Original Article

Outcome of Trabeculectomy with Collagen Matrix Implant versus Mitomycin C in Primary Glaucoma: A Comparative Study

Abstract

Background: Glaucoma is a serious vision-threatening condition appropriately called as the silent killer of sight. The effect of postoperative fibrosis on success of filtration surgeries requires modulation of the wound healing process. **Aim:** The aim of the study was to compare trabeculectomy augmented with collagen matrix implant with mitomycin C in primary glaucoma. **Materials and Methods:** This prospective, longitudinal, hospital-based, analytical, and interventional study was conducted on 36 eyes of 36 patients. Group 1 included 18 patients who underwent trabeculectomy combined with subconjunctival collagen matrix implant and Group 2 included 18 patients who underwent trabeculectomy augmented with intraoperative mitomycin C (0.04 mg/ml) for 2 min. Each patient underwent detailed ocular examination and comparison was drawn by recording intraocular pressure (IOP), bleb characteristics, and postoperative complications. **Results:** The cumulative success rates at the end of our study were similar in two groups, 94.44% in Group 1 and 88.89% in Group 2 (P = 1.000). The mean reduction in IOP at 24 weeks in Group 1 was 18.67 ± 7.59 mmHg and in Group 2 was 21.32 ± 5.84 mmHg. The reduction in IOP was similar between the two groups (P = 0.290). The mean fall in IOP was 56.46% in Group 1 and 64.70% in Group 2 at 24 weeks. Mean bleb score in Group 1 was 10.33 ± 1.23 and in Group 2 was 8.89 ± 1.41, and the difference was statistically significant (P = 0.002). Shallow anterior chamber, overfiltration, and hypotony were statistically higher in Group 2 than in Group 1 (P = 0.041, 0.041, and 0.046, respectively). **Conclusion:** Collagen matrix implant as an adjuvant to trabeculectomy is noble, safe, and effective option as compared to mitomycin C.

Keywords: *Collagen matrix implant, glaucoma, intraocular pressure, mitomycin C*

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Introduction

Glaucoma refers to a group of diseases that have in common a characteristic optic neuropathy with associated visual field loss, for which elevated intraocular pressure (IOP) is one of the primary risk factors.[1] Currently, worldwide, the number of people with glaucoma aged 40–80 years is 76.0 million and is expected to rise to 111.8 million by 2040.[2] The prevalence of glaucoma contributes to financial burden which increases as the disease severity increases. Medical management includes prostaglandin analogs, beta-adrenergic blockers, sympathomimetics, adrenergic agonists, carbonic anhydrase inhibitors, parasympathomimetics, and hyperosmotic agents. The goal of glaucoma filtration surgery is to lower IOP by creating an alternative outflow channel.

Glaucoma filtering surgery fails because of scarring of the filtering bleb. Outcome of filtering surgery has improved significantly with the use of antimetabolites such as mitomycin-C and 5-fluorouracil as they prevent episcleral fibrosis and bleb scarring.[3,4] However, the use of such toxic agents is associated with the risk of corneal toxicity, overfiltration, hypotony, and wound leak in the early postoperative period. The long-term follow-up of eyes that were treated with antimetabolites showed a higher risk of bleb leak, thin-walled avascular blebs, blebitis, and endophthalmitis as a result of impaired surface healing.[5-10] Because of the long-term complications of mitomycin C, there is a compelling need for safer alternatives to control bleb fibrosis. This led to the quest for safer antifibrotics for wound modulation which includes antipyrimidines, antineoplastic antibiotics, corticosteroids, amniotic membrane, antivascular endothelial growth factor agents, and lately biodegradable implants.[11,12]

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Collagen-glycosaminoglycan matrix implant is a disc shaped, porcine derived with a pore size of 10–300 μm. It is biodegradable in 90–180 days or more, leaving a porous skeleton of connective tissue in its place. It allows controlled resistance to aqueous outflow along with a random, relatively loose alignment of regenerating myofibroblasts, fibroblasts, and extracellular matrix, resulting in reduction of bleb scarring.[13-15] Due to porous structure, conjunctival fibroblasts and myofibroblasts tend to grow inside the pores, resulting in reduced scar formation and wound contraction.[15,16] Implant can be placed above the scleral flap (subconjunctival) or below the flap (subscleral) during the surgery, serving as a reservoir for bleb formation while enhancing wound healing.[17] The blebs treated with implants developed significant vasculature without thinning in contrast to those treated with MMC augmentation that developed thin avascular blebs.[15,18] The present study was undertaken to evaluate the results of collagen matrix implant as compared to mitomycin C as an adjuvant on the outcome of trabeculectomy for the treatment of primary glaucoma.

