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Research Article

**RANDOMIZED CONTROL TRIAL TO ASSESS THE EFFICACY  
OF CONJUNCTIVAL AUTO-GRAFT & MITOMYCIN – C ON  
PTERYGIUM SURGERY REOCCURRENCE RATE**<sup>1</sup>Dr. Ghulam Jafar, <sup>2</sup>Urva Musaddiq, <sup>3</sup>Dr Muhammad Umair<sup>1</sup>Medical Officer THQ Karor Lal Eson District Layyah<sup>2</sup>King Edward University<sup>3</sup>MD Cuba**Abstract:**

**Objective:** We aimed to compare the Pterygium recurrence rate followed by the intraoperative use of Conjunctival Auto-graft and Mitomycin – C.

**Methodology:** Our RCT (Randomized Controlled Trial) held at Ophthalmology Department of Allied Hospital, Faisalabad from September 2016 to April 2017 on a total of 130 patients. We divided the 130 patients into two groups through random distribution. Group – I had 65 patients treated with intraoperative Mitomycin – C; whereas, Group – II also had 65 patients treated with Conjunctival Auto-graft. Each group had an equal number of patients but managed differently with a six-month duration follow-up in order to observe the recurrence signs and symptoms in the patients.

**Results:** Reported reoccurrences in Group – I were ten (15.3%); whereas, in Group – II only two occurrences (3%) in the overall follow-up time period. Significant variation was in both groups as reflected in P-value (< 0.05); which implies better research outcomes in Group – II (Conjunctival Auto-graft) in terms of a success rate than Group – I (Mitomycin – C).

**Conclusion:** In visually significant pterygium cases, there is a decreased reoccurrence in the pterygium surgery with the application of Conjunctival Auto-graft than Group – I (Mitomycin – C) adjuvant.

**Keywords:** Mitomycin – C, Conjunctival Auto-graft, Pterygium Surgery, Reoccurrence Rate and Pterygium Excision.

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**INTRODUCTION:**

Conjunctiva fibrovascular proliferation on the cornea is "Pterygium", a worldwide condition that affects south and north of equator also called "Pterygium Belt" [1, 2]. Major risk factors of Pterygium include UV (Ultraviolet) radiations [3]. These patients have symptoms such as red eye, blurred vision, itching and cosmetic undesirable growth inside the eyes. It needs a surgical intervention and excision process has reoccurrence chances when once completed. Various studies reported a reoccurrence rate in the range of (24% – 89%) [3, 4]. Primarily two adjuvants commonly used to prevent pterygium reoccurrence are Conjunctival Auto-graft and Mitomycin – C.

An effective outcome is possible through adding (Mitomycin – C) in various concentrations used during surgical interventions; furthermore, it also prevents possible chances of reoccurrence [5]. An author reported Pterygium reoccurrence rate as (15.9%) after the treatment of Mitomycin – C. As Mitomycin – C inhibits Conjunctival fibroblasts cellular proliferation because it is an alkylating agent. It blocks the RNA and DNA synthesis in these cells [6]. However, there are chances of severe complications with the use of Mitomycin – C; these complications include scleral necrosis and bacterial infections [7].

Conjunctival Auto-graft is an alternative of the Mitomycin – C [7, 8]. With the application of an auto-graft; we perform the excision of the area of pterygium, limbus barrier function restores through healthy stem cells which prevents pterygium reoccurrence. Studies consider this procedure as an effective approach to prevent reoccurrence of pterygium. Various researchers reported a reoccurrence rate in the range of (2% – 13%) in various trials [8, 9]. National and international researchers also compared the effectiveness of conjunctival auto-graft against Mitomycin - C to prevent reoccurrence of pterygium [10 – 12].

In the dusty and hot area of Pakistan pterygium is common among outdoor workers and people exposed to dust and sunlight; after surgical interventions, the reoccurrence is also high among these cases [4, 13]. We aimed to compare the Pterygium recurrence rate followed by the intraoperative use of Conjunctival Auto-graft and Mitomycin – C. Furthermore, this research will be helpful for the eye surgeons to select an appropriate treatment procedure which is effective, safe and presents better outcomes with decreased reoccurrence rate and associated outcomes.

