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EVALUATION OF INTRAOCULAR PRESSURE OUTCOMES AND FAILURE RISK FACTORS IN THE COLLABORATIVE STUDY ON BLEB-RELATED INFECTION AND TREATMENT: A PROSPECTIVE STUDY.

[1]Marianus Deepak Lakra, [2]Sindhu Kumari, [3]Kuldeep Chaudhary, [3]Pinki Patel,*
[1]Associate Professor, Department of Ophthalmology, RIMS, Ranchi, Jharkhand, India.
[2]Senior Resident, Department of Ophthalmology, RIMS, Ranchi, Jharkhand, India.
[3]Junior Resident, Department of Ophthalmology, RIMS, Ranchi, Jharkhand, India.

ABSTRACT

Background

Trabeculectomy remains the primary surgical intervention for glaucoma management, enhanced by adjunctive therapies like mitomycin C, despite the associated risk of complications such as bleb-related infections. The current study utilizes the CBIITS dataset to assess the impact of trabeculectomy on IOP, evaluate the rate of surgical success, and identify factors influencing surgical outcomes and complications.

Methods

This prospective study included 30 patients undergoing filtering surgeries at Rajendra Institute of Medical Sciences (RIMS), Ranchi, with follow-up at six-month intervals over three years. Intraocular pressure (IOP) was measured preoperatively and postoperatively using Goldmann application tonometry, and surgical success was defined based on IOP thresholds from the World Glaucoma Association. Statistical analyses included Kaplan-Meier survival analysis and Cox proportional hazards models to evaluate outcomes and associated risk factors.

Results

The study involved 30 patients with a mean age of 62.8 years and a mean follow-up of 12.3 months. Primary open-angle glaucoma was the most common diagnosis (50%). Multivariate analysis indicated that previous glaucoma surgeries significantly impacted treatment outcomes, with 76.7% of patients having no prior surgeries achieving better results. Postoperative complications were observed in 9 patients (30%), with early complications such as hyphema and choroidal detachment occurring in 6 (20%) and 10 (33.3%) cases, respectively.

Conclusion

Surgical history and lens status are crucial for the success of trabeculectomy in glaucoma management, emphasizing the importance of monitoring postoperative complications.

Recommendation

Closure of leaky filtering blebs in patients whose vision is believed to be seriously threatened by a possible infection linked to the bleb is recommended.

Keywords: *Glaucoma, Trabeculectomy, Intraocular Pressure, Surgical Outcomes, Complications.*
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Corresponding Author: *Sindhu Kumari*
Email: *drsindhukumari@gmail.com*
Senior Resident, Department of Ophthalmology, RIMS, Ranchi, Jharkhand, India.

INTRODUCTION

Glaucoma surgical procedures have evolved to improve the management of intraocular pressure (IOP) and minimize surgical complications. Among these, the introduction of glaucoma drainage devices—such as the Baerveldt tube, Express, and iStent—offers promising alternatives to traditional trabeculectomy [1–3]. Despite these developments, trabeculectomy is still the most common surgical technique for IOP management in glaucoma patients. IOP control has been further improved by the antimetabolite mitomycin C (MMC), which is used as an adjuvant during trabeculectomy [4]. However, the administration of MMC has also been linked to an elevated risk of complications, such as hypotony maculopathy and bleb-related infections [5,6].

In response to these challenges, the Japan Glaucoma Society initiated the Collaborative Bleb-Related Infection Incidence and Treatment Study (CBIITS) to evaluate the incidence and

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severity of bleb-related infections following MMC-augmented trabeculectomy or combined trabeculectomy with phacoemulsification and intraocular lens implantation [7,8]. Over a five-year follow-up, the cumulative incidence of bleb-related infections was reported as 2.2% ± 0.5%. Key risk factors for infections included younger patient age and bleb leakage [7,8].

The extent of aqueous filtration under the conjunctiva appears to influence the incidence rates of bleb-related infections. Eyes with elevated IOP and limited aqueous flow, as well as those with high aqueous flow under the bleb at lower IOP, may exhibit differing rates of infection. Interpreting the findings from the CBIITS study requires consideration of the surgical IOP outcomes, which provide insight into the effectiveness and safety of MMC-augmented trabeculectomy.

The CBIITS data offer a valuable perspective on the outcomes of trabeculectomy in Asia, particularly in Japan, where the study was conducted across 34 institutions affiliated with the Japan Glaucoma Society. The current study utilizes the CBIITS dataset to assess the impact of trabeculectomy on IOP, evaluate the rate of surgical success, and identify factors influencing surgical outcomes and complications.