Materials and Methods

This prospective, longitudinal, hospital-based, randomized, analytical, and interventional study was conducted in a tertiary care institute of north India after taking due clearance from the "Institutional Ethics Committee." The proposed study was conducted over a period of 1 year from April 1, 2019, to March 31, 2020. Sample size was calculated by using G*Power statistical software for windows version 3.1.9.4. (Developed by Heinrich-Heine-Universität, Düsseldorf, Germany; Released 6 Feb. 2019). The parameters used were - α error probability 0.05 (two-tailed), power 80%, and ratio of sample size between two groups as 1. The means and standard deviations for collagen matrix implant and mitomycin C augmented trabeculectomy were taken from the previous study as 14.6 ± 2.7 and 11.9 ± 2.9, respectively, for the effect size.[16] After calculation, the sample size for the study was found to be 18 in each of the two groups.

The study included 36 patients of primary glaucoma which were divided randomly into two groups of 18 patients each. The process of randomization was based on random number table prepared using GraphPad random number generator. Group 1 included 18 patients who underwent trabeculectomy combined with collagen matrix implant [Figure 1] and Group 2 included 18 patients who underwent trabeculectomy augmented with intraoperative mitomycin C (0.04 mg/ml) for 2 min [Figure 2]. The inclusion criteria were (a) patients ≥18 years of age of either sex, with or without lenticular changes; (b) uncontrolled primary open angle glaucoma despite maximum medical therapy; and (c) uncontrolled primary angle closure glaucoma with angle closure >180° on gonioscopy. Exclusion criteria included: (a) secondary glaucoma; (b) congenital and developmental glaucoma; (c) previous surgical intervention or laser procedures; (d) presence of acute or chronic inflammatory eye disease; and (e) previous conjunctival damage (trauma and strabismus surgery).

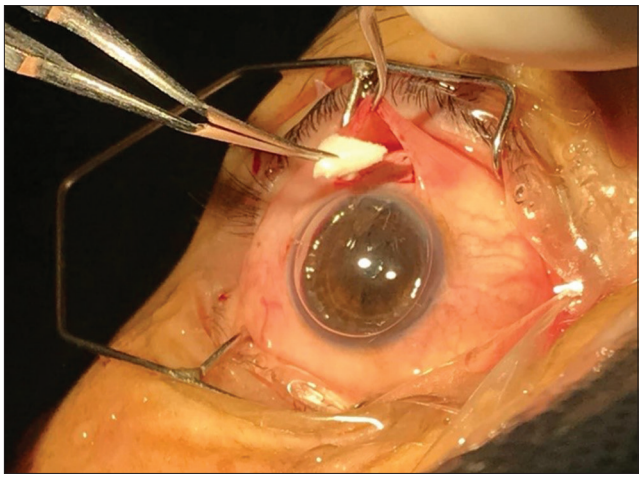

Figure 1: Collagen matrix implant placed over scleral flap

Informed written consent was obtained from all the patients enrolled in the study. Each patient underwent detailed ocular examination including uncorrected and corrected visual acuity, anterior segment examination with slit lamp, gonioscopy, posterior segment examination with direct and indirect ophthalmoscopy, and IOP was recorded with noncontact tonometer/applanation tonometer. Perimetry was done to examine visual fields with Opto Visual Field Analyzer.

In both the groups, a fornix-based conjunctival flap was created, 6 × 4 mm quadrangular partial thickness scleral flap was reflected; then a trabeculectomy of 4 × 2 mm was performed and was completed by peripheral iridectomy. In Group 1, it was followed by subconjunctival placement of collagen matrix implant over the scleral flap. In Group 2, trabeculectomy was augmented with intraoperative mitomycin C (0.04 mg/ml), a soaked sponge was placed before partial thickness scleral flap subconjunctivally for 2 min, followed by copious irrigation. In both the groups, conjunctival closure was done with continuous sutures. All the cases were operated by a single surgeon. Postoperative regimen was same in both the groups which included antibiotic steroids drops starting at day 1. Postoperative visits were scheduled at day 1, day 7, 1 month, 3 months, and 6 months. Examination was done for the condition of conjunctiva, cornea, bleb condition [Figure 3], anterior chamber (AC) depth, visual acuity, and IOP. Grading of blebs was done according to Wuerzburg Bleb Classification Score, 2010.[19] Criteria for success: absolute success – intraocular pressure <21 mmHg without any antiglaucoma medication, qualified success - intraocular pressure <21 mmHg with antiglaucoma medication, and failure – intraocular pressure >21 mmHg with antiglaucoma medication.

