Original Article

Viscoelastic-augmented trabeculectomy: A newer concept

Meghna Solanki, Ankur Kumar, Anubhav Upadhyay, Kishor Kumar

Purpose: Comparison of conventional trabeculectomy (CT) and viscoelastic-augmented trabeculectomy (VAT) in primary open-angle glaucoma. **Methods:** A total of 65 primary open-angle glaucoma cases were taken for each of the two groups, i.e., CT and VAT. Viscoelastic-augmented trabeculectomy constituted lamellar scleral flap, deep scleral flap, penetrating trabeculectomy, peripheral iridectomy, filling of the anterior chamber with viscoelastic (sodium hyaluronate) and balanced salt solution, movement of visco in bleb, and tight flap closure. Success criteria included intraocular pressure (IOP) <14 mmHg with no devastating complications. $P < 0.05$ was considered statistically significant. **Results:** Mean IOP was significantly lower after VAT compared to CT at 6 weeks, 12 weeks, and 6 months postoperatively. Target IOP was achieved in 60% cases in VAT group compared to 36.92% in CT group. **Conclusion:** VAT is effective in reducing IOP to the target level for advanced glaucoma with lower postoperative complications.

Key words: Conventional trabeculectomy, sodium hyaluronate, visco elastic augmented trabeculectomy

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Glaucoma is the leading cause of irreversible blindness worldwide and the second most common cause of blindness after cataract.[1,2] It is responsible for 14% of blindness worldwide.[3]

The most commonly used first surgical approach to lowering significantly high intraocular pressure (IOP) remains trabeculectomy. However, over the last few years, numerous techniques have been introduced as alternatives to conventional trabeculectomy (CT).

The viscoelastic-augmented trabeculectomy (VAT) study was undertaken with an aim to minimize CT-associated drawbacks including subconjunctival fibrosis leading to bleb failure, overfiltration causing shallow or flat anterior chamber (AC) further leading to raised IOP.

The present study was undertaken to assess whether placing viscoelastic (sodium hyaluronate) within bleb at the end of CT would augment bleb function. It was further hypothesized that placing viscoelastic within both the AC and the bleb would be helpful for preventing both a postoperative flat AC and early bleb fibrosis, thus helping gain better control of IOP.

Methods

The study was a hospital-based randomized comparative type. Before commencing the study, each patient was acquainted with its investigative nature, the advantages, and potential risks. The surgical technique and its visual prognosis were properly explained, and informed consent was taken. All the patients were admitted to the hospital at least 1 day before surgery for routine preoperative investigations.

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A total of 65 patients of primary open-angle glaucoma in both eyes were included in the study and randomly divided into two groups after signing an informed consent.

- Group T: CT with Mitomycin C (MMC)
- Group V: VAT.

Eligibility criteria

Inclusion criteria

Patients with primary open-angle glaucoma, ophthalmoscopically normal retina with adequate fundus visibility, and those willing to give written informed consent were included in the study.

Exclusion criteria

Angle-closure glaucoma or secondary glaucoma, age-related macular degeneration or diabetic macular edema, history of previous ocular surgery, recent ocular infection or inflammation, any corneal pathology, conditions with hazy optical media, trauma, patients not willing to undergo surgery, and those who were not able to come for follow-up were excluded from the study.

All patients had undergone ophthalmological, systemic, and full clinical evaluation. Patient data were recorded and analyzed.

Surgical techniques

Group T: Conventional trabeculectomy with Mitomycin C

Superior rectus bridle suture was placed, a fornix-based conjunctival flap prepared, hemostasis was achieved by

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Table 1: Distribution of the cases according to preoperative intraocular pressure

	Mean±SD (median) (minimum–maximum)			*P* value LS
	Group T (*n*=65)	Group V (*n*=65)	Total (*n*=130)	
Preoperative IOP	26.14±2.822 (26.00) (22-38)	25.23±3.181 (25.00) (21-36)	25.68±3.03 (25.00) (21-38)	0.08 NS

No significant difference was observed in preoperative IOP among the groups. The mean preoperative IOP was 26.14±2.822 (26.00) (22-38) in Group T and 25.23±3.181 (25.00) (21-36) in Group V (*P*=0.08 NS). IOP: Intraocular pressure, NS: Not significant, SD: Standard deviation, LS: Least square mean

