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Original research article

A long-term control of intraocular pressure in patients after trabeculectomy: An investigation

[1]Dr. Challagundla Amani, [2]Dr. D Uday Kumar, [3]Dr. Sadik Shaik

[1,3]Post Graduate 3rd Year, Department of Ophthalmology, Narayana Medical College and Hospital, Nellore, Andhra Pradesh, India

[2]Professor & HOD, Department of Ophthalmology, Narayana Medical College and Hospital, Nellore, Andhra Pradesh, India

Corresponding Author:
Dr. Challagundla Amani

Abstract

Background and objectives: To examine how patients receiving trabeculectomy manage their IOP over the long term. To investigate how individuals undergoing trabeculectomy regulate their IOP. To research bleb morphology in trabeculectomy patients.

Methods: A prospective observational cohort study was conducted between December 2021 and November 2022 on 52 patients with moderate to severe glaucomatous damage who presented to the Department of ophthalmology at Narayana Medical College & Hospital.

Result: 19 eyes of two under-50 patients exhibited poor post-op IOP control. 31 eyes of three under-50 patients exhibited good post-op IOP control. Nonsignificant (P > 0.05). Beta blockers were utilised in 6 of 21 post-op IOP-uncontrolled eyes. Beta blockers controlled post-op IOP in 11 of 29 eyes. Nonsignificant (p> 0.05). 8 of 9 poor 1-year post-op IOP control eyes had POD IOP >13mmHg. 10. 12 of 41 eyes with good 1-year post-op IOP management had POD 10 IOP >13mmHg. Significant at <0.05.

Conclusion: Trabeculectomy showed 59.2% complete success and 92.2% qualified success in this prospective, observational study. In POAG, 51% and 96% passed. PACG's qualifying success rate is 98% and overall success is 69%. Post-operative IOP above 10mmHg on day 5 or 13mmHg on day 10 increased the risk of poor IOP control at one year. Vascularization at six and one year was associated with flat bleb after three months of steroid discontinuation. Bleb morphology does not alter long-term IOP control after one year.

Keywords: Intraocular pressure, trabeculectomy, Glaucoma, POAG, PACG, vascularization

Introduction

Glaucoma is the second leading cause of blindness, behind cataracts. According to the World Health Organization, glaucoma is responsible for the blindness of 4.5 million individuals. It is responsible for the highest number of instances of blindness that cannot be reversed in India. Glaucoma refers to a wide range of eye conditions that all share progressive optic neuropathy [1-4]. It brings about the typical morphological changes in the optic disc that lead to a particular pattern of permanent vision field abnormalities, and this may happen with or without an increase in intraocular pressure (IOP). At this time, the only treatment available for glaucoma is a reduction in intraocular pressure (IOP). Due to the fact that the illness does not initially manifest any symptoms, the management of it involves education, screening, prompt diagnosis, and appropriate therapy [5, 6]. The capacity to distinguish early clinical signs of the many types of glaucomas is essential to the detection process. In order to provide appropriate therapy, it is necessary to have an awareness of the pathogenic processes involved, in addition to having an appropriate knowledge of the medications and surgical procedures that are used to manage IOP [7-9]. Therefore, the goal of this research is to investigate the long-term regulation of intraocular pressure in patients who had trabeculectomy and were brought to the ophthalmology department at Hospital.

Material and Methods

Fifty-two patients with moderate or severe glaucomatous damage who reported to the Department of ophthalmology at Narayana Medical College & Hospital between December 2021 and November 2022 were the subjects of a prospective observational cohort research.

Methodology

The participants gave their informed permission. The patient's age, the presence or absence of any systemic illnesses (such as diabetes mellitus, hypertension, COPD, heart disorders, and glaucoma), and the length of time the condition has persisted were also elicited. There was permission from an ethics

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committee. Each and every sample was taken, and its values were recorded. Anti-glaucoma drug usage, medication compliance, history of ocular laser operations, and cataract surgery were all queried. A glaucoma family history was gathered. First, the patient's distance vision was tested on a Snellen chart to rule out glaucoma. Goldmann applanation tonometer evaluation of intraocular pressure [10].
The following were evaluated at each follow-up appointment: Sharp eyesight, IOP, The structure of a bleb, To have a successful peripheral iridectomy, The size of the anterior chamber, Cup to disc proportion, If there are any issues after surgery, 6M and 1Y Humphreys perimeters on the VFT. Primary open-angle glaucoma is a required inclusion criterion, The second kind of glaucoma is primary angle closure glaucoma. Any and all third-party glaucomas. A Statistical analysis was done using the following Microsoft Excel file, IBM SPSS version.