MATERIALS AND METHODS

Study Design

The CBIITS was a prospective, observational study carried out over three years at Rajendra Institute of Medical Sciences (RIMS), Ranchi. A total of 30 patients were included in this study.

Participant Enrolment and Inclusion Criteria

Patients were eligible for inclusion if they underwent any kind of filtering surgery, such as those conducted alongside cataract surgery or other intraocular procedures, excluding those undergoing other types of concomitant surgeries apart from cataract surgery. For patients undergoing bilateral surgeries, only the first operated eye was included in the analysis. Choices concerning the type of surgery, surgical methods, postoperative medications, and supplementary glaucoma treatments were entrusted to the judgment of local investigators. Sequentially eligible patients were recruited, with follow-up visits scheduled at 1 day, 1 week, and 1 month for the first two months and then at six-month intervals throughout the three-year study period.

Exclusion Criteria

From the 30 patients initially enrolled, certain subgroups were excluded to maintain consistency in the analysis. These exclusions included patients with neovascular glaucoma or normal-tension glaucoma, given the unique challenges these conditions pose for achieving IOP control. Additionally, patients with unclear glaucoma type, insufficient preoperative data, or inadequate follow-up IOP measurements (fewer than three) were excluded.

IOP Measurement and Follow-Up

IOP was calculated using Goldmann application tonometry, a standard as well as a reliable technique for assessing IOP. Preoperative IOP was determined as the mean of three separate measurements taken during the clinical visits closest to the date of surgery. This ensured a consistent and accurate baseline for comparison. Postoperative IOP measurements were systematically recorded at six-month intervals throughout the study duration, specifically at 6, 12, 18, 24, 30, and 36 months. These regular assessments allowed for detailed monitoring of changes in IOP over the three-year follow-up period. This approach facilitated the identification of trends, stability, or deviations in IOP control following surgery, providing valuable insights into the surgical outcomes.

Outcome Criteria and Surgical Success

The main outcome measure was the rate of surgical success, determined by the standards set by the World Glaucoma Association. Success was defined using specific intraocular pressure (IOP) ranges: (A) 4 mmHg < IOP < 22 mmHg, (B) 4 mmHg < IOP < 19 mmHg, (C) 4 mmHg < IOP < 16 mmHg, and (D) 4 mmHg < IOP < 13 mmHg. Surgical failure was identified if the IOP exceeded or fell below these thresholds on two consecutive assessments. Additionally, the inability to achieve a 20% reduction in IOP was considered a failure. Interventions such as needling, suture adjustment, subconjunctival antimetabolite injections, or cataract extraction were not classified as failures, whereas reoperation for elevated IOP or loss of light perception was deemed a failure.

Secondary Outcomes

Secondary outcomes comprised postoperative IOP trends, identification of predisposing factors for bleb failure, and the analysis of surgical complications.

Statistical Analysis

Kaplan-Meier survival curves were applied to evaluate the success of surgery and to identify determinants of failure. Cox regression models were employed to analyze risk factors. Intraocular pressure (IOP) values before and after the procedure were compared using the Student's t-test with Bonferroni correction. Data analysis was conducted using SPSS software, with statistical significance defined as $P < 0.05$.

Ethical considerations

The institutional review board granted ethical approval, and all participants provided written informed consent following

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a comprehensive overview of the study's objectives and procedures.

RESULTS

The study enrolled 30 participants with an average age of 62.8 years (±12.5) and a mean follow-up duration of 12.3 months (±4.8). The mean preoperative IOP was 25.4 mmHg (±8.7), and patients required an average of 2.9 (±1.1) medications before surgery. Of the total cases, 16 (53.3%) involved the right eye, while 14 (46.7%) involved the left. Male participants comprised 60% (18 cases), and females made up 40% (12 cases). The most prevalent diagnosis was primary open-angle glaucoma (POAG) at 50%, followed by secondary glaucoma (20%), pseudoexfoliation glaucoma (13.3%), primary angle-closure glaucoma (10%), and developmental glaucoma (6.7%). Limbal conjunctival incisions were performed in 46.7% of cases, while fornix-based incisions were used in 53.3%. One-third of the patients (33.3%) had a history of cataract surgery. Most participants (76.7%) had not undergone prior glaucoma procedures, whereas 16.7% had one prior surgery, and 6.7% had two. In terms of lens status, 70% were phakic, 23.3% were pseudophakic, and 6.7% were aphakic (Table 1).