Table 2: Postoperative intraocular pressure among groups at different time intervals

Groups	Day 1	1 week	6 weeks	12 weeks	6 months
Group T					
n	65	65	65	65	65
Mean±SD	17.34±4.059	15.52±4.845	15.15±3.443	14.19±3.028	18.52±4.493
Group V					
n	65	65	65	65	65
Mean±SD	15.62±4.145	14.57±3.840	13.28±3.676	13.02±2.637	16.71±4.775
P	0.018 S	0.216 NS	0.003 S	0.020 S	0.055 NS

The mean postoperative IOP in Group T (trabeculectomy with MMC) was 18.52±4.493 mmHg and in Group V (viscoelastic-augmented trabeculectomy) was 16.71±4.775 mmHg at 6-month follow-up and similar pattern was observed in 6 weeks and 12 weeks also. IOP: Intraocular pressure, NS: Not significant, SD: Standard deviation, S: Significant, MMC: Mitomycin C

Table 3: Comparison of mean difference in intraocular pressure from baseline and postoperative intraocular pressure at 6 months

	Pre-post (6 months)		
	n	Mean±SD	*P* value LS
Group T	65	7.62±4.765	0.39 NS
Group V	65	8.37±5.234	
Total	130	7.99±5.000	

The comparison of mean changes in the baseline IOP and postoperative IOP at 6 months in Group T (7.62±4.765 mmHg) and Group V (8.37±5.234 mmHg) was not significant statistically (*P*=0.39). IOP: Intraocular pressure, NS: Not significant, SD: Standard deviation, LS: Least square mean

Table 4: Success rate of both the groups according to the postoperative intraocular pressure

Success rate	Group T, *n* (%)	Group V, *n* (%)	Grand total
Final IOP <14 mmHg			
No	41 (63.08)	26 (40.00)	67
Yes	24 (36.92)	39 (60.00)	63
Total	65 (100.00)	65 (100.00)	130

Success rate was significantly higher in Group V as compared to Group T (60% vs. 36.92%) (*P*=0.014 S). χ^2=6.036 with 1 degree of freedom; *P*=0.014 S. IOP: Intraocular pressure, S: Significant

adequate wet-field cautery, and subconjunctival MMC 0.2 mg/ml was applied for 2 min; 4 mm × 4 mm rectangular scleral flap one-third of the thickness dissected to within 1 mm of clear cornea with a bard-parker knife. After creating a paracentesis opening, inner sclerostomy block was dissected out with the blade in the dimensions 2 mm × 3 mm, at the base of the hinge of the superficial scleral flap. Peripheral iridectomy performed through the inner sclerostomy with a Vannas scissor and a single-toothed fine forceps. Scleral flap reapproximated with two 10-0 nylon suture, conjunctival flap closed watertight by running 10-0 nylon suture. Subconjunctival injection of 0.3 ml gentamycin and 0.3 ml dexamethasone was given, completing the procedure [Fig. 1].

Group B: Viscoelastic-augmented trabeculectomy

Superior rectus bridle suture was placed, fornix-based conjunctival flap was prepared, hemostasis was achieved by adequate wet-field cautery [Fig. 2], and subconjunctival MMC 0.2 mg/ml was applied for 2 min. A 4 mm × 4 mm rectangular scleral flap one-third of the thickness was dissected to within 1 mm of clear cornea with a bard-parker knife [Fig. 3]. After creating a paracentesis opening, inner sclerostomy block was dissected with the blade with the dimensions 2 mm × 3 mm at the base of the hinge of the superficial scleral flap [Figs. 4 and 5]. Peripheral iridectomy was performed through the inner sclerostomy with a Vannas scissor and a single-toothed fine forceps [Fig. 6]. Half the AC space was filled with viscoelastic (sodium hyaluronate) applied through the paracentesis site [Fig. 7]; a small amount of balanced salt solution (BSS) was injected into the AC through the same. While injecting BSS into the AC, when the AC was filled with viscoelastic, movement of viscoelastic into the bleb space and subsequent elevation of the bleb were easily differentiated [Fig. 8]. Thus, the bleb was well elevated by the underlying visco elastic [Fig. 9]. Half the AC space was again filled with viscoelastic. Scleral flap reapproximated with two 10-0 nylon suture. Conjunctival flap closed watertight by running 10-0 nylon suture. A subconjunctival injection of 0.3 ml gentamycin and 0.3 ml dexamethasone was given, completing the procedure.