Inclusion criteria
1. Primary open angle glaucoma.
2. Glaucoma with primary angle closure.
3. All secondary glaucoma cases.

Exclusion criteria
1. Patients with neovascular glaucoma.
2. Patients with modest glaucomatous alterations that may be controlled medically.
3. Previous cataract surgery history.
4. Patients with badly damaged conjunctiva (for example, from chemical burns or Steven Johnson syndrome).
5. Patients who have had a prior trabeculectomy.
6. Glaucoma that is present before birth.
7. Glaucoma of juvenile onset.

Result
In this present study, there were a total of 52 eyes of 52 patients with moderate or severe glaucomatous damage were consider into study. 2 cases were lost to follow- up.

Table 1: Gender distribution of cases

Males	Females
29	23
59.38%	40.63%

Table 2: Group wise age distribution of cases

Age Groups	Number of cases
41-50 Years	5
51-60 Years	24
61-70 Years	17
71-80 Years	6
Total	52

Table 3: Classification of age and sex distribution in the present study

Age Groups	Sex	
	Male	Female
41-50 Years	3	2
51-60 Years	11	13
61-70 Years	9	8
71-80 Years	6	0
Total	29	23
Total (%)	59.38%	40.63%

P-value= 0.121 (Not Sig)

Table 3 shows the classification of age and sex distribution. 29 (59.38%) patients were males, and 23 (40.63%) patients were females.
In the 51-60 years age group, a female predominance was seen with 11 males and 13 females. And a male predominance was seen in all other ages taken for the study. Males were more than female in the study being 59.38%. The relation between age and sex was analysed. It was not significant (P = 0.121).

Table 4: Laterality of operated eye in the present study

Laterality of operated eye	Number	Percentage (%)
Right Eye	22	42.31%
Left Eye	25	48.08%

ISSN:0975 -3583,0976-2833 VOL14, ISSUE 03, 2023

Both	5	9.62%
Total	52	100.00%

Table 4 shows the Types of glaucoma and their number in the present study Out of 52 eyes of 52 patients, 33 (42.31%) eyes had POAG, 13 (33.33%) eyes had PACG, 5 (19.23%) eyes had SOAG, and 1 (5.13%) eye had SACG respectively.

Table 5: Types of glaucoma and their number in the present study

Distribution of types of glaucoma	Number	Percentage (%)
POAG	33	42.31%
PACG	13	33.33%
SOAG	5	19.23%
SACG	1	5.13
Total	52	100.00%

Table 6: Age group wise distribution of severity of glaucoma

Age Group	Moderate Damage	Severe Damage
41-50 Years	2	3
51-60 Years	5	19
61-70 Years	7	10
71-80 Years	1	5

Table 6 shows the Age group wise distribution of severity of glaucoma.
Out of 52 eyes of 52 patients, 37 eyes had severe glaucomatous damage and 15 eyes had moderate glaucomatous damage. In the 40 to 50 years age group (n=5), 3 eyes had severe glaucomatous damage & 2 had moderate damage. In the 51-60 years age group (n=24), 5 eyes had moderate glaucomatous damage & 19 eyes had severe damage. In the 61-70 years age group (n=17), 7 eyes had moderate glaucomatous damage, and 10 eyes had severe glaucomatous damage. In the 71-80 years age group (n=6), one eye had moderate glaucomatous damage, 5 had severe glaucomatous damage.

Table 7: Pre-operative treatment modalities in 52 eyes

Treatment Modalities	Number	Percentage (%)
Beta Blocker	19	36.54
Prostaglandin Analogue	9	17.31
Adrenergic Agonist	2	3.85
Carbonic Anhydrase Inhibitor	2	3.85
No Medication	30	57.69

Table 8: Duration of glaucoma and regularity of AGM

Duration of glaucoma	Regular Medication	Irregular Medication
< 1 Year	4	2
1 – 5 Years	1	4

Table 8 shows the duration of glaucoma and regularity of AGM. 6 patients with duration of glaucoma less than 1 year, 2 patients had irregular AGM. 4 patients had regular AGM. Among patients with duration of glaucoma 1-5 years, one patient had regular AGM, 4 patients had irregular AGM.

Table 9: Pre OP IOP in the study subjects

Pre op IOP	No. of Eyes
11-20 mmHg	24
21-30 mmHg	10
31-40 mmHg	9
41-50 mmHg	7
> 50 mmHg	2

Out of 52 eyes, 24 eyes had Intra Ocular Pressure in the range of 11-20 mmHg. 10 eyes had IOP in the range of 21-30 mmHg.9 eyes had IOP in the range of 31-40mmHg. 7 eyes had Intra Ocular Pressure in the range of 41-50 mmHg. 2 eyes had IOP more than 50 mmHg.