**MATERIAL AND METHODS:**

Our RCT (Randomized Controlled Trial) held at Ophthalmology Department of Allied Hospital, Faisalabad from September 2016 to April 2017 on a total of 130 patients. We divided the 130 patients into two groups through random distribution. Group – I had 65 patients treated with intraoperative Mitomycin – C; whereas, Group – II also had 65 patients treated with Conjunctival Auto-graft. Each group had an equal number of patients but managed differently with a six-month duration follow-up in order to observe the recurrence signs and symptoms in the patients. We took approval of the hospital and patients before the commencement of this research. We included the cases with recurrent pterygium, double pterygium and acutely inflamed pterygium observed through slit lamp assessment; whereas, we did not include all unwilling cases. A completed a thorough assessment of visual acuity, slit lamp examination, intraocular pressure, extra-ocular movements and dilated fundus assessment.

All the operations took place by using anaesthesia eye drops (proparacaine 0.05%). We used a surgical blade (No. 11) to smoothly remove and detach Pterygium head which covered the cornea. The operation continued till the complete removal of pterygium. Group – I had the application of 0.02% (Mitomycin – C) for a period of five minutes in order to make bare Scleral area after the excision of Pterygium. Area applied with (Mitomycin – C) also thoroughly treated with Ringer's lactate solution (100 ml). After that, we sutured remaining edges of conjunctiva about two to three millimetres by using nylon suture from the limbus.

With the help of callipers, we measured the bare sclera area left after the excision of pterygium in Group – II. A two millimetres large free conjunctival graft helped to secure the site and post-operative padding also done for twelve to eighteen hours. After the removal of pads slit lamp examination completed in all patients. We gave a combination of steroid-antibiotic to all the patients for a period of three days. Oral analgesics and eyedrops helped in the patient recovery. Patients had a follow-up after six-months surgery which included an ocular assessment (extraocular movements, visual acuity, fundoscopy and slit lamp assessment). Research used SPSS for data entry and statistical analysis (P-Value under 0.05).

**RESULTS:**

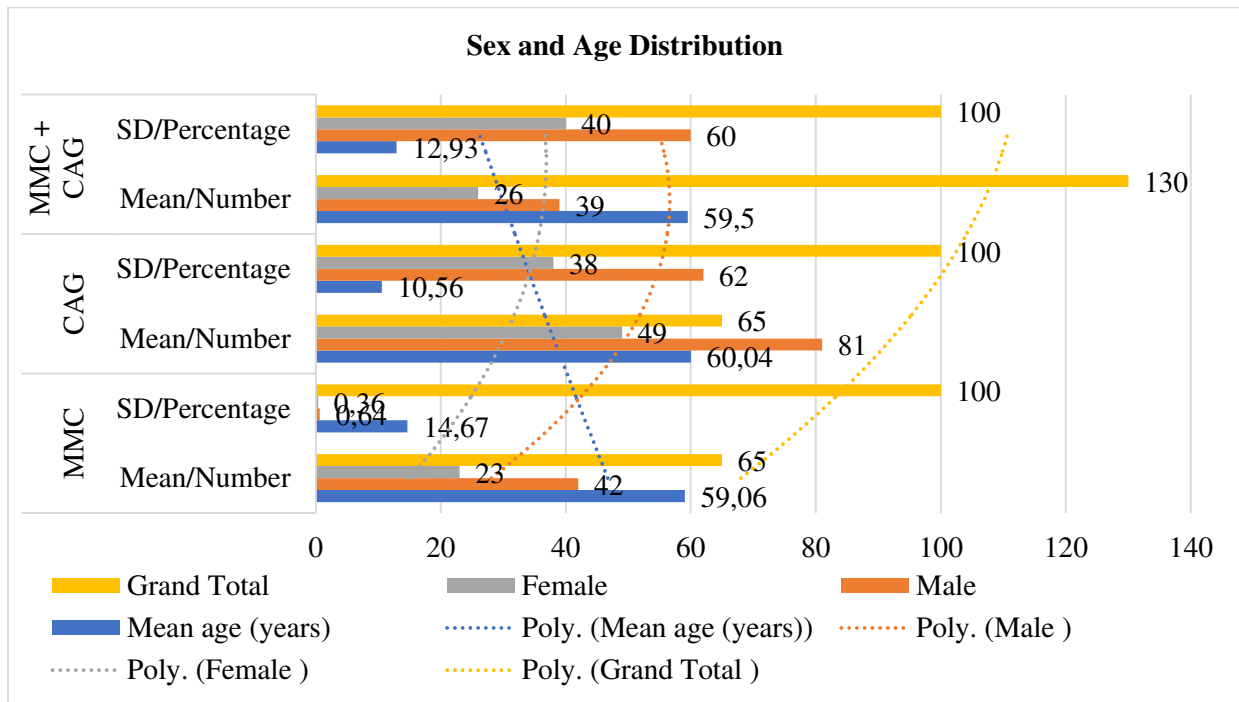
Reported reoccurrences in Group – I was ten (15.3%); whereas, in Group – II only two occurrences (3%) in the overall follow-up time

period. Significant variation was in both groups as reflected in P-value (< 0.05); which implies better research outcomes in Group – II (Conjunctival Auto-

graft) in terms of a success rate than Group – I (Mitomycin – C). Detailed outcomes analysis is as under:

