Outcomes of bleb needling with 5-fluorouracil post trabeculectomy among glaucoma patients in Kelantan.

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Abstract

Purpose: To evaluate the outcomes of bleb needling with 5-FU post-trabeculectomy among glaucoma patients in Kelantan.

Methods: A retrospective analysis of glaucoma patients undergoing bleb needling with 5-FU from January 2020 to December 2023 was conducted at Hospital Raja Perempuan Zainab II with at least one year of follow-up post-needling. Outcomes were assessed based on intraocular pressure (IOP), use of anti-glaucoma medication (AGM), complications, and overall success rates. Statistical comparisons were made using Fisher's exact test and Mantel-Haenszel chi-square.

Results: Twenty-four patients completed the one-year follow-up, all of whom were predominantly Malay (100%) with a median age of 54 years. Primary open-angle glaucoma accounted for 45.8% of cases. The median IOP was significantly reduced from 22 mmHg pre-needling to 12 mmHg at 12 months post-needling. AGM use decreased substantially, with nearly two-thirds requiring no AGM after one year. Complete and qualified success rates were 62.5% and 20.8%, respectively. Subconjunctival haemorrhage (87.5%) was the most common complication, while hypotony occurred more frequently in failed cases. Success was significantly associated with a reduction in AGM use ($p = 0.018$).

Conclusion: Bleb needling with 5-FU demonstrates high efficacy and acceptable safety in managing failing trabeculectomy blebs among glaucoma patients in Kelantan. Sustained IOP reduction and reduced AGM use highlight its potential in resource-constrained settings. Prior AGM usage and patient age might influence surgical success. Vigilance regarding complications like hypotony is essential for optimizing outcomes. Larger, prospective studies are recommended to validate predictive factors of success.

Keywords: 5-fluorouracil, Trabeculectomy, Post-trabeculectomy, Bleb needling, Intraocular pressure

Introduction

Glaucoma is characterized by progressive structural damage to the optic nerve head often associated with corresponding visual field loss.[1] It is the primary contributor to permanent blindness worldwide.[2] Trabeculectomy is the most common and gold standard surgical treatment for lowering IOP, particularly in moderate to advanced glaucoma cases where medical or laser therapy proves inadequate.[3] However, failure of trabeculectomy is often attributed to fibrotic tissue formation during the wound healing process. This complication is more commonly observed in individuals of Asian and Afro-Caribbean descent, who tend to exhibit a more vigorous fibrotic response compared to Caucasian patients.[4]

Bleb needling is a less invasive procedure aimed at re-establishing aqueous outflow in cases of unsuccessful or deteriorating trabeculectomy blebs by breaking down subconjunctival fibrotic tissue. The use of antifibrotic agents like 5-FU alongside needling helps improve outcomes by inhibiting fibroblast activity and minimizing scar formation.[5] Success rates of bleb needling vary, with reported complete success ranging from 30% to 70%, depending on factors such as

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timing of needling, prior bleb morphology, and underlying diagnosis.[4,6] While several studies from Western and Asian populations have evaluated the outcomes of bleb needling with 5-FU, there remains a paucity of local data from Malaysia, particularly in the east coast region such as Kelantan.

In Malaysia, glaucoma accounts for approximately a quarter of attendees at eye clinics, underscoring its substantial impact on ophthalmic services. Furthermore, it ranks among the top causes of blindness in the nation, highlighting the need for effective management strategies. Compounding this, almost one-third of the ophthalmology centres in Malaysia are classified as underperforming, reflecting systemic challenges in providing optimal eye care.[7-9] For patients with advanced glaucoma, surgical procedures like trabeculectomy are frequently required. However, the long-term follow-up and postoperative care, which are vital for bleb survival, may be inadequate due to systemic healthcare issues and geographical barriers.[10,11] While our centre routinely utilises bleb needling with adjunctive 5-FU to salvage failing blebs, there is a notable absence of local data assessing its effectiveness and safety in practice. Gaining insight into outcomes in this context is crucial for informing clinical practices, optimising patient selection, and guiding postoperative care strategies in similarly resource-limited settings.

This study aims to evaluate the outcomes of bleb needling with 5-FU over a one-year follow-up period in eyes with previously failed trabeculectomy, focusing on the success rates and complications. Factors affecting the success rate of bleb needling will also be identified.