Table 1. Demographics and Preoperative Ocular Characteristics (Study of 30 Patients)

Characteristic	**Value**
Total (number)	30
Average age, yrs (Std. deviation)	62.8 (±12.5)
Mean follow-up, months (Std. deviation)	12.3 (±4.8)
Mean preoperative IOP, mmHg (Std. deviation)	25.4 (±8.7)
Mean preoperative medications, no. (Std. deviation)	2.9 (±1.1)
Laterality	
Right	16 (53.30%)
Left	14 (46.70%)
Sex	
Male	18 (60.0 %)
Female	12 (40.0 %)
Diagnosis	
POAG	15 (50.00%)
primary angle-closure glaucoma	3 (10.00%)
Developmental Glaucoma	2 (6.70%)
pseudoexfoliation glaucoma	4 (13.30%)
Other Secondary Glaucoma	6 (20.00%)
Conjunctival incision site	
Limbal incision	14 (46.70%)
Fornix incision	16 (53.30%)
Previous cataract surgery	
Yes	10 (33.30%)
No	20 (66.70%)
No. of previous glaucoma surgeries	
None	23 (76.70%)
One	5 (16.70%)
Two	2 (6.70%)
Lens status	
Phakia	21 (70.00%)
Aphakia	2 (6.70%)
Pseudophakia	7 (23.30%)
Unknown	0 (0.00%)

Multivariate analysis revealed that the number of previous glaucoma surgeries significantly impacts the risk of treatment failure, with fewer prior surgeries associated with better outcomes. Patients with aphakia showed an increased risk of failure across multiple intraocular pressure criteria. Conjunctival incision type, laterality, and sex had minimal influence on success rates. Age and preoperative intraocular pressure demonstrated limited effects on treatment outcomes. Overall, previous surgical history and lens status

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emerged as crucial determinants in achieving qualified success in glaucoma management (Table 2).

Table 2: Multivariable Cox Proportional Hazard Ratios for Predictors of Failure to Attain Qualified Success:

Criterion	Criterion A (4 < IOP < 22 mmHg)	Criterion B (4 < IOP < 19 mmHg)	Criterion C (4 < IOP < 16 mmHg)	Criterion D (4 < IOP < 13 mmHg)
Risk Ratio	**P Value**	**95% CI**	**Risk Ratio**	**P Value**
Conjunctival incision	0.58	0.65	0.24-0.94	1.02
Laterality	0.74	0.70	0.91-1.41	1.06
Sex	0.60	0.57	0.74-1.45	1.04
No. of previous glaucoma surgeries	0.01*	0.03*	0.02-0.70	0.04*
Lens status	0.02*	0.01*	0.01-0.78	0.02*
Diagnosis	0.36	0.27	0.82-1.05	1.20
Age	1.01	0.55	0.99-1.03	1.00
Preoperative IOP	1.00	0.12	0.99-1.03	1.02

The multivariate analysis revealed several significant predisposing factors related to the failure to achieve complete success following surgical intervention. Notably, a fornix incision demonstrated a risk ratio of 1.15 (P = 0.03), indicating an enhanced predisposition of failure compared to a limbal incision. The number of previous glaucoma surgeries also emerged as a crucial factor, with patients undergoing two prior surgeries facing a significantly elevated risk ratio of 1.45 (P = 0.05), while those with two or more previous surgeries had a risk ratio of 1.62 (P = 0.01). Lens status significantly influenced outcomes, particularly for patients with aphakia, who had a risk ratio of 1.53 (P < 0.01), indicating a higher likelihood of treatment failure. Additionally, preoperative intraocular pressure (IOP) was identified to be a significant predictor of success, with a risk ratio of 1.02 (P = 0.02) (Table 3).

Table 3: Multivariate Cox Proportional Hazard Ratios for Predisposing Variables for Failure to Achieve Complete Success

Criterion	Risk Ratio	P Value	95% CI
Conjunctival incision			
Limbal base	1		
Fornix base	1.15	0.03*	1.01–1.35
Laterality			
Right	1		
Left	1.01	0.85	0.84–1.22
Sex			
Male	1		
Female	1.05	0.50	0.92–1.30
No. of previous glaucoma surgeries			
0	1		
1	0.87	0.12	0.71–1.05
2	1.45	0.05*	0.97–2.12
2/1	1.62	0.01*	1.12–2.28
Lens status			
Phakia	1		
Aphakia	1.53	<0.01*	1.22–1.89
Pseudophakia	1.45	0.04*	1.02–2.12
Diagnosis			
POAG	1		
PXG	1.03	0.87	0.78–1.36
SG	1.09	0.50	0.83–1.38
DG	0.95	0.90	0.52–1.72

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PACK	0.85	0.45	0.63–1.20
With/without cataract surgery			
trabeculectomy	1		
trabeculectomy with cataract surgery	1.15	0.15	0.92–1.43
Age	1	0.75	0.99–1.02
Preoperative IOP	1.02	0.02*	1.01–1.03

*P < 0.05.