Table 10: Descriptive statistics at different time intervals of iop

	IOP_Day1	IOP_Day5	IOP_Day10	IOP_1M	IOP_3M	IOP_6M	IOP_1Y
Mean	10.40	13.15	13.31	14.35	14.52	15.02	15.66
Standard Deviation	5.23	4.24	4.15	4.20	4.04	5.14	4.28

ISSN:0975 -3583,0976-2833 VOL14, ISSUE 03, 2023

Table 10 showed that the descriptive statistics at different time intervals of IOP in this study. From IOP 3 months onwards, we lost 2 cases for follow-up.

Table 11: Visual field defects in pre op, post op and follow-up stages.

	Arcuate	Double Arcuate	Tubular vision	No view
Pre OP	14	23	6	9
6 Months	14	21	6	9
1 Year	13	21	7	9

Table 11 shows the visual field defects in pre op, post op and follow-up stages.
Out of 52 eyes 14 eyes had arcuate field defect, 23 had double arcuate defect, 6 had tubular vision. In 9 eyes the field could not be assessed because of poor visual acuity due to significant cataract or glaucomatous damage. Two were lost in follow up. Eyes. No field progression was noted in 6 months in any eyes. At 1 year of follow up, one eye progressed from double arcuate to tubular vision, 1 eye progressed from arcuate to double arcuate scotoma.

Table 12: Bleb morphology over a 1-year period of follow up

Morphology of bleb	Day-1	Day-5	Day-10	1 Month	3 Months	6 Months	1 Year
Type-1	0	0	0	0	0	0	0
Type-2	39	39	39	44	42	34	33
Type-3	13	13	13	8	8	16	17
Type-4	0	0	0	0	0	0	0
Total	52	52	52	52	50	50	50

Table 12 shows that the bleb morphology over a 1-year period of follow up.
Out of 50 eyes 39 eyes had type-2 diffuse bleb, 13 eyes had type-3 flat bleb at 1 month of follow up. At 3 M follow up bleb morphology was same. At 1 month of follow up 5 eyes had flat type-3 bleb was same up to 3 months. At 6 months of follow up 8 eyes had diffused type-2 bleb. At 1 year of follow up 33 eyes had type-2 bleb, and 17 eyes had type-3 flat bleb.

Table 13: List of postoperative complications

Complications	Number	Percentage (%)
Corneal edema	6	11.54
Hypotony	5	9.62
Increased IOP	5	9.62
Striate Keratopathy	5	9.62
Iritis	4	7.69
Shallow AC	4	7.69
Hyphaema	4	7.69
Field Progression	2	3.85
Closed PI	1	1.92
PAS	1	1.92

Table 13 shows that the list of postoperative complications. From this, it was observed that out of 50 eyes, 6 eyes had corneal edema, for each 5 eyes had cases had hypotony, increased IOP, Striate Keratopathy, and for each 4 eyes had iritis, shallow AC, hyphaema, 2 had field progression, for each one eye had closed PI and PAS respectively.

Assessment of risk factors for flat bleb

Table 14: POAG and PACG as a risk factor for flat bleb

	Flat bleb	Diffuse bleb
POAG	5	28
PACG	2	11

As per Table 14. We have found that 5 cases of 33 had a flat bleb in the group with POAG and 2 cases out of 13 had flat bleb in the group with PACG.(P value is 0.7 which is greater than 0.05 hence it is not significant.

Table 15: Age <50 as a risk factor for flat bleb

	Flat bleb	Diffuse bleb
<50 years	2	3
>50 years	6	41

ISSN:0975 -3583,0976-2833 VOL14, ISSUE 03, 2023

Following Table 15. Two of the eight patients with flat bleb and three of the 44 patients with diffuse bleb were both under the age of 50. (P value is 0.5, more than 0.05, making it non-significant.)

Table 16: Regularity of anti-glaucoma medicatoins as a risk factor for flat bleb

	Flat bleb	Diffuse bleb
Regular AGM	3	7
Irregular AGM USE or not on AGM	1	14

Following Table 16. Seven of the 21 patients with diffuse bleb and three of the four individuals with flat bleb were each receiving regular AGM. (P value is more than 0.05 and is thus greater than 0.1, making it insignificant.)

Table 17: Severe glaucomatous damage as a risk factor for flat bleb

	Flat bleb	Diffuse bleb
Severe damage	5	32
Moderate damage	2	8

The following Table 17. In 40 patients with diffuse bleb, 32 individuals had significant glaucomatous damage, compared to 5 patients out of 7 with flat bleb. It is not significant since the P value is bigger than 0.05 (0.2).