**Table – I: Sex and Age Distribution**

Age & Sex		Mean age (years)	Male	Female	Grand Total
MMC	Mean/Number	59.06	42	23	65
	SD/Percentage	14.67	0.64	0.36	100
CAG	Mean/Number	60.04	81	49	65
	SD/Percentage	10.56	62	38	100
MMC + CAG	Mean/Number	59.5	39	26	130
	SD/Percentage	12.93	60	40	100



**Table – II: Recurrences in MMC group**

Age Range	Male		Female		Total	
32 - 84 Years	39	60	26	40	65	100
Recurrence	7	10.7	3	4.6	10	15.3

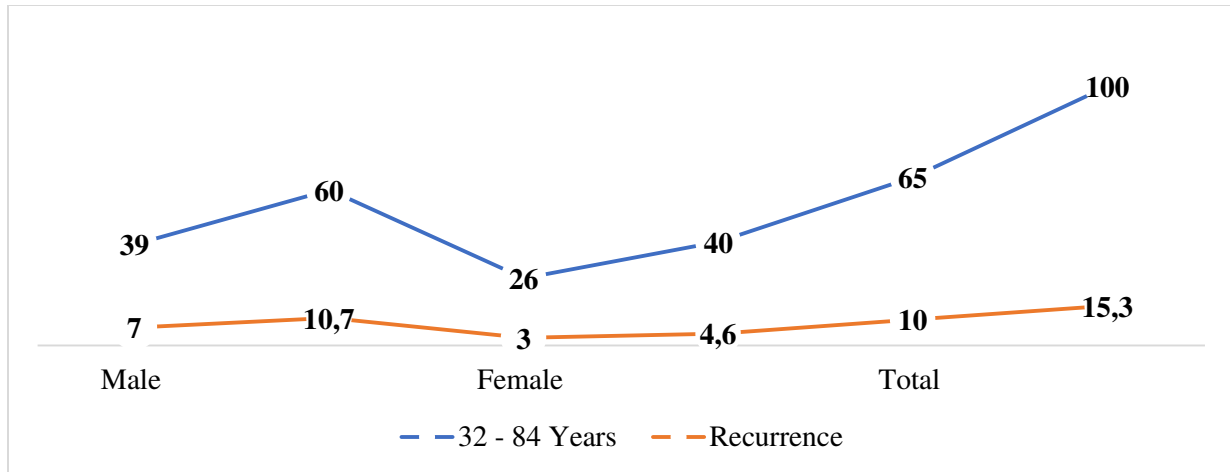


Table – III: Recurrences in CAG group

Age Range	Male		Female		Total	
39 - 81 Years	42	64	23	36	65	100
Recurrence	2	3	0	0	2	3

