Original Article

Outcomes of ab-interno irrigating goniectomy with trabectome in primary and secondary glaucoma from a single center in India

Suneeta Dubey, Tanima Bansal[#], Prerna Garg[#], Aparna Hegde[1#], Ranajit Das[1#], Rekha PD[1]

Purpose: This study was done to report intermediate-term outcomes of irrigating goniectomy with trabectome (trabectome) surgery among different types of glaucoma eyes from a single center in India using a cross-sectional, longitudinal, observational study design. **Methods:** Fifty-three patients (58 eyes) with glaucoma who underwent irrigating goniectomy with trabectome between January 2019 and February 2020 were included. Pre-operative data included age, gender, eye laterality, specific diagnosis, number of anti-glaucoma medications (AGMs), prior glaucoma surgeries, visual acuity, and intraocular pressure (IOP) on medical treatment. Post-operative data included IOP changes during the follow-up till 1-year, number of AGMs, any complications, or additional surgical intervention required. Success was defined as IOP ≤ 21 mmHg and ≥ 20% reduction of IOP from pre-operative IOP with no additional glaucoma surgery. **Results:** The cohort included 58 eyes (male 53.4% and female 46.6%) ranging from 0.6 to 81 years of age. The average baseline IOP was 23.4 ± 10.2 mmHg and reduced significantly with surgery to 14.1 ± 5.3 mmHg at 1-year follow-up. The AGMs reduced from 2.4 ± 1.4 pre-surgery to 1.6 ± 1.4 at 1-year follow-up. Four eyes required additional glaucoma surgeries for IOP control. The success rate of trabectome with phacoemulsification (88%) was discernibly higher than with trabectome alone (67%). Intra-operatively, significant blood reflux was noticed in 27 eyes, of which only one required tamponading with a viscoelastic agent. **Conclusion:** This study concludes that irrigating goniectomy with trabectome has good efficacy and safety in both pediatric and adult cases of glaucoma in terms of IOP control, reduction in AGMs, and low incidence of complications in the Indian population.

Key words: Combined surgery, glaucoma, IOP, irrigating goniectomy with trabectome, minimally invasive glaucoma surgery, trabectome

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Glaucoma is a chronic optic neuropathy characterized by progressive degeneration of retinal ganglion cells, most commonly associated with elevated intraocular pressure (IOP). It is the leading cause of irreversible blindness (10%). More than 70 million are affected by glaucoma worldwide and it is projected to affect 111.8 million in 2040.[1-3] Though it is not possible to reverse the neuronal damage that takes place in glaucoma, reducing the IOP can control or retard the progression of the disease. IOP can be reduced with medications, laser therapy, or surgery. Conventional surgeries like trabeculectomy have been successfully employed for several decades; however, they may be associated with sight-threatening complications. Another surgery frequently performed is tube implant surgery, more so in secondary and refractory glaucoma. Minimally invasive glaucoma surgery (MIGS) is slowly gaining popularity due to its better safety profile. Recent studies have suggested IOP elevation observed in primary open-angle glaucoma (POAG) is caused by a combination of three factors: loss of permeability of trabecular meshwork, the collapse of Schlemm canal, and closing of collector channel entrances.[4-6] MIGS procedures like iStent, trabectome, and Kahook dual blade target this area of outflow resistance.

Trabectome (Neomedix Corporation, Tustin, CA) is a handheld device approved by the Food and Drug Administration (FDA) in 2004 for clinical use.[7] It works by ablating the trabecular meshwork with a bipolar 550 kHz electrode and thus helps to restore the original aqueous outflow pathway. It can be used in patients with open-angle glaucoma, either primary or secondary, and can be combined with cataract surgery.[8-13]

Though India is one of the major hubs for glaucoma in the world,[13] only one recently published study reported the 6-month outcomes of Kahook dual blade.[14] To our knowledge, no study on irrigating goniectomy with trabectome (trabectome) has been published from India to date.