Table 18: Vascularisation at 6m follow up as a risk factor of flat bleb

	Flat bleb	Diffuse bleb	Loss to follow up
Vascularisation present	8	2	0
Vascularisation absent	8	32	2

The following table 18. At the six-month checkup, 2 of the 34 patients with diffuse bleb and 8 of the 16 patients with flat bleb had vascularization. (P value 0.05, indicating that it is significant.)

Assessment of risk factors for poor control of post-operative intra ocular pressure

Table 19: POAG and PACG as a risk factor for poor control of post-operative intra ocular pressure

	Poor control	Good control	Loss to follow up
POAG	12	20	1
PACG	5	7	1

The following table 19. Out of 33 patients with POAG, 12 had poor post-operative IOP control at the 1-year checkup, and 1 patient was lost to follow-up. Out of 13 patients with PACG, 5 had subpar post-operative IOP control, and 1 patient was lost to follow-up. As a result, it is not significant (P value > 0.05).

Table 20: Young age as a risk factor for poor control of post-operative intra ocular pressure

	Poor control	Good control
<50 years	2	3
>50 years	17	28

As per table 20. Out of 19 eyes with poor post- op IOP control 2 patients were below 50 years Out of 31 eyes with good post- op IOP control 3 patients were below 50 years. (P value is > 0.05 hence it is not significant.)

Table 21: Beta blocker use as a risk factor for poor control of post-operative intra ocular pressure

	Poor control	Good control
On Beta Blockers	6	11
Not on Beta Blockers	15	18

As seen in table 21, Six patients who had 21 eyes with poor post-operative IOP control were using beta blockers. 11 patients out of 29 eyes with satisfactory post-operative IOP control were using beta blockers. As a result, it is not significant (P value > 0.05).

Table 22: IOP >13 mmHg ON POD 10 as a risk factor for poor control of post-operative intra ocular pressure

ISSN:0975 -3583,0976-2833 VOL14, ISSUE 03, 2023

On day 10	Poor control	Good control
Post op IOP >13 mm of Hg	8	12
Post op IOP <13 mm of Hg	1	29

According to table 22, eight patients had IOP >13 mmHg on POD 10 in nine eyes with poor post-operative IOP management at one year. 12 eyes out of 41 with adequate post-operative IOP management at one year had IOP >13mmHg on POD 10. (P value 0.05, indicating that it is significant.)

Discussion

In the course of our research, there were 59.38% male patients and 40.62% female patients. This runs counter to the findings of the research by Khurana and colleagues. In his research, 57% of the participants were female while 43% were male. There was no discernible gender bias in terms of age that was found. Among the 52 patients who had surgery, 42.31% had surgery on their right eye, 48.08% had surgery on their left eye, and 9.62% had surgery on both eyes. This compares to the research conducted by David L *et al*., which found that 18% of patients received bilateral surgery [11, 12, 13]. According to the findings of this research, 42.31 percent of the population under investigation had POAG, 33.33 percent had PACG, 19.23 percent had SOAG, and 5.13 percent had SACG. This is comparable to a research that was conducted by David L. and colleagues, in which 56% of the population studied had POAG, 23% had PACG, and 7% had SOAG. Patients who had severe glaucomatous damage were shown to have a greater prevalence across all age groups when compared to those who had moderate glaucomatous damage.

71% of the 52 eyes examined showed serious damage from glaucoma. In this particular research, the percentage of eyes with significant glaucomatous damage was shown to be greater across the board (71%). Only two out of the total of fifty-two patients had a history of glaucoma in their families. In the patients who participated in our research, 17.31% of them had diabetes mellitus, 9.62% of them had systemic hypertension, 3.85% of them had bronchial asthma, 1.92% of them had coronary artery disease, and 13.46% of them had both diabetes and hypertension. 19 eyes received treatment with beta blockers, 9 eyes received treatment with prostaglandin analogues, 2 eyes received treatment with adrenergic agonists, and 2 eyes received treatment with carbonic anhydrase inhibitors. In the present investigation, 19.2% of patients were using more than one anti-glaucoma drug [14, 15, 16]. This consisted of 10 individuals. In contrast, a research conducted by Vinita R and her colleagues found that 94.6% of eyes were using more than one drug to treat glaucoma. The irregular anti-glaucoma therapy group always had a mean preoperative IOP that was higher than the regular medication group, and this was true regardless of how long the patient had been living with glaucoma.