Materials and Methods

This study employed a retrospective design through an extensive review of medical records of glaucoma patients who underwent bleb needling with adjunctive 5-FU following trabeculectomy. The data collection covered procedures performed between January 2020 and December 2023 at Hospital Raja Perempuan Zainab II, Kelantan. Ethical approval was obtained from the Malaysian Medical Research and Ethics Committee (MREC), with the assigned NMRR ID: 29-00927-378. This study included all eligible cases during the study period. The sample size was calculated using a single-proportion formula,[12] with an expected success rate of 65%,[13] with the precision of 20% and a 95% confidence interval. The adjusted sample size was determined to be 25 participants after accounting for a 10% dropout rate.

Patients eligible for inclusion in this study were adults aged 18 years or older, diagnosed with either primary open-angle glaucoma (POAG), primary angle-closure glaucoma (PACG), or secondary glaucoma. They had undergone trabeculectomy followed by bleb needling with 5-FU. Additionally, all included patients had at least one year of documented follow-up after needling for the outcome assessment. Patients were excluded if they had a history of more than one glaucoma filtering surgery, prior glaucoma drainage device implantation, or inadequate follow-up, defined as less than one year.

The procedure was performed under sterile conditions in the operating theatre by different glaucoma surgeons and fellows. The patient's eye and periorbital area were cleaned with povidone-iodine, followed by instillation of topical anaesthesia (proparacaine 0.5%) or sub-tenon's anaesthesia. A 26-gauge needle was carefully introduced posterior to the bleb, beneath the conjunctiva, and advanced towards the scleral flap to lyse adhesions and scar tissue, thereby restoring aqueous humour outflow. Immediately after disruption of fibrosis, a subconjunctival injection of 5-FU (0.1–0.3 mL at a concentration of 50 mg/mL) was administered adjacent to the bleb area. The area was then irrigated with 30 mL of sterile water for injection. Post-procedure management included topical antibiotics and corticosteroids, which were tapered based on clinical response during follow-up visits. Repeat bleb needling with 5-fluorouracil (5-FU) was performed during follow-up in patients with suboptimal IOP control, defined as IOP >21 mmHg in moderate glaucoma and >18 mmHg in severe glaucoma. The procedure was also repeated in the presence of clinically significant bleb fibrosis identified at any follow-up visit.

The variables collected in this study included demographic characteristics (age and gender), clinical parameters, and surgical details. Clinical variables comprised glaucoma type, interval between trabeculectomy and the first bleb needling procedure, and the total number of needling procedures performed. IOP was assessed using Goldmann applanation tonometry

at baseline (prior to needling) and subsequently at 3, 6, and 12 months following the procedure. Medication-related variables included the number of AGMs used before and after the procedure, as well as changes in AGM usage over time. Data on postoperative complications and the need for additional surgical interventions during the one-year follow-up period were also documented.

The primary outcome of interest was the success rate at one-year post-procedure, categorised as either complete success or qualified success. Complete success was defined as achieving an IOP ≤18 mmHg without the need for AGMs. Qualified success was defined as patients who achieved an IOP ≤18 mmHg while with AGM use or IOP 18-21mmHg with or without AGM. Secondary outcomes included the degree of change in IOP from baseline, changes in AGM usage, and the frequency and type of complications observed postoperatively.

Descriptive statistics were used to summarise sociodemographic and baseline clinical characteristics, with categorical variables presented as frequencies and percentages, and continuous variables as medians with interquartile ranges. IOP trends were visualised using box plots at key follow-up intervals: pre-needling, and 3, 6, and 12-month post-needling. Postoperative AGM use, complications, and one-year surgical outcomes were also reported using appropriate summary measures.

For inferential analysis, Fisher's exact test was used to compare categorical variables between the success group (including both complete and qualified success) and the failure group; and to compare success rates between primary and secondary glaucoma. The Clopper-Pearson exact binomial method was employed to calculate 95% confidence intervals (Cis). A Mantel-Haenszel chi-square test was performed post hoc, stratified by age group to adjust for potential confounding by age. A two-sided p-value <0.05 was considered statistically significant. Both eyes of a patient were eligible for inclusion if they met the criteria, and outcomes were analysed at the eye level. All statistical analyses were conducted using R version 4.4.[14]

Results

A total of 24 patients completed the one-year follow-up. The median age was 54 years (Q1, Q3 = 25, 65), and all patients were of Malay ethnicity. More than half of the patients were males (54.2%). The demographic details are summarised in Table 1.