Department of Glaucoma, Dr. Shroff's Charity Eye Hospital, New Delhi, [1]Yenepoya Research Centre, Yenepoya (Deemed to be University), Derlakatte, Mangalore, Karnataka, India
# Equally contributed

Correspondence to: Dr. Suneeta Dubey, Department of Glaucoma, Dr. Shroff's Charity Eye Hospital, New Delhi, India. E-mail: dubeysuneeta@hotmail.com; Dr. Rekha PD, Yenepoya Research Centre, Yenepoya (Deemed to be University), Deralakatte, Mangalore, Karnataka, India. E-mail: rekhapd@yenepoya.edu.in

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Hence, in this pilot study, we describe the efficacy and safety of trabectome surgery over a one-year period in Indian patients presenting with different types of open-angle glaucoma to a single tertiary care center.

Methods

This was a single-center, non-randomized, cross-sectional, longitudinal, retrospective study. The study included patients with open-angle glaucoma who underwent ab interno goniectomy with trabectome between the period January 2019 and February 2020. Ethical approval following the tenets of the Declaration of Helsinki was taken before the collection of data.

The inclusion criterion was patients of all ages presenting with all types of glaucoma, and ocular hypertension requiring surgery. Ocular hypertension was diagnosed as IOP >21 mmHg on three consecutive visits with normal retinal nerve fiber layer thickness on spectral domain optical coherence tomography (OCT) and normal visual field. Those on >2 anti-glaucoma medications (AGMs) were included in the study. Congenital glaucoma was diagnosed by the presence of ≥2 of the following: (a) IOP >21 mmHg, (b) Haab's striae or increased corneal diameter, (c) Optic nerve head cupping - Increased C:D ratio (CDR) or asymmetry ≥0.2 or focal thinning, (d) Myopic shift or increased axial length. Adult glaucoma was diagnosed based on IOP >21 mmHg on no AGM, or IOP <21 mmHg on >1 AGM or presence of CDR >0.6:1 or focal notching or CDR asymmetry of ≥0.2:1 with or without corresponding visual field defects on the Humphrey (Zeiss Humphery Field Analyzer) 24-2 Swedish Interactive Threshold Algorithm (SITA) standard program. Patients with significant cataracts were diagnosed based on clinical examination alone. Patients with prior history of glaucoma surgery, with angle closure glaucoma in whom posterior trabecular meshwork was visible post-Nd:YAG PI (peripheral iridectomy), and with secondary open-angle glaucoma were also included. Patients with primary or secondary angle closure in whom the angle structures were not visible were excluded. The IOP measured on the last visit before the trabectome surgery was taken as the baseline IOP.

The pre-surgery evaluation included type of glaucoma, details regarding prior eye surgery, best-corrected visual acuity (BCVA), IOP, corneal status, lens status, examination of the angle and grading by Shaffer classification using a four mirror gonioprism, and number of AGMs. Patients with significant cataracts underwent combined trabectome and phacoemulsification (phaco) surgery.

Intra-operative and post-operative details such as complications during or after surgery, changes in IOP, and changes in the number of AGMs were collected at follow-up of 1-day, 1-week, 1-month, 3-months, 6-months, and 1-year.

The outcome measures included a reduction in IOP, reduction in AGMs, success percentages, and intra- and post-operative complications. Based on other studies, the absolute success of the surgical technique was defined as a reduction of IOP by 20% or more from baseline and IOP ≤ 21 mmHg with no secondary surgery throughout the follow-up period.[10] Eyes requiring additional glaucoma surgery that developed phthisis or showed a loss of light perception were considered as failures.

Surgical technique

The surgery was performed by a single surgeon (SD) and the standard procedure was followed. A 1.7-mm near-limbal temporal corneal incision was made with a keratome. Under gonioscopic view, the trabectome handpiece was advanced nasally with irrigation on and inserted through the trabecular meshwork. Ablation was commenced at a power of 0.8 mW and approximately 120–140° of the trabecular meshwork and the inner wall of the Schlemm canal was removed. The ablated tissue was aspirated via the irrigation/aspiration lumen of the handpiece. Patients with cataracts underwent trabectome first and then phacoemulsification through the same port.

Post-operatively, a moxifloxacin 0.5% drop was given QID (4 times a day) for a week, along with prednisolone acetate 1% eight times per day in a weekly tapering dose.

