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RESEARCH ARTICLE

EVALUATION OF SUB-TENON MITOMYCIN-C TRABECULECTOMY WITH AMNIOTIC MEMBRANE TRANSPLANTATION IN GLAUCOMA: A SINGLE ARM PROSPECTIVE STUDY

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Abstract

Background: Long term success of trabeculectomy is largely dependent on modulation of postoperative wound healing. Conventional sponge-applied mitomycin-C (MMC), although effective, is associated with variability in dosing and bleb-related complications. Sub-tenon MMC injection and amniotic membrane transplantation (AMT) have emerged as adjuncts aimed at improving bleb quality and surgical safety.

Aim: To evaluate the efficacy and safety of trabeculectomy augmented with sub-tenon MMC and amniotic membrane transplantation in patients with glaucoma.

Materials and Methods: This prospective interventional study included 21 patients with medically uncontrolled primary open-angle or primary angle-closure glaucoma.All patients underwent trabeculectomy with standardized sub-tenon MMC injection followed by placement of cryopreserved amniotic membrane over the scleral flap. Pre- and postoperative intraocular pressure (IOP), anti-glaucoma medication requirement, bleb morphology, complications, and surgical outcomes were assessed during follow-up.

Results: The majority of patients were above 50 years of age with a slight male predominance. Primary open-angle glaucoma was the most common type (76.2%). Mean IOP decreased from 28.4 ± 4.6 mmHg preoperatively to 14.2 ± 2.8 mmHg at 1 month and 13.6 ± 2.4 mmHg at 3 months postoperatively. Postoperatively, 71.4% of patients required no antiglaucoma medications. Diffuse functioning blebs were observed in 76.2% of eyes. Postoperative complications were minimal. Complete surgical success was achieved in 66.7% of patients, while qualified success was observed in 23.8%.

Conclusion: Sub-tenon MMC-augmented trabeculectomy combined with AMT provides effective IOP control, favorable bleb morphology, and a low complication profile, representing a promising surgical approach in glaucoma management.

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Introduction:-

Glaucoma remains a leading cause of irreversible blindness, and in India the clinical burden is amplified by late presentation, limited awareness, and long-term adherence challenges with topical therapy. As disease severity advances, many patients ultimately require surgery to achieve a target intraocular pressure (IOP) that is low enough to prevent further optic nerve damage. Trabeculectomy continues to be the most widely performed filtering procedure for medically uncontrolled glaucoma because it can produce substantial and durable IOP reduction. However, the long-term success of trabeculectomy is primarily determined by postoperative wound healing at the conjunctival–Tenons–scleral interface. Exuberant fibroblast proliferation and subconjunctival scarring can encapsulate or close the filtration pathway, resulting in bleb failure and loss of IOP control, especially in eyes with aggressive healing responses and in populations with higher scarring tendency. Therefore, modern trabeculectomy increasingly depends on safe, reproducible modulation of healing to balance efficacy (diffuse functioning bleb, low IOP) with safety (avoiding thin avascular blebs, leaks, hypotony, infection).Mitomycin-C (MMC) has remained the most accepted intraoperative antimetabolite used to reduce subconjunctival fibrosis and improve trabeculectomy outcomes. Conventionally, MMC is delivered using soaked sponges placed under the conjunctiva and scleral flap for a defined time. While effective, sponge application has practical drawbacks: variability in effective dose, risk of retained sponge fragments, localized spots of high concentration, and a bleb phenotype that may predispose to avascularity, late leaks, and bleb-related infection. These concerns have driven interest in alternative MMC delivery methods that are more standardized and potentially produce healthier bleb morphology.

Sub-Tenon injection of MMC is a key innovation intended to improve dose uniformity and surgical workflow while maintaining antifibrotic efficacy. Randomized evidence has shown that sub-tenon MMC injection can be comparable to sponge application in IOP control, while also influencing bleb characteristics in a direction that may be clinically advantageous. A randomized trial comparing sub-tenon injection versus soaked sponges reported that sub-tenon MMC was a safe and effective alternative and was associated with more favorable bleb morphology after trabeculectomy. [1] Subsequent randomized clinical trial data have similarly supported the concept that sub-Tenon MMC injection can be as safe and efficacious as sponge application at one year, with notable differences in bleb morphologic features that could translate into improved longer-term outcomes.[2] More recent prospective interventional work has explored lower-dose approaches to sub-tenon MMC during trabeculectomy (including combined procedures) and highlighted practical benefits such as eliminating multiple sponges while maintaining meaningful IOP reduction with acceptable complication profiles. [3] Contemporary comparative studies continue to evaluate delivery methods, including noninferiority designs assessing sub-Tenon injection against sponges for surgical failure endpoints, reflecting ongoing momentum toward more standardized MMC administration in filtration surgery.[4]