For the baseline clinical characteristic, POAG was the most common diagnosis (45.8%). The median interval between trabeculectomy and the first needling procedures was 14 weeks (Q1, Q3 = 7, 25). Most patients required one (45.8%) or two (33.3%) needling procedures. The baseline clinical characteristics are summarised in Table 1.

Table 1: Sociodemographic and Baseline Clinical Characteristics (n = 24)

Characteristic	Median (Q1, Q3) / n (%)
Age (year)	54 (25, 65)
Ethnicity	
Malay	24 (100.0)
Gender	
Female	11 (45.8)
Male	13 (54.2)
Type of Glaucoma	
POAG	11 (45.8)
PACG	3 (12.5)
Secondary	10 (41.7)

Table 1: Sociodemographic and Baseline Clinical Characteristics (n = 24) (Cont.)

Characteristic	Median (Q1, Q3) / n (%)
Duration between Trabeculectomy and Bleb Needling (weeks)	14 (7, 25)
Needling Number	
One Needling	11 (45.8)
Two Needlings	8 (33.3)
Three Needlings	2 (8.3)
Four Needlings	3 (12.5)

There was sustained reduction in IOP following bleb needling, with median IOP at pre-needling was 22 mmHg (Q1, Q3 = 19, 27), decrease to 16 mmHg (Q1, Q3 = 12, 18) at 3 months, 13 mmHg (Q1, Q3 = 12, 17) at 6 months and 12mmHg (Q1, Q3 = 10, 15) at 12 months post-needling, as shown in Figure 1. On average, the median change in IOP from pre-needling to 12 months post-needling is a 10 mmHg reduction (Q1, Q3 = 7, 18).

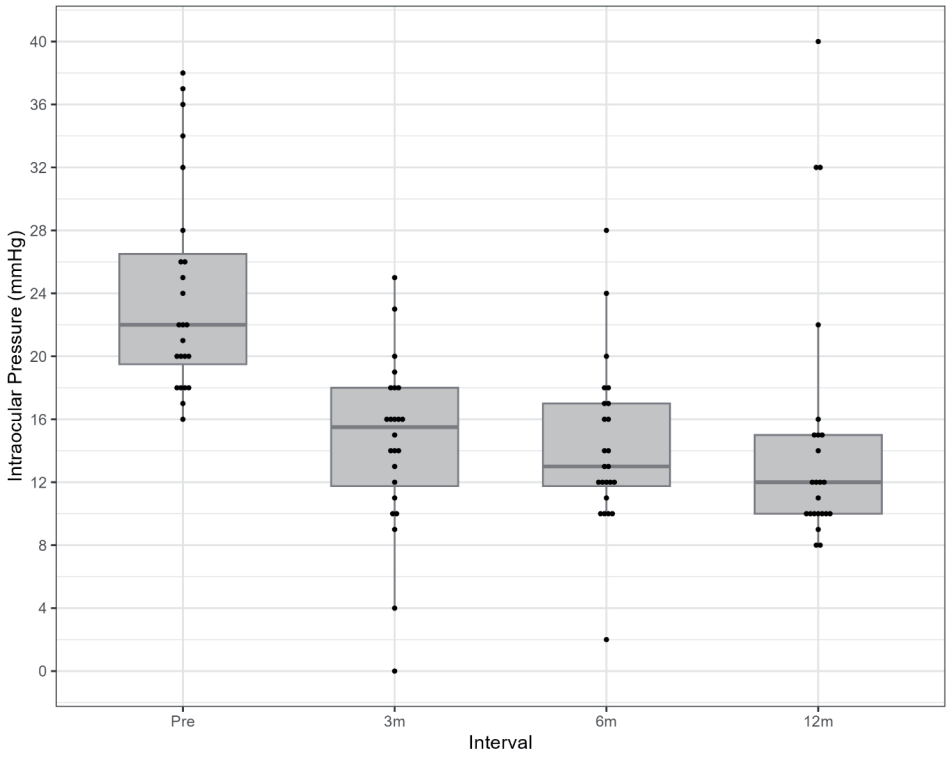


Figure 1: IOP distribution at pre-needling and 3, 6, and 12 months post-needling (n = 24). Box plots show the median and interquartile range, while dot plots show individual IOP measurements.

Pre-operatively, more than one-third were not on AGM (37.5%), one-third were on a single AGM (33.3%), and less than one-third required two to four AGM (29.2%). After one year, almost two-thirds did not require an AGM, while the rest needed either a dual AGM (25.0%) or a triple AGM (12.5%), as shown in Table 2.