Statistical analysis

Continuous data were expressed as mean and standard deviation, median, and/or percent. Paired t-test was used for within-group comparison at different time points; an independent t-test was used for between-group (trabectome with and without phaco) and one-way analysis of variance (ANOVA) followed by Tukey's multiple comparisons were performed for comparing between groups. The success of the procedure was analyzed using Kaplan–Meier analysis. Mantle–Cox test was performed for survival analysis. Tests for significance of difference were two-sided, and $P < 0.05$ was considered statistically significant unless specified. GraphPad Prism version 9 (GraphPad Software, California , USA) was used for these analyses.

Results

Demographics

The study cohort included 58 eyes of 53 patients out of which 24 (45.3%) were female and 29 (54.7%) male. The mean age of the cohort was 48.2 ± 24.3 years (Range: 0.6 to 81 years).

The demographic details, baseline mean IOP (without and with AGM), number of AGMs, diagnosis of the type of glaucoma, and history of prior glaucoma surgery have been described in Table 1. The cohort also included 17.2%[10] eyes of children <15 years (0.6–15) with the diagnosis of juvenile/congenital/secondary glaucoma. Among these, seven eyes had a gonioscopy Schaffer grading of III, two had grade II, and one had grade IV. Twenty-six eyes (44.8%) underwent combined surgery whereas the rest underwent trabectome surgery alone.

The pre-operative C:D ratio, gonioscopy grading, lens status, corneal status, and BCVA have been described in Supplementary Table 1.

Intra-operative findings

Intra-operatively, significant blood reflux was observed in 27 (46.5%) eyes. Out of these, only one eye required tamponade with a viscoelastic agent, remaining were managed by anterior chamber (AC) wash without any additional maneuvers.

Post-operative outcomes

The patients were followed up at 1-day, 1-week, 1-month, 3-month, 6-month, 1-year post-surgery.

Change in IOP

The change in IOP was measured and compared between follow-up time intervals. Pair-wise comparison between intervals showed significant decrease in IOP from the baseline (20.9 ± 9.1 mmHg) to 1-day post-surgery (11.4 ± 3.9 mmHg) ($p < 0.001$). However, there was a significant increase from 1-day to 1-week (15.3 ± 6.8 mmHg). Subsequently, the IOP reduced significantly to 13.3 ± 3.1 mmHg ($p < 0.0001$) at 3 months; and after 6 months, there was a slight but statistically not significant increase in IOP at 1-year follow-up (14.1 ± 5.3 mmHg). The changes in the IOP during the follow-up period are given in Fig. 1a and the percent reduction in the mean IOP levels is given in Fig. 1b-d.

At baseline, IOP ≥21 mmHg was reported in 32.8% (19) eyes and it reduced significantly to 1.7% (1) on the first post-operative day. At 1-week, eight patients (13.8%) showed IOP ≥21 mmHg; however, at the last follow-up, only three patients (5.2%) had higher IOP compared to their 6-months' IOP. Further, the IOP was compared between the groups with and without phacoemulsification and a detailed comparison of the data is given in Table 2. At all-time points, a lower IOP value was obtained in the phaco group, however, the percentage IOP reduction was significantly greater in the non-phaco group, owing to a higher baseline IOP reading in that group.

Reduction in AGM

The details of different medications and the distribution of patients with respect to the number of AGMs are given in Table 3. The percentage reduction in the number of AGMs over the follow-up visits is depicted in Fig. 2.

Compared to baseline (2.2 ± 1.4), the decline in AGM was highly significant ($p < 0.0001$) at 1-week, 1-month, and 3-months follow-up with respective mean AGMs of 0.5 ± 0.7, 1 ± 1.1, and 1.4 ± 1.2. However, there was a significant increase in the number of AGMs to 1.5 ± 1.3 ($p = 0.0008$) and 1.5 ± 1.4 ($p = 0.0005$) at 6-months and 1-year post-surgery, respectively.

Survival analysis and success rate

To evaluate the success rate between trabectome + phaco and trabectome alone groups, log-rank Mantle–Cox's method was used. The success rates in the combined surgery group were significantly higher ($p = 0.0004$) than in the trabectome-only group [Fig. 3]. Overall success rate was 76%. While patients undergoing combined surgery had 88% and patients undergoing only trabectome surgery had a 67% success rate.

Complications and failures

Four out of 58 eyes (6.8%) required additional glaucoma surgery and were considered as failures.