Statistical analysis was performed by applying IBM SPSS statistics for windows version 25.0 (IBM Corp.

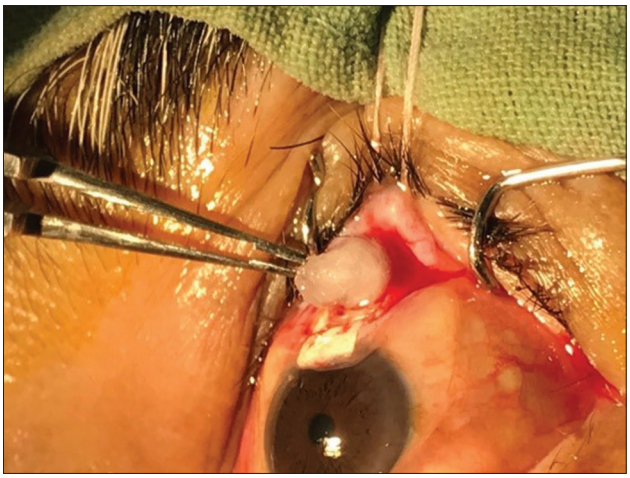

Figure 2: Mitomycin C soaked sponges placed subconjunctivally

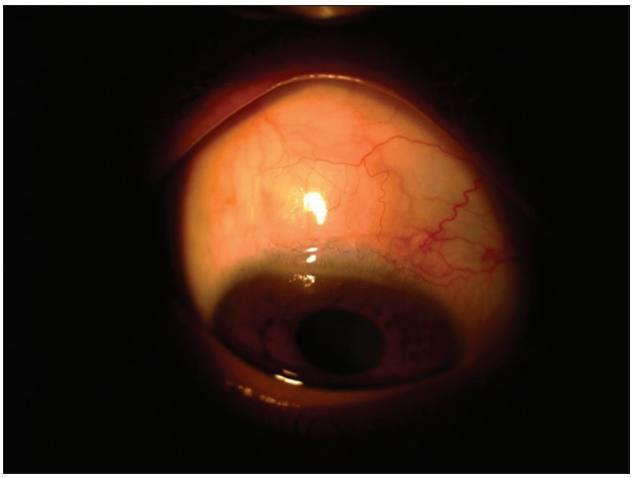

Figure 3: Slit-lamp photograph of bleb in Group 1 patient at 6 months

Released 2017, Armonk, NY, USA). Categorical variables were represented in the form of number and percentage while continuous variables as mean ± standard deviation. Comparison of qualitative variables between two groups was done using Fisher's exact test and quantitative variables with independent sample *t*-test. Change from pre- to post-operative values in continuous variables in each group was done using paired sample *t*-test. All the tests were done at 5% level of significance and $P \leq 0.05$ was considered to be statistically significant.

Results

Thirty-six eyes of 36 patients were enrolled in the study. Of which, 26 (72.2%) were males and 10 (27.7%) were females. Male-to-female ratio was 2.6:1. Mean age was 59.72 ± 8.64 years in Group 1 and 61.94 ± 7.54 years in Group 2 ($P = 0.581$). Patients were divided randomly into two groups of 18 each (Group 1 underwent trabeculectomy combined with collagen matrix implant and Group 2 trabeculectomy augmented with intraoperative mitomycin C).

Mean preoperative IOP in Group 1 was 32.67 ± 7.130 mmHg and in Group 2 was 32.28 ± 6.120 mmHg, and the difference were statistically not significant ($P = 0.536$). Mean postoperative IOP at 24 weeks in Group 1 was 13.98 ± 2.960 mmHg and in Group 2 was 10.96 ± 2.248 mmHg, and the difference between two groups was statistically not significant ($P = 0.289$) [Table 1]. The mean reduction in IOP at 24 weeks in Group 1 was 18.67 ± 7.59 mmHg and in Group 2 was 21.32 ± 5.84 mmHg. The reduction in IOP was similar between the two groups ($P = 0.290$). In both groups, there was statistically significant drop of IOP from the baseline ($P < 0.001$). The mean fall in IOP was 56.46% in Group 1 and 64.70% in Group 2 at 24 weeks.