Postoperatively, patients were prescribed a combination of antibiotic-steroid (tobramycin 0.3% + dexamethasone 0.1%) eye drops every 2 h for 1 week which tapered over the following 5 weeks. Cycloplegic-mydriatic (homatropine 2%) eye drops

Table 5: Distribution of the cases according to postoperative complications

Complications	Group T (*n*=65), *n* (%)	Group V (*n*=65), *n* (%)	Total
Nil	37 (56.92)	55 (84.62)	92
Present	28 (43.08)	10 (15.38)	38
Conjunctival hyperemia	6 (21.43)	0	6
Hyphema	6 (21.43)	2 (20)	8
Shallow AC	6 (21.43)	4 (40)	10
Shallow AC with hyphema	4 (14.29)	0	4
Subconjunctival hemorrhage	6 (21.43)	4 (40)	10

Significant complication rates were more in Group T (40%) as compared to Group V (21.54%) (*P*=0.037 S). Conjunctival hyperemia, hyphema, shallow AC, subconjunctival hemorrhage were equal; 15% of all the complications present in Group T. No cases of conjunctival hyperemia and shallow AC with hyphema were present in Group V. AC: Anterior chamber, S: Significant

Table 6: Distribution of the cases according to postoperative number of antiglaucoma medication

Postoperative number of antiglaucoma medication	Group T (*n*=65), *n* (%)	Group V (*n*=65), *n* (%)	*P* value LS
0	47 (72.308)	58 (89.23)	7.513 with 2 df; *P*=0.023
1	13 (20)	3 (4.62)	
2	5 (7.6923)	4 (6.15)	
Mean±SD (median) (minimum–maximum)	0.35±0.623 (0.00) (0-2)	0.17±0.517 (0.00) (0-2)	0.075 NS

0.35±0.623 (0.00) (0-2) number of postoperative antiglaucoma medications were required in Group T while 0.17±0.517 (0.00) (0-2) in Group V (*P*=0.75 NS). NS: Not significant, SD: Standard deviation, LS: Least square mean

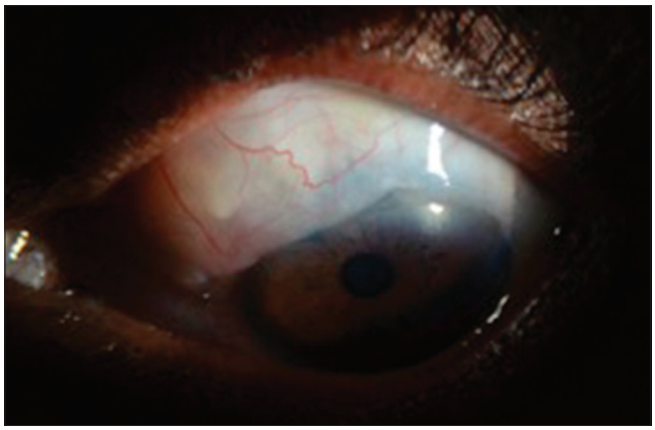

Figure 1: Bleb photograph of conventional trabeculectomy

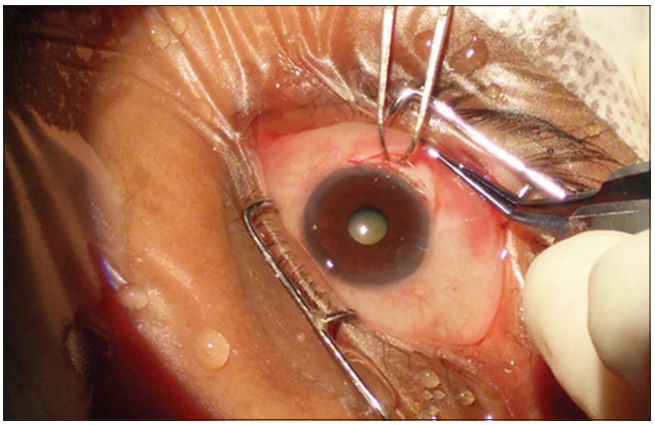

Figure 2: Preparation of conjunctival flap and wet-field cautery

were used when signs of early inflammation appeared and shallow A/C or hypotony was present.