Among the pediatric eyes, one surgery was unsuccessful; this was a case of a 1.1-year-old with a pre-surgery IOP of 32 mmHg, presenting with congenital glaucoma. This patient required a trabeculectomy + trabeculotomy surgery within one month of the trabectome surgery. During the 6-month follow-up, it was observed that a 15-year-old male patient (juvenile open-angle glaucoma, JOAG) had pre-surgery IOP of 33 mmHg which was reduced to 24 mmHg with AGM and further to 17 mmHg with surgery (1 day), however, increased to 38 mmHg (1-week) requiring additional four AGMs. The reduction in the IOP was short-lived and showed an increase to 23 mmHg at 6-month and 27 mmHg at 1-year follow-up due to which an additional trabeculectomy surgery was conducted. In another case, a 60-year-old male (primary angle closure glaucoma, PACG), had to undergo an Ahmed glaucoma valve (AGV) implant as the trabectome surgery had failed due to raised IOP at 6 months. Post-6-month follow-up, another patient (63 years, male, POAG) required trabeculectomy surgery to reduce the IOP that was not manageable with additional AGMs. This patient presented with an IOP of 44 mmHg that was maintained at 12 mmHg post-surgery till one week, however, it increased to 21 mmHg at 1 month and 22 mmHg at 6 months with additional AGMs.

Table 1: Baseline demographic presentations of 53 patients who underwent irrigating goniectomy with trabectome with and without phaco (*n*=58 eyes)

Details	Without Phaco (*n*=32)	With Phaco (*n*=26)
Mean age (year)	35.2 (Range: 0.66-66)	64.1 (Range: 46-81)
Male eyes	19	12
Female eyes	13	14
Mean IOP (without AGM)	32.1±9.4 mmHg	23.7±8.2 mmHg
Mean IOP (with AGM)	24.4±9.9 mmHg	16.6±5.4 mmHg
No. of AGM	2.4±1.5	2.2±1.2
Types of glaucoma (% and *n*)		
Primary open-angle glaucoma	37.5% (12)	61.54% (16)
Juvenile open-angle glaucoma	25% (8)	-
Congenital glaucoma	18.8% (6)	-
Primary angle-closure glaucoma	-	23.1% (6)
Pigmentary	6.3% (2)	7.7% (2)
Pseudoexfoliation	-	3.9% (1)
Secondary glaucoma	6.3% (2)	-
Ocular hypertension	3.1% (1)	-
Uveitic glaucoma	-	3.9% (1)
Normal tension glaucoma	3.1% (1)	-
Prior Surgery (*n*=58 eyes)		
Trabeculectomy	10.3% (*n*=06)	
No surgery	89.7% (*n*=52)	

Table 2: Variation in IOP (mmHg) changes during the follow-up among patients with phaco and without phaco

	Combined surgery				*t*	*P*
	Without Phaco		With Phaco			
	Mean	SD	Mean	SD		
Baseline	24.4	10.0	16.6	5.4	3.6	0.001*
1-Day	11.1	3.8	11.7	4.1	0.5	0.623
1-Week	17.1	8.3	13.5	4.3	2.0	0.051#
1-Month	16.8	6.4	13.8	3.6	2.1	0.039*
3-Months	15.1	5.1	13.2	2.7	1.7	0.097
6-Months	13.9	3.8	12.5	1.9	1.7	0.103
1-Year	14.6	6.2	13.4	3.4	0.6	0.539

*Statistically significant, #Marginally significant

Table 3: Distribution of patients with respect to the number of AGM and IOP without AGM <21 and IOP without AGM ≥21 (Patients with AGM 0/1/2/3/≥4 and IOP >21 and IOP <21) during the follow-up intervals

Follow-up*	Patients with number of AGMs (%)									
	AGM=0		AGM=1		AGM=2		AGM=3		AGM ≥4	
	IOP ≥21	IOP <21	IOP ≥21	IOP <21	IOP ≥21	IOP <21	IOP >=21	IOP <21	IOP >=21	IOP <21
Baseline (*n*=58)	5.2	6.90	1.7	17.24	8.6	13.79	6.9	15.52	10.3	13.79
1-Day (*n*=52)	1.9	63.46	0.0	32.69	0.0	1.92	0.0	0.00	0.0	0.00
1-Week (*n*=53)	9.4	43.40	5.7	32.08	0.0	9.43	0.0	0.00	0.0	0.00
1-Month (*n*=54)	3.7	37.04	5.6	29.63	0.0	12.96	3.7	1.85	0.0	5.56
3-Months (*n*=56)	5.4	25.00	1.8	28.57	0.0	23.21	0.0	7.14	1.8	7.14
6-Months (*n*=48)	2.1	20.83	0.0	31.25	0.0	22.92	0.0	12.50	2.1	8.33
1-Year (*n*=25)	0.0	24.00	0.0	24.00	0.0	24.00	4.0	12.00	0.0	12.00