Cumulative success rate was found to be 94.44% (absolute success: 72.22% and qualified success rate: 22.22%) in Group 1 and 88.89% (absolute success: 77.78% and qualified success rate: 11.11%) in Group 2 [Table 2]. Mean bleb score in Group 1 was 10.33 ± 1.23 and in Group 2 was 8.89 ± 1.41, and the difference between the two groups was statistically significant ($P = 0.002$). No major intraoperative complications were seen in our study. Postoperative complications are depicted in Table 3. Overall postoperative complications rate was higher in Group 2 as compared to Group 1, but it was not statistically significant ($P = 0.176$). However, shallow AC, overfiltration, and hypotony were statistically higher in Group 1 than Group 2 ($P = 0.041$, 0.041, and 0.046, respectively). The cause of hypotony was overfiltration in all the cases.

Table 1: Preoperative and postoperative intraocular pressure at different stages of follow-up

Follow up	Group	Mean IOP (mmHg)±SD	*P*
Preoperative	Group 1	32.67±7.130	0.536
	Group 2	32.28±6.120	
1 day	Group 1	15.87±4.256	0.938*
	Group 2	13.47±4.338	
1 week	Group 1	12.41±5.408	0.129*
	Group 2	10.90±3.707	
4 weeks	Group 1	14.51±3.586	0.141*
	Group 2	11.17±2.486	
12 weeks	Group 1	14.95±3.099	0.268*
	Group 2	10.50±2.356	
24 weeks	Group 1	13.98±2.960	0.266*
	Group 2	10.96±2.248	

*Not significant. SD: Standard deviation; IOP: Intraocular pressure

Discussion

Collagen matrix implant is increasingly being explored as a substitute for antimetabolites in glaucoma filtration surgery. Evaluation of IOP is one of the measures for the primary outcomes of success in trabeculectomy.

In the present study, the mean preoperative IOP in Group 1 was 32.67 ± 7.130 mmHg and in Group 2 was 32.28 ± 6.120 mmHg, and it fell to 13.98 ± 2.960 mmHg

Table 2: Success outcome in both the groups

Success outcome	Group 1, *n* (%)	Group 2, *n* (%)	*P*
Absolute success	13 (72.22)	14 (77.78)	1.000*
Qualified success	4 (22.22)	2 (11.11)	0.418*
Cumulative success**	17 (94.44)	16 (88.89)	1.000*
Failure	1 (5.56)	2 (11.11)	1.000*

*Not significant, **Cumulative success=Absolute+qualified success

Table 3: Early postoperative complications

Complications	Group 1, *n* (%)	Group 2, *n* (%)	*P*
Hyphema	5 (27.78)	2 (11.11)	0.402
Shallow AC	1 (5.56)	7 (38.89)	0.041
Overfiltration	1 (5.56)	7 (38.89)	0.041
Hypotony	0	5 (27.78)	0.046
AC reaction	3 (16.67)	2 (11.11)	0.418
Cataract	2 (11.11)	4 (22.22)	0.658
Total	5 (27.78)*	10 (55.56)**	0.176

*Three patients had more than one complication, **Seven patients had more than one complication. AC: Anterior chamber

and 10.96 ± 2.248 mmHg, respectively, after 24 weeks of follow-up. The difference between the two groups was statistically not significant ($P = 0.289$) The mean reduction in IOP at 24 weeks in Group 1 was 18.67 ± 7.59 mmHg and in Group 2 was 21.32 ± 5.84 mmHg. The reduction in IOP was similar between the two groups ($P = 0.290$). In both groups, there was statistically significant drop of IOP from the baseline ($P < 0.001$). Senthil *et al*.[16] reported mean IOP reduction at 6 months significantly lower in the Mitomycin C group (11.9 ± 2.9 mmHg) as compared to collagen matrix implant group (14.6 ± 2.7 mmHg). Mohsen[20] reported IOP dropped from 43.07 ± 6.23 to 16.03 ± 4.2 mmHg at the 12th month in group with ologen ($P < 0.0001$) and from 41.41 ± 5.11 to 15.13 ± 2.75 mmHg in group with mitomycin ($P < 0.0001$).