Follow-up was done postoperatively 1 day, 1 week, 6 weeks, 12 weeks, and 6 months afterward, and best-corrected visual acuity (BCVA), IOP, postoperative use of IOP-lowering medication, and proportion of cases with postoperative complications (hyphema, inflammatory reaction, and so on) were recorded and compared in the above two groups.

Results

Surgical success was defined in terms of IOP measurement according to the following criteria:

1. Complete success – final IOP <14 mmHg without medication
2. Qualified success – final IOP <14 mmHg with medication
3. Failure – IOP >14 mmHg with medications.

Outcome analysis

BCVA, IOP, and postoperative use of antiglaucoma medication of both the groups were assessed in mean ± standard deviation (SD).

Postoperative complications of both the groups were expressed in percentage and proportions. Significance of difference in means was inferred by unpaired *t*-test. Significance of difference in proportions was inferred by Chi-square test.

For significance, $P \leq 0.05$ was considered statistically significant.

The mean age of patients in Group T was 56.72 ± 12.378 years and in Group V was 53.15 ± 10.708 years ($P = 0.08$ NS).

The preoperative mean BCVA (in log mar) in Group T and Group V was found to be 0.771 ± 5367 and 0.703 ± 5673, respectively. The postoperative mean BCVA (in log mar) in Group T was 0.646 ± 3340 and 0.555 ± 3619 in Group V.