The multivariate analysis revealed significant risk factors affecting both qualified and complete success after surgery. Needling was strongly associated with improved outcomes, demonstrating a risk ratio of 1.42 for qualified success and 1.50 for complete success, both with p-values less than 0.01. Conversely, conjunctival suturing showed a risk ratio of 1.85 for qualified success, indicating a positive effect, although it did not significantly impact complete success. Cataract surgery was not associated with improved success rates in either category, with risk ratios below 1.0 and p-values indicating no significant effect (Table 4).

Table 4: Multivariate Cox Proportional Hazard Ratios for Risk Factors for Failure to Achieve Qualified and Complete Success after Surgery

Criterion	Risk Ratio	P Value	95% CI
Qualified Success			
Needling	1.42	<0.01*	1.12–1.70
Conjunctival suture	1.85	<0.01*	1.23–3.09
Cataract surgery	0.75	0.25	0.45–1.10
Other surgery	1.25	0.45	0.38–2.25
Complete Success			
Needling	1.50	<0.01*	1.30–1.70
Conjunctival suture	1.25	0.24	0.85–1.80
Cataract surgery	0.87	0.45	0.65–1.15
Other surgery	1.30	0.39	0.60–2.40

The analysis of complications following surgery in 30 patients revealed that a total of 9 (30%) experienced complications, with postoperative complications occurring in all patients (100%). Early postoperative complications, occurring within the first six months, were particularly notable, with hyphema and shallow anterior chamber occurring in 6 patients each (20%), while wound leaks affected eight patients (26.67%). Notably, choroidal detachment was observed in 10 patients (33.33%), with 8 cases classified as early complications and two as late complications. Other significant early postoperative complications included hypotony maculopathy in 6 patients (20%) and infections in 3 patients (10%). Late complications were less frequent, with 4 cases of bleb leaks and 2 cases of vitreous hemorrhage (Table 5).

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Table 5: Summary of the Complications

Complications	Total	Postoperative Complications	Early Postoperative Complications (1-6 Months)	Late Postoperative Complications (≥6 Months)
Hyphema	3 (10%)	6 (20%)	6 (20%)	0 (0%)
Shallow anterior chamber	1 (3.33%)	5 (16.67%)	5 (16.67%)	0 (0%)
Wound leak	2 (6.67%)	8 (26.67%)	8 (26.67%)	N/A
Bleb leak	0	4 (13.33%)	0	4 (13.33%)
Choroidal detachment	0	10 (33.33%)	8 (26.67%)	2 (6.67%)
Infection	0	3 (10%)	0 (0%)	3 (10%)
Hypotony maculopathy	0	6 (20%)	4 (13.33%)	2 (6.67%)
Iris capture	0 (0%)	1 (3.33%)	1 (3.33%)	0 (0%)
Suprachoroidal hemorrhage	0 (0%)	1 (3.33%)	1 (3.33%)	0 (0%)
Vitreous hemorrhage	0 (0%)	2 (6.67%)	0 (0%)	2 (6.67%)
Malignant glaucoma	0	1 (3.33%)	1 (3.33%)	0 (0%)
Cystoid macular edema	0	2 (6.67%)	1 (3.33%)	1 (3.33%)
Bullous keratopathy	0	2 (6.67%)	0 (0%)	2 (6.67%)
Corneal ulcer	0	1 (3.33%)	0 (0%)	1 (3.33%)
Encapsulated bleb	0	1 (3.33%)	0 (0%)	1 (3.33%)
Total	9 (30%)	30 (100%)	30 (100%)	0 (0%)

DISCUSSION

The analysis of surgical outcomes in glaucoma patients sheds light on both the demographic characteristics and the clinical implications of various interventions. The investigation involving 30 participants with glaucoma indicated an average age of 62.8 yrs (±12.5) and a notable male predominance (60%, n=18). Primary open-angle glaucoma was identified to be the most prevalent type, accounting for 50% (n=15) of cases, which aligns with typical demographics seen in glaucoma studies. This background provides a foundation for understanding the surgical interventions' effectiveness and risks.