In the present study, cumulative success rate was found to be 94.4% (absolute success: 72.2% and qualified success rate: 22.2%) in Group 1 and 88.8% (absolute success: 77.7% and qualified success rate: 11.1%) in Group 2. Papaconstantinou *et al*.[21] reported 100% complete success probability in both ologen and mitomycin C groups at the end of 6 months. Senthil *et al*.[16] also reported a complete success rate in implant group at the end of 6 months ($P = 0.53$). However, Cillino *et al*.[22] reported lower complete success rates at ≤21 mmHg target IOP of 65% and 70% in mitomycin and ologen implant, respectively, in their 5-year follow-up study comparing trabeculectomy with ologen implant versus trabeculectomy with mitomycin C.

In the present study, mean bleb score at 6 months was 10.33 ± 1.23 in Group 1 and was 8.89 ± 1.41 in Group 2, and the difference was statistically significant ($P = 0.002$). At 24 weeks, about 88.8% of patients in Group 1 had bleb score ≥11 and only 61.1% in Group 2. Furrer *et al*.[23] observed that patients with a bleb score of more than 8 points had a lower IOP (≤12 mmHg) 1 year postoperatively, whereas those with bleb score <7.0 presented with higher IOP. Rosentreter *et al*.[15] found more avascular blebs in the MMC group as compared to the collagen matrix implant group at the end 1 year.

Postoperatively, the number of eyes which experienced one or more complications was 5 out of 18 eyes (27.78%) in Group 1 and 10 out of 18 eyes (55.56%) in Group 2. The frequency of overall postoperative complications was higher in Group 2 as compared to Group 1, but it was not statistically significant ($P = 0.176$). Postoperatively, hyphema was observed in 5 (27.78%) patients in Group 1 and 2 (11.11%) patients in Group 2; in all cases, hyphema resolved on its own. Postoperative hyphema and AC reaction were the most common postoperative complications in Group 1.[20] Senthil *et al*.[16] observed in their study that complications in the early postoperative period were comparable between the two groups, apart from hyphema, which was remarkably more in collagen matrix implant group ($P = 0.02$).

Hypotony was seen in none of the patients in Group 1 and 5 (27.78%) patients in Group 2, and the difference was statistically significant between the two groups ($P = 0.008$). As compared to the present study, an increased rate of early hypotony was seen in both MMC 0.2 mg/ml and ologen groups (40% and 20%, respectively) in the study conducted by Cillino *et al*.[22] Mohsen[20] also reported that mitomycin C group had statistically higher rate of hypotony with thin blebs. Hypotony can result in serious vision-threatening complications; therefore, prevention of hypotony is the preferred approach as compared to treating hypotony.[24]

Shallow AC was found in 5.56% of patients in Group 1 and 38.89% of patients in Group 2. Rosentreter *et al*.[15] reported two cases (20%) in ologen group developed shallow AC, whereas MMC group developed shallow AC in a single case (10%). AC reaction was seen in 3 (16.67%) in Group 1 and 2 (11.1%) in Group 2. As the collagen matrix implant is nonhuman in origin, so there is a theoretical risk of increased inflammation in the implant group.[25] Senthil *et al*.[16] reported that, in collagen matrix implant group, 8 (42.1%) patients had an AC reaction, whereas in mitomycin C group, 6 (30%) patients had same complication. Cataract progression was seen in 2 (11.11%) in Group 1 and 4 (22.22%) in Group 2. Casson *et al*.[26] reported cataract progression in 20% of cases.

The main limitation of our study is the short-term follow-up. Longer follow-up will help us to compare the long-term success as well as complications of the two groups. In our study, the reduction in IOP and the cumulative success rates were similar in both the groups. The bleb characteristics and postoperative complication rate varied, bleb score was higher in the group with collagen matrix implant, and postoperatively, hypotony was more prevalent in the group treated with mitomycin C. These

results indicate that trabeculectomy with biodegradable collagen matrix implant is useful adjuvant and is new, safe, and effective alternative to mitomycin C, with similar success rate but with low complications rates and can be preferred when antimetabolite-related risks need to be avoided or when they are contraindicated, for example, during pregnancy, or in patients with previous blebitis in their fellow eye because of prior mitomycin use.

Conclusion

Our study found biodegradable collagen matrix implants to be safe and efficacious adjuvant in trabeculectomy. Collagen matrix implant appears to be safer than mitomycin C regarding postoperative complications, especially postoperative hypotony and can be preferred when antimetabolite-related risks need to be avoided or when they are contraindicated.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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