Table 2: AGM use before and after needling (n = 24)

Medication Use	Pre-needling, n (%)	Post-needling, n (%)
No AGM	9 (37.5%)	15 (62.5%)
Single AGM	8 (33.3%)	-
Dual AGM	5 (20.8%)	6 (25%)
Triple AGM	1 (4.2%)	3 (12.5%)
Quadruple AGM	1 (4.2%)	-

The most common complications were subconjunctival haemorrhage (87.5%). At the end of the one-year follow-up, 62.5% of patients achieved complete success. The complications and outcomes were summarised in Table 3.

Table 3: Complications and surgical outcomes at one-year follow-up (n = 24)

Variables	n (%)
Complications*	
Subconjunctival haemorrhage	21 (87.5%)
Bleb leaking	3 (12.5%)
Hypotony	3 (12.5%)
Hyphaemia	1 (4.2%)
Outcomes	
Complete success	15 (62.5%)
Qualified success	5 (20.8%)
Failure	4 (16.7%)

*Patients may experience more than one complication

Patients were categorised into two groups based on surgical outcome: the success group, which included both complete and qualified successes, and the failure group, as shown in Table 4. Among the variables compared between these groups, only the change in AGM use was statistically significant. A reduction in the number of AGMs was observed in 55.0% (95% CI = 31.5, 76.9) of patients in the success group, whereas 75.0% (95% CI = 19.4, 99.4) of patients in the failure group required an increase in medications ($p = 0.018$).

Although other variables did not reach statistical significance, notable differences were observed between the groups. Older patients (aged 51–75 years) constituted a higher proportion of the success group (60.0%), whereas younger patients (aged 18–50 years) comprised a larger share of the failure group (75.0%). Similarly, 60.0% of the success group were male, whereas 75.0% of the failure group were female. Pre-needling medication use also differed: 70.0% of patients in the success group were already on at least one AGM, compared to 75.0% of the failure group who were not on any AGM. Postoperative hypotony occurred in 50.0% of patients in the failure group, compared to only 5.0% in the success group. Additionally, 75.0% of patients in the failure group required restarting eye drops postoperatively, compared to only 25.0% in the success group.

Table 4: Comparison between success and failure groups (n = 24)

Characteristic	Overall N = 24 n (%) (95% CI)	Success (Complete/ Qualified) N = 20 n (%) (95% CI)	Failure N = 4 n (%) (95% CI)	p-value[a]
Age Group				
18-50 years	11 (45.8) (25.6, 67.2)	8 (40.0) (19.1, 63.9)	3 (75.0) (19.4, 99.4)	0.300
51-75 years	13 (54.2) (32.8, 74.4)	12 (60.0) (36.1, 80.9)	1 (25.0) (0.6, 80.6)	
Gender				
Female	11 (45.8) (25.6, 67.2)	8 (40.0) (19.1, 63.9)	3 (75.0) (19.4, 99.4)	0.300
Male	13 (54.2) (32.8, 74.4)	12 (60.0) (36.1, 80.9)	1 (25.0) (0.6, 80.6)	
Needling Number				
One Needling	11 (45.8) (25.6, 67.2)	9 (45.0)	2 (50.0) (6.8, 93.2)	0.075
Two Needlings	8 (33.3) (15.6, 55.3)	8 (40.0) (19.1, 63.9)	0 (0.0) (0.0, 60.2)	
Three Needlings	2 (8.3) (1.0, 27.0)	2 (10.0) (1.2, 31.7)	0 (0.0) (0.0, 60.2)	
Four Needlings	3 (12.5) (2.7, 32.4)	1 (5.0) (0.1, 24.9)	2 (50.0) (6.8, 93.2)	
Medications (Pre-needling)				
No AGM	9 (37.5) (18.8, 59.4)	6 (30.0) (11.9, 54.3)	3 (75.0) (19.4, 99.4)	0.130
At least one AGM	15 (62.5) (40.6, 81.2)	14 (70.0) (45.7, 88.1)	1 (25.0) (0.6, 80.6)	
Medication Changes				
Decrease	11 (45.8) (25.6, 67.2)	11 (55.0) (31.5, 76.9)	0 (0.0) (0.0, 60.2)	0.018
Static	7 (29.2) (12.6, 51.1)	6 (30.0) (11.9, 54.3)	1 (25.0) (0.6, 80.6)	
Increase	6 (25.0) (9.8, 46.7)	3 (15.0) (3.2, 37.9)	3 (75.0) (19.4, 99.4)	

Table 4: Comparison between success and failure groups (n = 24) (Cont.)