*Only individuals with both AGM and IOP data were included in this table

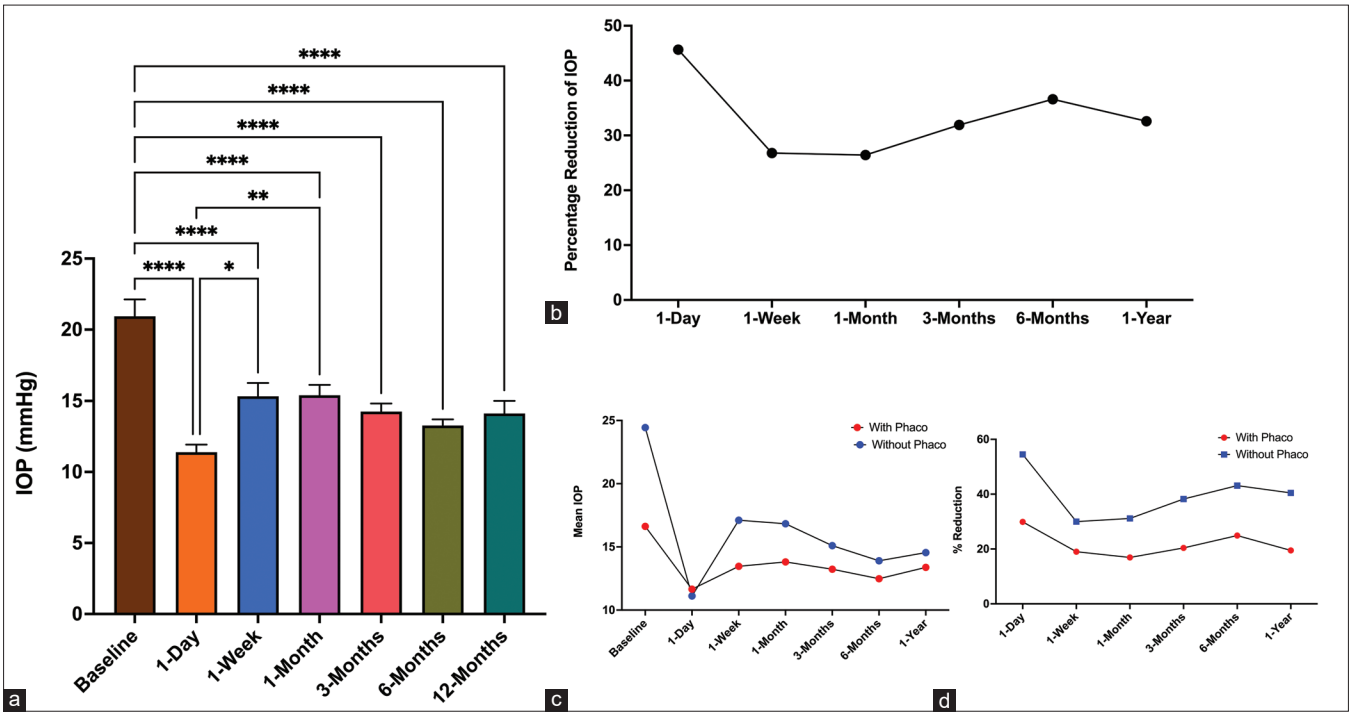

Figure 1: IOP changes from baseline post-surgery (a) Mean IOP values - IOP values for different time points were compared using one-way ANOVA, followed by Tukey's *post-hoc* multiple comparisons, implemented in GraphPad Prism v9. $P < 0.05$ was considered significant. (b) Percentage reduction in IOP, (c) Mean IOP changes with and without phacoemulsification, and (d) Percentage reduction in IOP with and without phacoemulsification. **** = $P < 0.0001$, *** = $P < 0.001$, **= $P < 0.01$, and *= $P < 0.05$

No eye developed phthisis bulbi or loss of perception of light.