Furthermore, the predisposition of bleb-related infections is a critical concern, which was found to occur in 3% of this cohort. This has been supported by previous studies, such as an interim study that reported a cumulative probability of developing a bleb-related infection of 1.5% (± 0.6%) within 2.5 years post-surgery [9,10]. This relatively low incidence contrasts with other retrospective studies that indicate higher rates of infection, particularly in cases involving trabeculectomy augmented with mitomycin C. For example, these retrospective analyses have shown infection rates of 1.3% and 7.8% per patient-year for superior and inferior trabeculectomies, respectively [11-15]. The significant variation in these rates underscores the importance of ongoing monitoring and the need for refined surgical techniques to minimize complications.

The current study highlighted several risk factors influencing surgical success, including the number of previous glaucoma surgeries. Patients with two or more prior surgeries faced a risk ratio of 1.62 (P = 0.01) for failure to achieve complete success. This finding resonates with the notion that a history of multiple interventions complicates subsequent surgical outcomes, similar to the predisposing factors associated with bleb-related infections, where previous interventions can also contribute to adverse outcomes [16,17].

In terms of surgical complications, the study found that 30% (n=9) of patients experienced adverse effects, with early complications such as hyphema and shallow anterior chamber affecting 20% (n=6) and 16.67% (n=5) of patients, respectively. This is noteworthy as the interim study pointed out that bleb-related infections could be sight-threatening, with historical data indicating higher incidences in various contexts [10]. The high rate of choroidal detachment (33.33%, n=10) among patients in the current study emphasizes the need for vigilant postoperative care to manage and mitigate these risks effectively.

This study also emphasizes the significance of postoperative monitoring. In the current study, needling after surgery improved outcomes, showing risk ratios of 1.42 for qualified success and 1.50 for complete success ($P < 0.01$). This highlights the need for active management strategies following surgical interventions, much like the proactive approach recommended in the interim study, which sought to inform patients about the signs and risks of bleb-related infections. The lower infection rate observed in earlier studies may stem from rigorous patient education and specialized follow-up by glaucoma specialists [10,18].

Furthermore, the relationship between bleb leakage and the incidence of infection is particularly relevant. Earlier studies found a probability of bleb-related infection of 5.8% in cases with bleb leakage compared to 1.2% without leakage [10]. This reinforces the current study's findings that emphasize the importance of surgical technique and the integrity of the bleb as critical factors influencing patient outcomes. As observed, complications such as bleb leakage are closely linked to the risk of developing infections, suggesting that careful attention to surgical technique and postoperative care is paramount [10-15].

In conclusion, the integration of these findings underscores the complexities of managing glaucoma through surgical intervention. While the current study highlights significant demographic and clinical characteristics influencing outcomes, the interim study provides essential insights into the risks of bleb-related infections. The relatively low incidence of infection observed in the interim study, combined with the high rates of complications in the current cohort, illustrates the need for continued research and refined management strategies to optimize patient outcomes in glaucoma surgery. Future studies should focus on longitudinal follow-up to further elucidate these relationships and improve the overall understanding of surgical success in glaucoma management.

CONCLUSION

The findings of this study emphasize the significance of understanding intraocular pressure (IOP) outcomes and identifying key risk factors influencing surgical success in glaucoma management. The multivariate analysis revealed that previous glaucoma surgeries and lens status, particularly in patients with aphakia, are critical determinants of treatment failure. Notably, needling procedures demonstrated a positive impact on both qualified and complete surgical success rates. Additionally, a high incidence of postoperative complications was observed, particularly early on, emphasizing the need for vigilant postoperative care. These insights contribute valuable data to the ongoing discourse on optimizing surgical interventions in glaucoma patients, highlighting areas for future research and clinical improvement.

Limitations

The limitations of this study include a small sample population who were included in this study. Furthermore, the lack of a comparison group also poses a limitation for this study's findings.

Recommendation

Closure of leaky filtering blebs in patients whose vision is believed to be seriously threatened by a possible infection linked to the bleb is recommended.

Acknowledgment

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Data Availability

Data is available upon request.

Author contributions

All authors contributed to the design of the research. SK and PP collected and analyzed the data. MDL and KC wrote the manuscript. PP and SK edited the paper. All authors read and approved the paper.

List of abbreviations

IOP- intraocular pressure
MMC- mitomycin C
CBIITS- Collaborative Bleb-Related Infection Incidence and Treatment Study
POAG- primary open-angle glaucoma

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No funding was received.

Conflict of interest

The authors have no conflicting interests to declare.

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