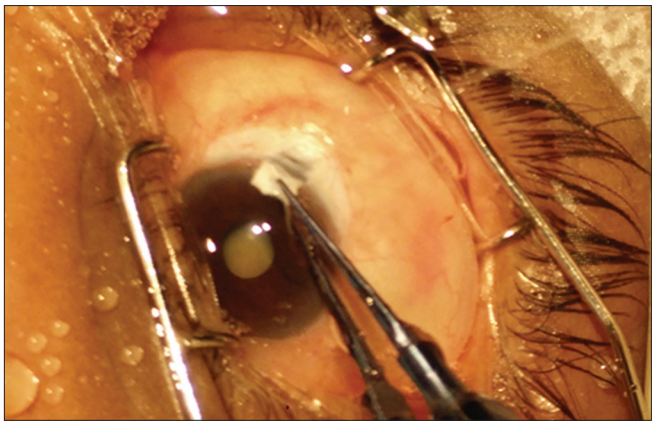

Figure 3: Dissection of superficial rectangular scleral flap

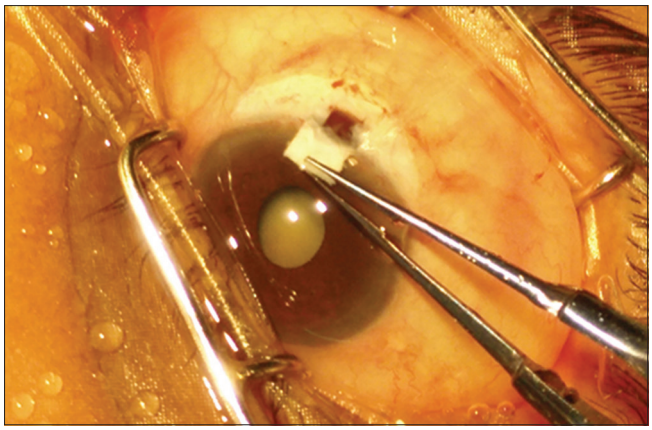

Figure 4: Dissected deep flap

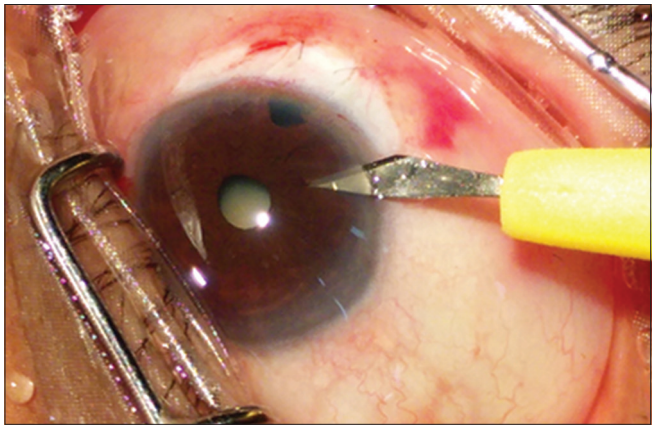

Figure 5: Paracentesis opening created

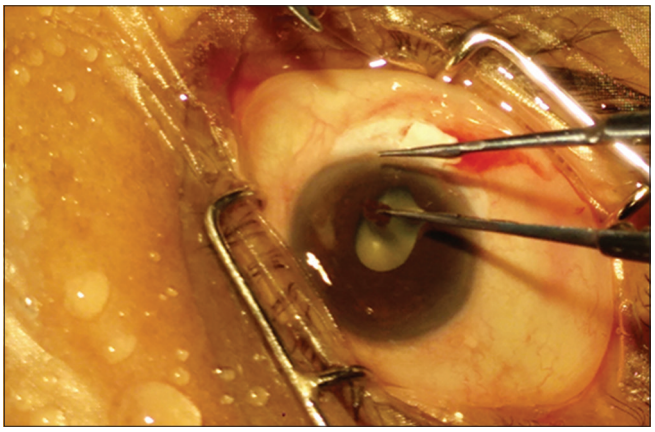

Figure 6: Superior peripheral iridectomy

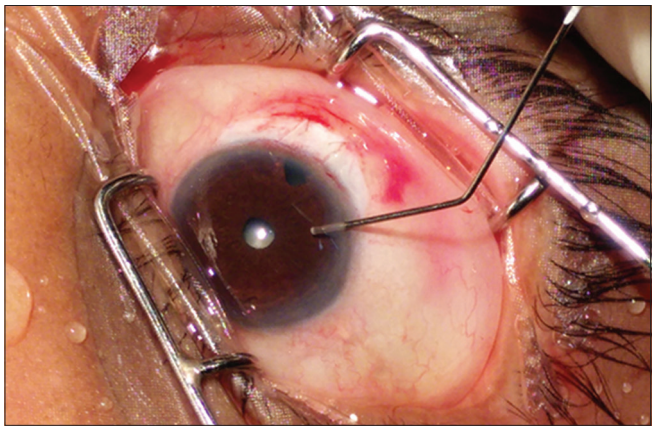

Figure 7: Injection of viscoelastic into anterior chamber

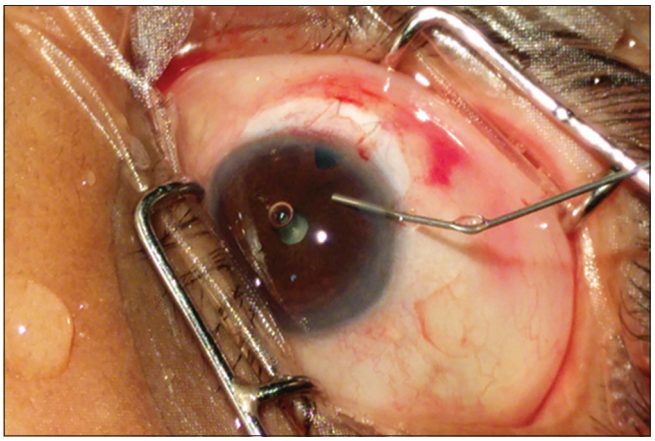

Figure 8: Balanced salt solution injected in the anterior chamber. Movement of visco elastic in bleb space and subsequent elevation of bleb noted

The preoperative number of antiglaucoma medications was similar in both the groups: 2.42 ± 527 in Group T and 2.42 ± 497 in Group V. The mean number of postoperative antiglaucoma drugs used was 0.35 ± 0.623 (0.00) SD and 0.17 ± 0.517 (0.00) in Group T and V, respectively [Fig. 10].

In the present study, mean preoperative IOP was 26.14 ± 2.822 (26.00) (22–38) mmHg in Group T and 25.23 ± 3.181 (25.00) (21–36) mmHg in Group V (P = 0.08NS) according to Table 1 and Fig.11. Table 2 and Fig. 12 show mean postoperative IOP in Group T (trabeculectomy with MMC) was 18.52 ± 4.493 mmHg and in Group V (VAT), it was 16.71 ± 4.775 mmHg at the 6-month follow-up.

In Group T (trabeculectomy with MMC), 28 patients (40%) had complications during 1 week of postoperative follow-up. Six patients had shallow AC with hypotony, conjunctival hyperemia, hyphema, and subconjunctival hemorrhage each, and four patients had shallow AC with hyphema.