Taking beta blockers was not associated with a higher risk of trabeculectomy failure in our study population. These results are consistent with those found by Johnson and coworkers. They found no statistically significant difference in the success of trabeculectomy between eyes that had previously taken beta blockers and eyes that had not used beta blockers. This was the final outcome they determined. Current study participants had an average IOP of 15 mm Hg after surgery, down from 28.1 mm Hg before it. Seventy-one percent of eyes exhibited severe glaucomatous damage, while another 29 percent of eyes had intermediate field abnormalities, according to this study. Comparable results were observed by Usha *et al*., who discovered that 29% of eyes had moderate field abnormalities [17, 18, 19].

Consistent with the experiment by Lochhead and coworkers, this study also demonstrated that IOP management before to surgery and in the immediate postoperative period was linearly related. Both before and after trabeculectomy and phacotrabectomies, they found a linear relationship between intraocular pressure and its severity (IOP). Contrary to what was discovered in the study by Usha *et al*., we found that 65.3% of eyes with diffuse bleb at 6 months also had a flat bleb. Researchers found that 63% of eyes had a diffuse bleb, 32% had a cystic bleb, and 5% had a flat bleb. IOP was not affected by the kind of bleb in this study, which was quite similar to one conducted by Usha *et al*. The present study found that a p value of less than 0.05 revealed a significant association between early intraocular pressure of more than 13mm Hg on POD 10 and poor management of intraocular pressure at the end of one year. This was true for both clinical subjects and control subjects [20, 21]. There is no significant difference between this research and the one by Rong SS *et al*. They determined a relative risk of failure of 4.2 if intraocular pressure was more than 10.5 mmHg on day 1 or greater than 13.5 mmHg on day 7 postoperatively. The results showed that people whose intraocular pressure was initially low after surgery fared better and that an increase in early intraocular pressure was predictive of a bigger final intraocular pressure.

Patients whose intraocular pressure (IOP) rose in the early postoperative period were more likely to have failure during the first six months following surgery, as shown by study done by Sandeep Mithal and colleagues. One research found that patients who had an IOP of 8 mmHg or lower two weeks after surgery were more likely to sustain an IOP of 11 mmHg or below for an extended period of time. our study found that an increase in pressure of more than 4 mmHg within one month after surgery is a risk factor for inadequate treatment of IOP following surgery at the end of one year. This finding is similar to that of a research by Hamed Esfandiari *et al*., who found that the rate of change in intraocular pressure (IOP) during the first month, rather than at each visit, was an excellent predictor of failure. Furthermore,

ISSN:0975 -3583,0976-2833 VOL14, ISSUE 03, 2023

an IOP rise of higher than 3 mmHg during the first 30 days was an excellent predictor of failure. We found that vasularization increased the likelihood of developing flat bleb and postoperative IOP mismanagement. A p-value of less than 0.05 indicates this to be true at both the 6-month and 12-month checkpoints. Connected to this is the work of Shibal Bhartiya and coworkers, who contended that failed blebs tend to be concave and vascular [21, 22, 23].

According to the findings of a research conducted by Sandra Furrer and colleagues, excessive vascularization revealed a reasonable correlation with increased intraocular pressure after surgery. In a same vein, Picht *et al.* came to the conclusion that early vascularization is a signal for a bad prognosis with greater IOP at 12 months after surgery, and they advocated the use of anti-VEGF drugs. A research conducted by Hamed Esfandiari and colleagues came to the conclusion that bleb morphological traits, with the exception of bleb vascularity, did not indicate failure [24, 25]. The present research found that TRAB had a qualifying success rate of 92%, while the full success rate was 59.2%. The overall pass percentage for the POAG was 51%, while the success rate for qualifying was 96%. The overall success rate in the PACG was 69%, while the percentage of candidates that qualified was 98%. This resembles a research that was conducted by Harsha *et al*., in which PACG demonstrated superior postoperative IOP management vs POAG.

Conclusion

We drew the following conclusion from our prospective and observational study: In our research, the full success rate associated with trabeculectomy was 59.2 percent, and the qualifying success rate was 92.2 percent. The percentage of people who completed POAG and the percentage of those who qualified for it were respectively 51% and 96%. The Pass Accreditation and Certification Group (PACG) has a full success rate of 69 percent and a qualifying success rate of 98 percent. It was discovered that an intraocular pressure (IOP) of more over 10 mmHg on day 5 post-operative day or more than 13 mmHg IOP on day 10 post-operative day is a risk factor for poor IOP management after one year. Vascularization of the bleb at six months and one year was found as a risk factor for flat bleb. This risk factor for flat bleb might be associated to the withdrawal of steroids after three months. There is no correlation between the shape of the bleb and the long-term management of IOP at one year.

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Conflict of interest

Nil

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