 mm). Step 4 : After rotation (point of rotation being the point 'A' suturing of the graft at 3 points (B,C,D)]

after surgery. As the handling of the graft is more in case of LBCA (the graft has to be cut from the superior conjunctiva and lifted up to place it on the bare sclera and then 4 sutures, 1 extra than ACRF technique) and there remains a continuous sub-conjunctival capillary network beneath the anchored part in case of ACRF, the incidence of graft oedema and granuloma are more in the first group though it has no long term effect especially on recurrence (no graft oedema noted in all the recurrence cases). Early

Table 1 — Statistical analysis of pre-operative assessments
Pre-Operative parameters

	LBC Autograft	ACR Flap
Mean Age (years)	37.65 (±5.351)	37.85 (±5.843) (p=0.902)
Gender	Male	16 (61.5%)
	Female	10 (38.5%)
Occupation	Farmer	14 (53.8%)
	House Wife	08 (30.8%)
	Tea Garden Worker	04 (15.4%)
		03 (11.5%) (p= 0.904)
Mean Pterygium Size (mm)	03.19 (±0.694)	03.19 (±0.694) (p=1.000)

Table 2 — Statistical analysis of early and late post-operative complications
Postoperative parameters

Incidence of	LBC Autograft	ACR Flap
Graft Oedema	42.3% (n=11)	07.7% (n=2) (p=0.004)
Granuloma	34.6% (n=10)	03.8% (n=1) (p=0.005)
Recurrence	03.8% (n=1)	07.7% (n=2) (p=0.50)

Table 3 — Statistical analysis of recurrence according to stage of pterygium

Stage of pterygium	Recurrence rate
Stage 2	0/8 (0.00%)
Stage 3	0/26 (0.00%)
Stage 4	3/18 (16.7%) (p = 0.049)

Table 4 — Statistical analysis of time taken for surgery

Pterygium group (n)	Mean	Std. Deviation	Sig. (2-tailed)
LBCA	26	45.731	1.9505
ACRF	26	35.692	2.3455
			0.000

postoperative complications were not observed after 2 months. In ACR Flap group single granuloma was foreign body granuloma at one of the sutured site, but in the other group, six were foreign body granuloma (66.67%), two were pyogenic granuloma (22.22%), and one was Tenon's granuloma (11.11%). Recurrences were observed and noted upto 18 months and it was found that no statistically significant difference between the two procedures. Thorough examination of the cases postoperatively did not reveal any sign suggestive of graft detachment or displacement in either group. Stage 4 pterygium shows statistically significant increase incidence of recurrence (p = 0.049). Time taken for the surgery compared between the two groups through means and t-test which shows statistically significant less time in ACRF group (p=0.000).

DISCUSSION

To prevent the recurrence of pterygium after surgery different methods are tried. Among them the Conjunctivo-

Author	Comparison between	Results
Arain MA, Yaqub MA, Ameen SS, Iqbal Z, Naqvi AH, Niazi MK (2012)	Amniotic membrane transplantation in primary pterygium compared with bare sclera technique	Recurrence of pterygium in bare sclera technique were 37.5% and in Amniotic membrane transplantation were 12.9% ⁸ .
Kheirkhah A, Hashemi H, Adelpour M, Nikdel M, Rajabi MB, Behrouz MJ (2012)	Randomized trial of pterygium surgery with mitomycin C application using conjunctival autograft (CAU) versus conjunctival-limbal autograft (CLAU)	No eye in the CLAU group developed pterygium recurrence; however, recurrence was seen in 2 eyes (5.1%) in the CAU group, including 1 of 31 patients (3.2%) with primary pterygium and 1 of 8 patients (12.5%) with recurrent pterygium ⁹ .
Kim SH, Oh JH, Do JR, Chuck RS, Park CY (2013)	A Comparison of Anchored Conjunctival Rotation Flap and Conjunctival Autograft Techniques in Pterygium Surgery	The recurrence rate was 8.0% in the conjunctival auto-graft group and 8.6% in the anchored conjunctival rotational flap group (P =0.659). Graft oedema was lower for anchored conjunctival rotational flap surgery (14.3% versus 72.0%, P<0.001) ⁶ .
Majumdar S, Baidya K P (2016)	Comparison Between Free Limbal Based Conjunctival Autograft and Anchored Conjunctival Rotational Flap In Primary Pterygium Surgery In Adults; A Randomised Controlled Trial	Graft oedema-in ACR Flap group 07.70% compared to 42.30% in LBCAutograft group (p=0.004) Granuloma – in ACR Flap group 03.80% compared to 34.60% (p=0.005) Recurrence – 07.70% in ACRFlap group compared to 03.80% in LBCAutograft (p=0.50) Stage 4 pterygium shows recurrences more compared to others irrespective of the surgical procedure done (p=0.049). Time taken for the surgery compared between the two groups through means and t-test which shows statistically significant less time in ACRF group (p=0.000).

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limbal autograft (limbal based conjunctival autograft in this study) is considered as a standard procedure now-a-days as different other methods fail to show better outcome. Here from this study we have found reduced early complications with equal effectiveness to prevent recurrences— 07.70% in ACR Flap group compared to 03.80% in LBC Autograft. Stage 4 pterygium shows recurrences more compared to others (p=0.049).

ACRF technique is very much helpful in reducing post-operative graft oedema and granuloma formation in early post-operative period compared to LBCA technique. Patent sub-conjunctival capillary network underneath the anchored conjunctiva, one less suture with less handling of the graft are the causative factors. In this modern era of sutureless pterygium surgery, studies are needed with large sample size with sutureless surgical procedures to be conducted. Apart from the limitation ie, small sample size, relatively short follow up, Vascularity (V)- Conjunctival tissue thickness(C)- Corneal tissue thickness(K) grading to denote the characteristics of pterygium and their correlation with recurrence not studied. As the graft orientation is different in two groups and the surgeon and the outcome assessor was the same person, so assessment bias is a major limitation. To conclude we can say that this newer flap technique is less time consuming, more effective to reduce early post-operative complication and equally effective in reducing recurrence as in the standard surgical treatment.

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