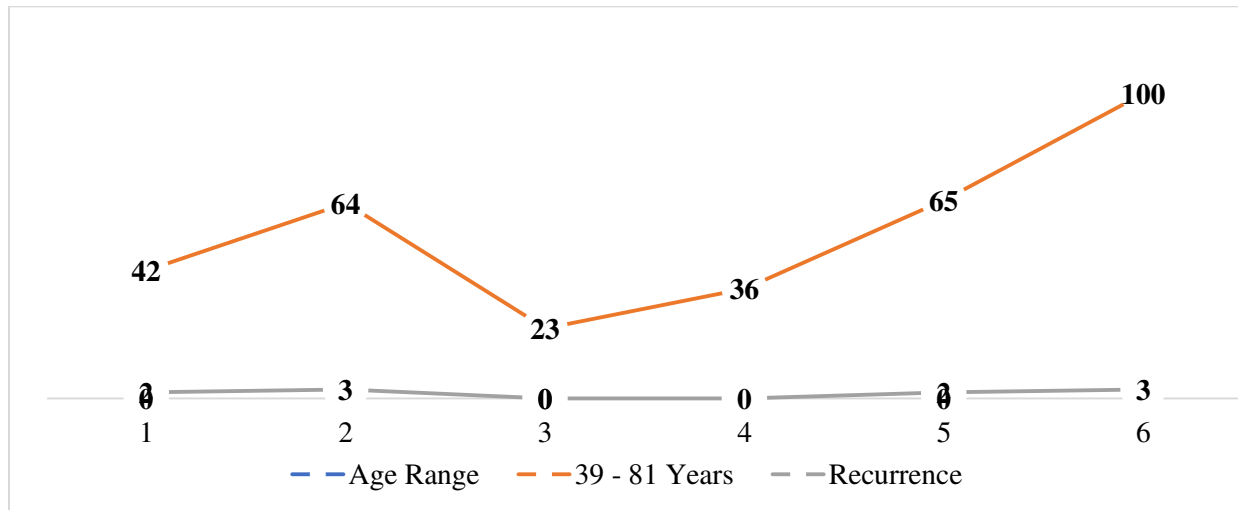


Table – IV: Recurrences of MMC versus CAG group

Follow-up	MMC	CAG	MMC + CAG
First Month	0	0	0
Second Month	0	0	0
Third Month	2	0	2
Fourth Month	2	0	2
Fifth Month	0	0	0
Sixth Month	6	2	8

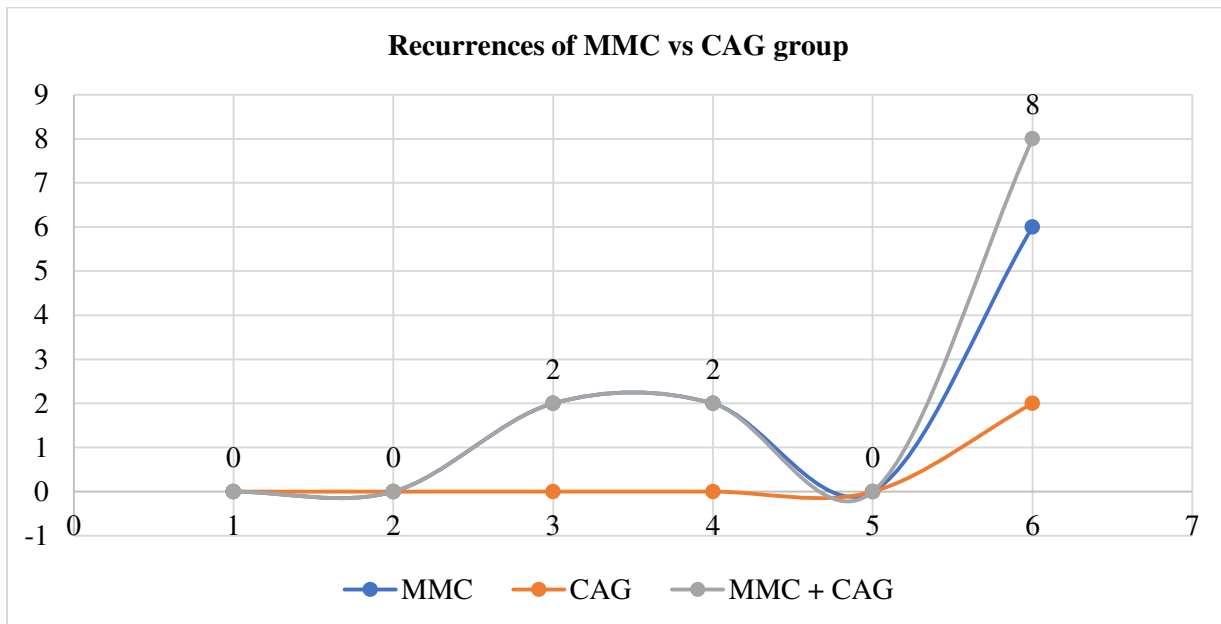
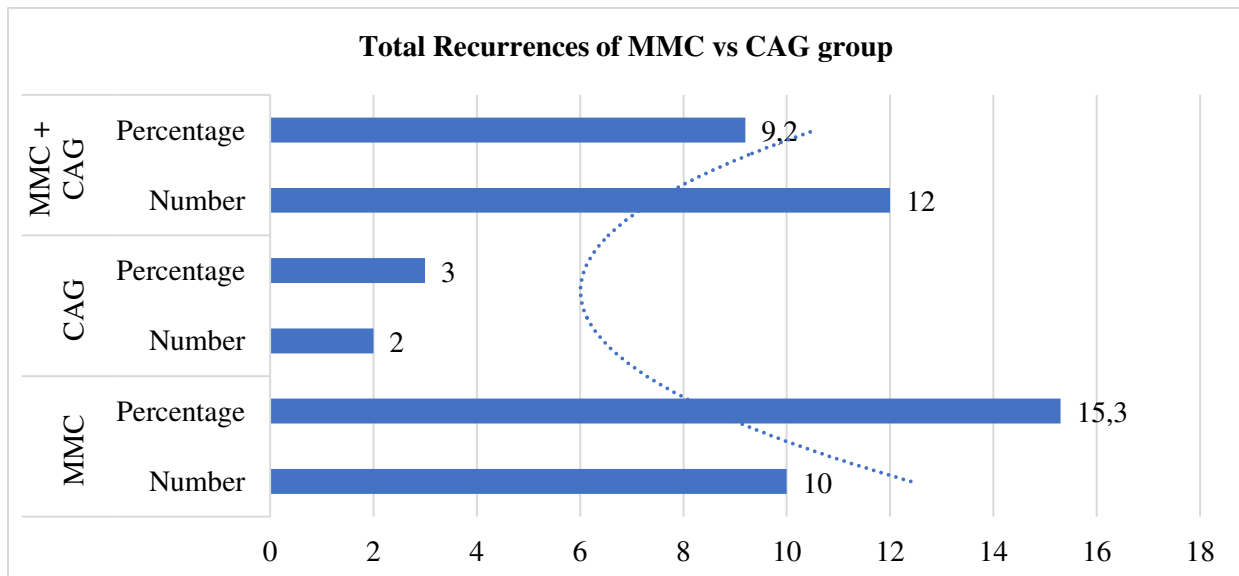