Discussion

In this retrospective non-comparative study, we evaluated the outcomes of ab interno goniectomy with trabectome surgery over a one-year period in patients with different grades of glaucoma in both adult and pediatric age groups from a single center. The outcomes of the study hint at the effectiveness of the intervention in terms of reduction of IOP and AGM.

There are different types of glaucoma and the risk factors include a family history of the disease, black race, advanced age, use of systemic or topical corticosteroids, high IOP, decrease in corneal thickness and rigidity, diabetes, and a high degree of myopia and hyperopia.[3]

The study cohort included 10 eyes that belonged to those below 18 years of age (Range: 0.6–15 years) and the rest 48 eyes belonged to the 19–81 years age group. These patients also showed poor visual acuity and were mostly dependent on glaucoma medication. One of the major findings observed was a rapid drop in IOP with a subsequent slight increase and stabilizing at later months post-surgery. The baseline IOP with AGM was 20.9 ± 9.1 mmHg with a maximum reported IOP of 49 mmHg. The IOP reduction seen in our study is very similar to the reported outcomes post trabectome intervention.[8-10,12,13,15-17] At one year, the IOP had reduced significantly to 14.1 ± 5.3 mmHg which is similar to the results reported in the study by Ngai *et al.*,[18] in patients with steroid-induced glaucoma. Trabectome is also performed in patients with failed previous surgeries and in this cohort, six patients having failed outcomes from

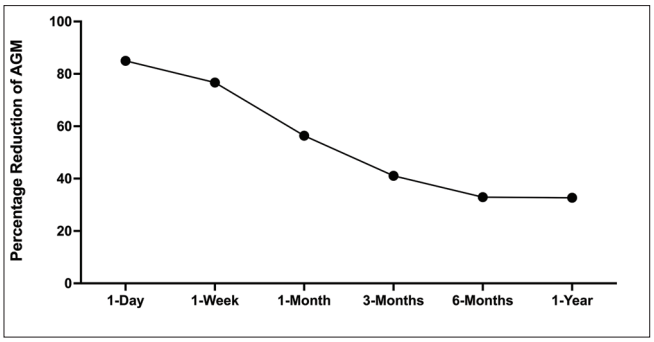

Figure 2: AGM changes from baseline during post-surgery follow-up. Percent reduction in AGM over time. Compared to baseline, there has been a highly significant decline in AGM at 1-week, 1-month, 3-month, 6-month, and 12-month follow-ups

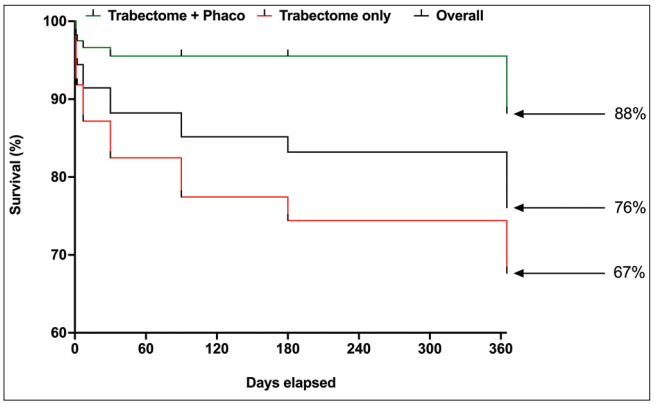

Figure 3: Kaplan–Meier plot for survival analysis showing survival against success rate in IOP. Log-rank Mantle–Cox's method implemented in GraphPad Prism v9 was used for survival analysis to evaluate the success rate. IOP <21 *vs* IOP ≥21 was used as the "survival" benchmark. This benchmark was used for comparing irrigating goniectomy with trabectome (trabectome) + phaco and irrigating goniectomy with trabectome-only groups. The overall success rate was 76%. While individuals undergoing combined surgery had an 88% success rate, individuals undergoing only trabectome surgery had a 67% success rate

the previous surgeries were successfully treated. Trabectome has also been reported to be better than other types of MIGSs in terms of reduction in IOP and other surgical outcomes.[19,20]