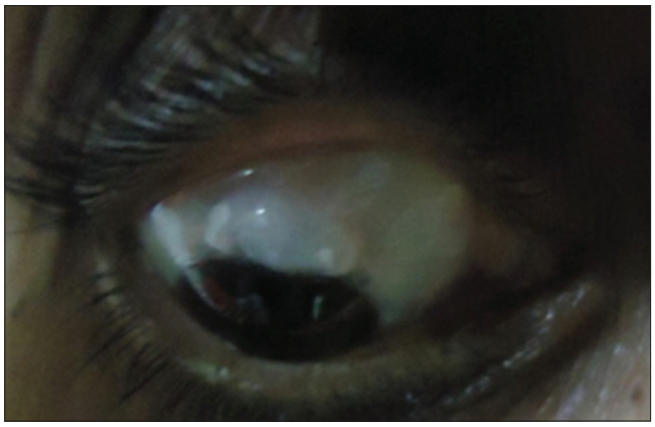

Figure 9: Bleb photograph of viscoelastic-augmented trabeculectomy

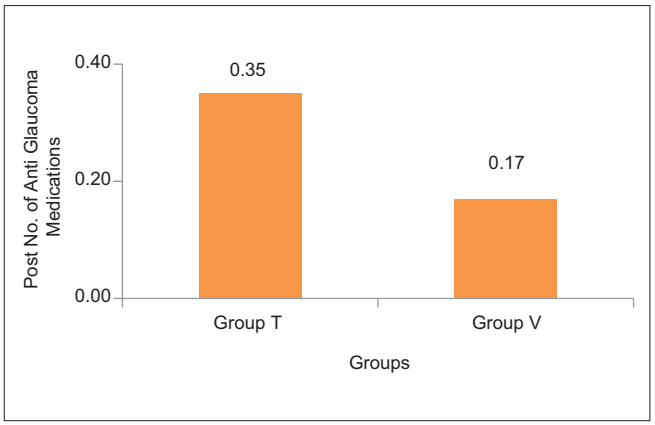

Figure 10: Postoperative number of antiglaucoma medication

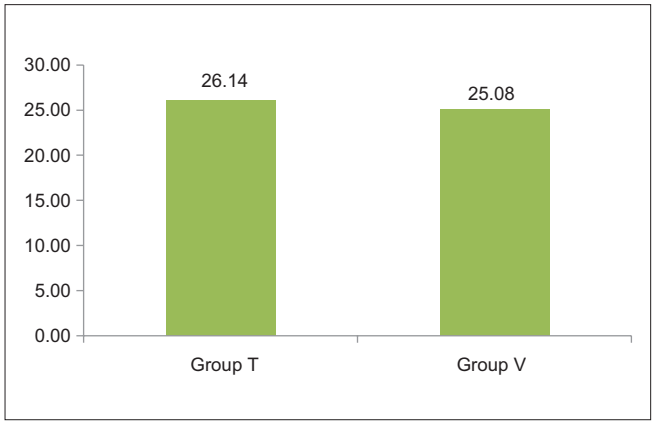

Figure 11: Preoperative intraocular pressure

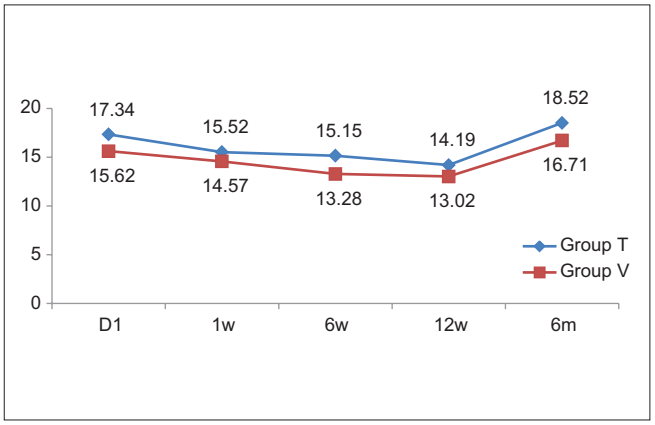

Figure 12: Postoperative intraocular pressure among groups at different time intervals