Characteristic	Overall N = 24 n (%) (95% CI)	Success (Complete/ Qualified) N = 20 n (%) (95% CI)	Failure N = 4 n (%) (95% CI)	p-value[a]
Complication				
Subconjunctival Hemorrhage	21 (87.5) (67.6, 97.3)	18 (90.0) (68.3, 98.8)	3 (75.0) (19.4, 99.4)	0.437
Leaking	3 (12.5) (2.7, 32.4)	2 (10.0) (1.2, 31.7)	1 (25.0) (0.6, 80.6)	0.437
Hypotony	3 (12.5) (2.7, 32.4)	1 (5.0) (0.1, 24.9)	2 (50.0) (6.8, 93.2)	0.061
Hyphaema	1 (4.2) (0.1, 21.1)	1 (5.0) (0.1, 24.9)	0 (0.0) (0.0, 60.2)	0.999
Restart Eyedrop	8 (33.3) (15.6, 55.3)	5 (25.0) (8.7, 49.1)	3 (75.0) (19.4, 99.4)	0.091

[a]Fisher's Exact Test, 95% CI with the Clopper-Pearson exact binomial test

Although the difference was not statistically significant, higher success rates were observed in primary glaucoma (85.7%) compared to secondary glaucoma (80.0%). Notably, 100% of the older age group (51-75 years old) with primary glaucoma had success. The success rate by glaucoma type and age group was summarised in Table 5.

Table 5: Success rate by glaucoma type and age group (n = 24)

Characteristic	Overall n (%) (95% CI)[c]	Primary Glaucoma (POAG/PACG) n (%) (95% CI)[c]	Secondary Glaucoma n (%) (95% CI)[c]	p-value
Overall	20/24 (83.3) (62.6, 95.3)	12/14 (85.7) (57.2, 98.2)	8/10 (80.0) (44.4, 97.5)	0.950[a]
18-50 years old	8/11 (72.7) (39.0, 94.0)	3/5 (60.0) (14.7, 94.7)	5/6 (83.3) (35.9, 99.6)	0.545[b]
51-75 years old	12/13 (92.3) (64.0, 99.8)	9/9 (100.0) (66.4, 100.0)	3/4 (75.0) (19.4, 99.4)	0.308[b]

[a]Mantel-Haenszel Chi-squared with Yates Correction, [b]Fisher's Exact Test with Yates Correction, [c]Confident Interval, CI using Binomial Test

Discussion

This retrospective study assessed the one-year results of bleb needling combined with adjunctive 5-FU after trabeculectomy in glaucoma patients from Kelantan. To our knowledge, this represents the first reported data from Kelantan, and potentially one of the earliest published Malaysian series, on the outcomes of bleb needling with 5-FU, addressing a notable gap in the local ophthalmic literature. The objective was to outline surgical success and complication rates while investigating clinical factors that might affect these outcomes. In this discussion, we emphasise the study's significant findings, including sustained IOP decline, trends in AGM usage, the distribution of complications, and the success rate.

The demographic profile of the study population reflects the local patient distribution in Kelantan, with a predominantly Malay patient population, consistent with the state's population structure.[15] Just over half of the analysed eyes belonged to male patients, with the median age falling within the older adult range, corresponding to the typical age group vulnerable to glaucoma progression and surgical treatment.[16] Clinically, POAG represented the highest percentage of cases, followed by secondary glaucoma and PACG.[17] The median time between trabeculectomy and the first bleb needling procedure was relatively brief, indicating that most cases had early detection and intervention for bleb failure.[18] These aspects reinforce the applicability of findings within a Malaysian tertiary public hospital context and provide insights into current glaucoma management practices in a predominantly rural state environment.

The present study demonstrated a sustained and clinically meaningful reduction in IOP following bleb needling with 5-FU. This consistent downward trend is comparable to findings from other studies.[13] The efficacy of this intervention may be attributed to the ability of 5-FU to inhibit fibroblast proliferation, thereby preserving bleb function and maintaining aqueous outflow. Re-establishing flow through the subconjunctival filtration pathway is crucial, as it relieves pressure on the optic nerve head and reduces the risk of glaucomatous progression.[19] This sustained IOP control is crucial in settings where access to repeated surgery or intensive follow-up is limited. It highlights the role of bleb needling as a valuable intermediate intervention that prolongs the life of the initial trabeculectomy, especially in resource-constrained environments.[20]

The overall complication profile observed in this study supports the relative safety of bleb needling with adjunctive 5-FU, with most adverse events being transient and self-limiting.[18] Subconjunctival haemorrhage was the most frequently reported complication, which was also reported elsewhere.[21] Importantly, this complication was not associated with poorer surgical outcomes in our cohort, supporting the notion that it represents a benign consequence of needle manipulation rather than a marker of surgical failure.