Table – V: Total Recurrences of MMC vs CAG group

MMC		CAG		MMC + CAG	
Number	Percentage	Number	Percentage	Number	Percentage
10	15.3	2	3	12	9.2



**DISCUSSION:**

Numerous surgical interventions are available in order to manage pterygium. Major issues and modalities include the reoccurrence timing and rate

of unpredictability [7]. A recurrent case of pterygium can cause reduced restricted ocular motility, visual acuity and formation of symblepharon [6, 7]. Conjunctival Auto-graft and Mitomycin – C are two

different useful adjuncts; eye surgeons use them for the reduction of reoccurrence of pterygium. Thomas et al; reported an average to follow up the rate of 12.1 months in Mitomycin treated patients without any incidence of reoccurrence [14]. Whereas, in the other group not treated with Mitomycin had an average follow-up period of 42.6 months. Nine-time occurrence repetition was also available in this group with a proportion of (32%); which required another surgical intervention. A significantly reduced trend of reoccurrence was available in Mitomycin group with a significant P-value of 0.006. Another recent research reported thirty months mean follow-up with reoccurrence rate of 8.3% in Mitomycin group against a reoccurrence rate of 75% in bare sclera technique [15]. We reported a reoccurrence rate of 15.38% in the group treated with Mitomycin – C; which is comparable to the outcomes as reported by Young in his research study where reoccurrence rate was 15.9% in Mitomycin – C treated group [8].

Fahim reported reoccurrence rate of 13.33% in Conjunctival Auto-graft group [9]. Whereas, Hirst reported a reoccurrence in the bracket of (0% – 40%) in Conjunctival Auto-graft group [16]. Whereas, in the primary pterygium cases there were 42 cases (12.2%). Fernandes reported 5 cases of recurrent pterygium (31.3%) in his research [4].

In a retrospective research conducted by Riordan-Eva, recurrences were present in seventeen out of forty-seven eyes with a proportion of six percent [17]. Fernandes reported higher recurrence (5 / 11) in a small series trial conducted on the patients of recurrent pterygium (31.3%) [4]. Shimazaki applied a combination of both Conjunctival Auto-graft in order to restore the function of the limbal barrier and amniotic membrane transplant for the suppression of fibrous growth with better outcomes. Reported reoccurrence rate was about 17.3% in this combined management [18]. Our research outcomes reported three percent recurrent cases in the group treated with Conjunctival Auto-graft. The variation is attributable to the factors of different techniques applied by various surgeons with an influence on the rate of reoccurrence after the act of excision [6, 7, 12]. Koryani reported a reoccurrence rate of 38% in the patients treated with Mitomycin; whereas, in fifteen percent reoccurrence in the patients treated with Conjunctival Auto-graft with a significant P-value (< 0.05)

#### CONCLUSION:

Acceptable outcomes are possible through withering Conjunctival Auto-graft or Mitomycin – C; Whereas, in visually significant pterygium cases, there is a

decreased reoccurrence in the pterygium surgery with the application of Conjunctival Auto-graft than Group – I (Mitomycin – C) adjuvant.

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