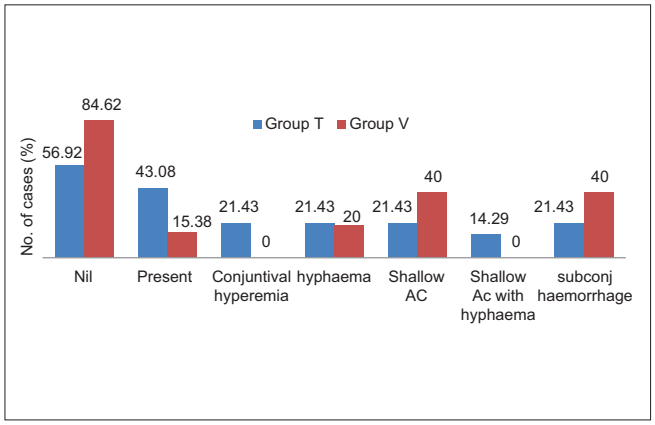

Figure 13: Distribution of the cases according to postoperative complications

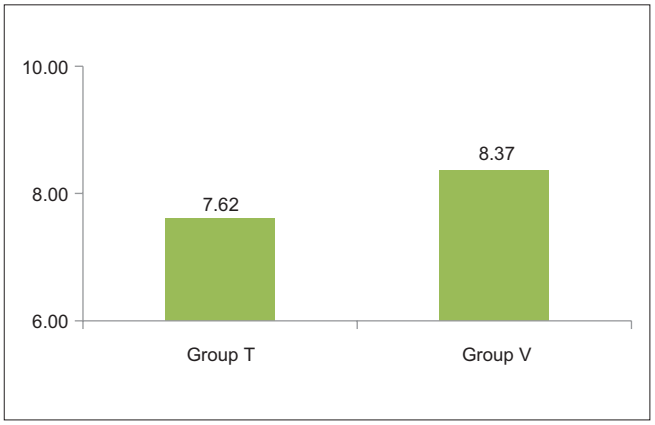

Figure 14: Difference between mean intraocular pressure at baseline and postoperative intraocular pressure (6 m)

In Group V (VAT) of ten patients (21.54%) who had complications, shallow AC with hypotony and subconjunctival hemorrhage was seen in four. Two patients had hyphema in the 1st week of postoperative follow-up as shown in Fig. 13.

Discussion

Reducing IOP in a glaucoma patient limits disease progression and slows visual field loss. Therefore, the primary goal in the management of glaucoma is to lower the IOP to a predetermined level (target IOP) which is based on the patient's baseline IOP level, at which further glaucomatous nerve damage is minimal.

Viscoelastic within a bleb might function as a valve that can prevent overfiltration because it would be absorbed more slowly than aqueous humor. VAT is based on the speculation that an ongoing presence of viscoelastic within the bleb

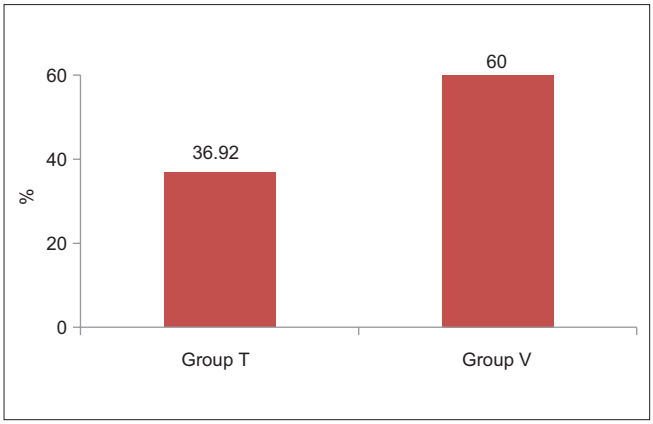

Figure 15: Success rate

may prevent AC collapse caused by overfiltration, which causes corneal endothelial decompensation or permanent peripheral anterior synechiae formation with subsequent IOP elevation. It also prevents adhesion of the subconjunctival since viscoelastics act as an antifibrotic agent, thus preventing subconjunctival fibrosis and allowing for better control of IOP.

This barrier is reabsorbed from the site of application within 7 days and therefore does not require a second operation for removal.

In the present study, 130 patients of primary open-angle glaucoma were included. They were divided into two groups.
- Group T: 65 patients underwent trabeculectomy with MMC
- Group V: 65 patients underwent VAT.