Other outcomes included a decrease in the number of medications. Initially, pre-operatively, 49 eyes were on AGM; however, by the last follow-up, only 25 eyes required continuation of AGM. Also, there was a significant reduction in the number of medications required. This is one of the important outcomes of the trabectome as patients during prolonged periods fail in drug compliance due to various reasons including socio-economic status, healthcare-seeking behavior, and high frequency of dose requirement.[15-17,19,21]

Trabectome is known for its ease of use and incorporation with phacoemulsification surgeries. In this cohort, we had surgeries that were trabectome alone and also with phacoemulsification. The reduction in the IOP of the patients who underwent the combined surgery was comparatively better than those who underwent trabectome alone. Though the overall success rate was 76%, patients undergoing trabectome alone had 67% success against 88% success in trabectome with phaco together. This could, however, be attributed to the lower baseline IOP in the combined surgery group. A study by Akil *et al*. analyzed the short-term clinical outcomes of the Ab interno technique in open-angle glaucoma among 49 patients.[22] Intra-subject, same surgeon comparison of two techniques with phacoemulsification also reported similar results.[20]

The advantage of MIGS is a lower risk of serious complications, which was also evident in this study. One major complication of hyphema was observed intra-operatively which was successfully managed with viscoelastic tamponade. Other complications like prolonged pain, cystoid macular edema, hypotony, choroidal effusions, choroidal hemorrhages, or infections were not reported in this study that are otherwise seen.[7,8,12] The advantage of Ab interno goniectomy with trabectome is that the trabecular meshwork is ablated and excised, while in goniotomy, the trabecular meshwork is only incised, hence there is a chance of scarring from the residual leaflets. Also, trabectome incorporates irrigation and aspiration which increases intra-operative visibility, maintains AC stability, and decreases blood reflux.

The use of irrigating goniectomy with trabectome is less practiced in pediatric cases and is recently gaining popularity. In our study, out of 10 eyes in the age group <18 years, only one required additional glaucoma surgery, while all others had a satisfactory outcome. Also, in the case of advanced glaucoma, where surgery is generally not preferred, we have performed irrigating goniectomy with trabectome with successful follow-up outcomes.

Trabectome has a wide application and can be performed in all cases of glaucoma in which the trabecular meshwork is visible, including pediatric glaucoma. Therefore, this would be an added advantage for a glaucoma specialist who deals with both adult and pediatric glaucoma. The estimated approximate cost of goniectomy with a trabectome probe is ₹60,000 and private insurance schemes cover the cost.

While this trabectome study is the first in India, globally several long-term follow-up studies have been conducted to establish its efficacy over the years.[23] This pilot study will be followed up with more patients on a long-term basis to establish the efficacy of this surgical procedure. More such long-term studies may be conducted to expand local evidence of trabectome in the Indian context.

Conclusion

From this study, we can conclude that irrigating goniectomy with trabectome, an Ab interno minimally invasive technique can be safely used in Indian eyes presenting with different types of glaucoma with good clinical outcomes in terms of reduced IOP and burden of AGMs. It can also be used safely and successfully in pediatric cases presenting with congenital and juvenile glaucoma.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Supplementary Table 1: Pre-operative status of cornea and visual acuity (*n*=58)

Details	Percentage (%) and Frequency (*n*)
C:D Ratio	
<0.7	19%(11)
0.7-0.8	44.8% (26)
>0.8	34.5% (20)
Gonioscopy Shaffer grading	
Grade II	6.9% (4)
Grade III	19% (11)
Grade IV	74.1% (43)
Lens status	
Phakic	94.8% (55)
Pseudophakic	5.17% (3)
Corneal Status	
Corneal edema	8.6% (*n*=5)
Habb's striae	3.5% (*n*=2)
Normal	87.9% (*n*=51)
Best Corrected Acuity	
6/6	24.1% (14)
6/9	13.8% (8)
6/12	6.9% (4)
6/18	22.4% (13)
6/24	5.2% (3)
6/36	1.7% (1)
2/60	3.5% (2)
1/60	1.7% (1)
6/60	3.5% (2)
HM+	3.5% (2)
Cannot be assessed	12.1% (7)
CF	1.7% (1)