Of greater clinical significance is the occurrence of hypotony, which was disproportionately observed in the failure group. Hypotony following bleb needling may result from over filtration or excessive disruption of scleral and conjunctival tissue, leading to persistently low intraocular pressure and structural compromise. Chronic hypotony has been linked to complications such as maculopathy, choroidal effusion, and optic nerve head damage, all of which may jeopardise visual function despite IOP control. This association between hypotony and poor surgical outcome has been previously reported, suggesting that while bleb needling is effective, it requires careful postoperative monitoring and possibly pre-emptive modulation of aqueous outflow to avoid overcorrection.[22] These findings underscore the need for vigilance in patient selection and technique, particularly in balancing adequate bleb revitalisation with the risk of over filtration.

The patterns of AGM use observed in this study may offer important insights into factors influencing bleb needling outcomes. Notably, a higher proportion of patients in the failure group required the reintroduction of AGM postoperatively, suggesting that failed blebs were unable to sustain sufficient aqueous outflow following needling.[23] This may reflect a more advanced fibrotic response or structural compromise that limited the bleb's filtration capacity despite surgical revision. Conversely, patients in the success group were more likely to have been on anti-glaucoma medications before needling, which may suggest a form of physiological adaptation whereby the ocular tissues had become more

accustomed to lower intraocular pressure levels.[18] Such adaptation may have enhanced the eye's capacity to maintain IOP control following intervention. This observation aligns with the hypothesis that baseline medication use might facilitate postoperative stability by maintaining partial outflow through pharmacological means while surgical healing occurs. These findings emphasise the importance of both structural and physiological readiness in achieving favourable outcomes and highlight the potential role of preoperative medication status as a predictive factor in bleb needling success.

The high overall success rate observed in this study is consistent with previous reports on bleb needling with adjunctive 5-FU, which have shown success rates ranging from 60% to over 90%, depending on patient selection, surgical technique, and timing of intervention.[13,18,21] The high success rate, particularly among older patients and those with primary glaucoma, may be attributed to more stable wound healing responses and less aggressive fibroblastic activity compared to younger individuals or those with secondary glaucoma, such as neovascular or uveitic subtypes, which are known to have more complex pathophysiology and higher risk of scarring.[24] However, the lack of statistically significant differences between groups must be interpreted cautiously, given the small sample size, which likely limited statistical power and increased the risk of type II error. These trends, although not conclusive, are clinically relevant and support the need for larger studies to verify predictors of success following bleb needling.

This study has several limitations that merit consideration. Firstly, the sample size was relatively small, which limits statistical power and restricts the analysis to univariable comparisons. Although the target sample size was estimated at 25 based on an expected 65% success rate and a 20% precision level, the final sample comprised 24 patients, representing all eligible cases over the four-year study period. This reflects the true procedural volume at Kelantan's main glaucoma referral centre and provides an authentic snapshot of real-world practice in a resource-limited tertiary setting. Secondly, the retrospective nature of the study introduces potential biases related to missing data and measurement inconsistency. Furthermore, the relatively broad range of 5-FU dosing used (0.1–0.3 mL at a concentration of 50 mg/mL) may have influenced treatment outcomes. Nonetheless, standardised eligibility criteria and complete case inclusion help mitigate selection bias and support the exploratory value of the findings within the local context.

Conclusion

The overall high success rate of bleb needling with 5-FU in this study supports its role as an effective intervention for failing trabeculectomy blebs. Although some complications arose, most were minor and did not impact the overall success of the procedure. Although postoperative reduction in AGM use was significantly associated with surgical success, this likely reflects an outcome of successful bleb function rather than an independent predictive factor. Other variables, including age, gender, and preoperative medication use, showed trends toward association with outcomes but did not reach statistical significance. Conversely, hypotony appears to be a potential predictor of failure, emphasising the need for strategies to minimise this complication.

Overall, bleb needling remains a valuable, minimally invasive option, particularly in resource-limited settings. However, larger prospective studies are necessary to more effectively identify independent predictors of success and to enhance patient selection.

Conflict of Interest

None to declare.

Acknowledgements

None to declare.

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