All the surgeries were performed by single surgeon to minimize the variability in the results. Postoperative follow-up in both groups was done at 6 months.

No significant statistical difference was observed among the groups according to sex. The males were 58.46% in Group T as compared to 50.77% in Group V and females were slightly less in Group T (41.54%) and as opposed to Group V (49.23%).

The change in the mean BCVA in both groups postoperatively was found to be −0.125 and −0.148 in Group T and Group V, respectively, which was not significant.

In both groups, there was significant reduction in the mean number of drugs required to control IOP postoperatively [Table 6]. In both groups, the difference was significant ($P = 0.75$ NS).

Similar outcomes were seen in a study done by Jeong and Sung[4] in which postoperative reuse of IOP-lowering medications at 1 year (%) was 70.2 ± 4.6 in CT group and 42.4 ± 4.9 in VAT group. Number of medications at 1 year (n) was 1.30 ± 1.08 in CT group and 0.73 ± 0.98 in VAT group.

The mean postoperative IOP in Group T (trabeculectomy with MMC) was 18.52 ± 4.493 mmHg, and in Group V (VAT), it was 16.71 ± 4.775 mmHg at 6-month follow-up.

Jeong and Sung[4] conducted a study in which the mean postoperative IOP was significantly lower in the VAT group than in the CT group at 1 day, 1 week, and 1 month postoperation. At 3 months, 6 months, and 1 year, the mean IOP was not significantly different between the two groups. The mean postoperative IOP at 3 months and 6 months was 13.1 ± 3.9 and 13.9 ± 4.3 in CT group and 11.9 ± 4.1 and 13.4 ± 5.4 in VAT group, respectively.

The comparison of mean changes in the baseline IOP and postoperative IOP at 6 months in Group T (7.62 ± 4.765 mmHg) and Group V (8.37 ± 5.234 mmHg) was not significant statistically ($P = 0.39$) as shown in Table 3 and Fig. 14, which was comparable to a study done by Jeong and Sung who found that mean postoperative IOP for both groups was significantly lower than preoperative levels ($P < 0.05$).

Lopes *et al*.[5] studied 28 eyes in which subconjunctival 2.3% sodium hyaluronate was injected in trabeculectomy versus 27 eyes in control group in which BSS was injected. Mean IOP decreased from 26.0 ± 10.0 mmHg to 11.6 ± 4.1 mmHg in the study eyes ($P < 0.001$) and from 24.9 ± 9.7 mmHg to 13.0 ± 4.1 mmHg in the control eyes ($P < 0.001$).

In our study, overall success rate (complete success and qualified success) at 6 months was 36.92% in Group T and 60% in Group V. (Table 4 and Fig. 15) The difference between the two groups in success rate was significant statistically ($P = 0.014$S).

Jeong and Sung[4] in their study found the probability of success using Kaplan–Meier graphs and concluded that the complete success rate was significantly higher in the VAT group ($P = 0.042$).

Lopes *et al*.[5] studied 28 eyes in which subconjunctival 2.3% sodium hyaluronate was injected in trabeculectomy versus 27 eyes in control group in which BSS was injected. Complete success rates were 77.8% for the study group and 84.0% for the control group, 12 months after surgery ($P > 0.5$).

According to Table 5, the comparison of postoperative complications in both the groups was found to be significant statistically (P = 0.037 S), which was comparable to a study done by Hoffman *et al*.[6] who studied injection of 2.3% sodium hyaluronate in a patient of flat AC after trabeculectomy. Sodium hyaluronate restabilized the AC, facilitated filtration, and prevented complications from hypotony.

Limitations

1. Small population size: The study would have been more informative if the sample size was larger
2. Smaller follow-up duration: If a longer follow-up duration was given, the results could have been more informative, especially with regard to the late bleb complications associated with MMC
3. This study had undertaken patients with primary open-angle glaucoma alone. Further research on other types of glaucoma such as angle closure glaucoma, secondary glaucomas, juvenile glaucoma is required.

Conclusion

We found that although both CT and VAT surgeries significantly lower IOP in primary open-angle glaucoma patients, VAT provided comparable IOP reduction with fewer complications.

Although the results of this study have been encouraging, we believe a longer duration of follow-up will be more

informative in deciding whether VAT is superior to CT for the long-term management of glaucoma.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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