In parallel, amniotic membrane transplantation (AMT) has emerged as an adjunct with biologically plausible antifibrotic, anti-inflammatory, and epithelial-supportive properties that may improve bleb function and safety. The amniotic membrane contains extracellular matrix components and growth factor modulators that can reduce inflammation, suppress transforming growth factor-β–driven fibrosis, and support healthier ocular surface and conjunctival healing. Ophthalmic literature increasingly recognizes AMT beyond corneal indications, including its expanding role in conjunctival and glaucoma-related procedures. [5] In glaucoma surgery, AMT has been applied in different configurations (e.g., under the scleral flap, over exposed sclera, or to reinforce compromised conjunctiva), aiming to create a more diffuse, vascular, and durable bleb while reducing complications such as leaks or dysesthesia. Reviews focused on AMT in glaucoma describe its use alongside trabeculectomy and suggest it can be a safe procedure that may improve IOP control and potentially enhance success when combined with MMC, while also offering options for managing bleb-related complications. [6]

Clinical studies evaluating AMT as an adjunct to trabeculectomy have provided supportive, though not uniform, evidence. In primary MMC-augmented trabeculectomy, simultaneous use of amniotic membrane has been proposed as an additional modulator of wound healing, particularly aiming for improved bleb profile and fewer bleb-related adverse events. [7] More recent evaluations of AMT added to MMC-augmented trabeculectomy have assessed incremental benefit and have helped define where AMT may fit within contemporary practice, including its potential influence on postoperative course, bleb appearance, and complication patterns. [8] Systematic review evidence synthesizing randomized trials has suggested that trabeculectomy with AMT may provide superior IOP reduction versus trabeculectomy alone and may influence complete success rates, supporting the rationale for AMT as a meaningful wound-healing adjunct in selected contexts. [9] At the same time, real-world outcomes of MMC-trabeculectomy show that achieving durable success without late bleb-related morbidity remains a central challenge,

underscoring the need for adjunctive strategies that optimize both efficacy and safety. [10]Against this background, a prospective evaluation of sub-tenon MMC trabeculectomy combined with AMT is timely and clinically relevant in the Indian setting. Sub-tenon MMC offers a potentially more standardized, reproducible antifibrotic delivery method, while AMT may provide biologic scaffolding and modulation of healing to promote a healthier, more diffuse filtering bleb. Studying this combined approach prospectively can clarify feasibility, postoperative IOP control, bleb morphology and survival, medication reduction, and complication spectrum in an Indian patient population, where scarring responses and follow-up realities can meaningfully shape surgical outcomes. Such evidence can guide protocol refinement (dose, placement technique, and follow-up pathway) and support more predictable filtering surgery with improved long-term patient benefit.

Materials and Methods:-

Study Design and Setting:-

This prospective interventional study was carried out in the Department of Ophthalmology of Shri BM Patil Medical college and hospital, BLDE University, Vijayapura during the study period. Institutional Ethics Committee approval was obtained prior to initiation of the study, and the protocol adhered to the principles of the Declaration of Helsinki.

Study Population and Sample Size:-

A total of 21 patients diagnosed with glaucoma and requiring surgical intervention were included in the study. All eligible patients were enrolled consecutively after obtaining written informed consent.

Inclusion and Exclusion Criteria:-

Patients aged 18 years and above with medically uncontrolled primary open-angle glaucoma or primary angle-closure glaucoma showing documented progression of optic nerve damage and/or visual field loss despite maximal tolerated medical therapy were included. Patients with secondary glaucoma, previous glaucoma surgery, active ocular infection or inflammation, significant ocular surface disorders, or known hypersensitivity to mitomycin-C were excluded.

Preoperative Evaluation:-

Patients underwent assessment of visual acuity, slit-lamp biomicroscopy, Goldmann applanation tonometry, gonioscopy, optic disc evaluation, and automated perimetry wherever feasible. Baseline details were documented in a structured proforma.

Surgical Technique:-

All procedures were performed under peribulbar anesthesia. A superior fornix-based conjunctival flap was created, followed by sub-Tenon mitomycin-C administration, trabeculectomy with peripheral iridectomy, placement of amniotic membrane over the scleral flap (figure 1) and watertight conjunctival closure.

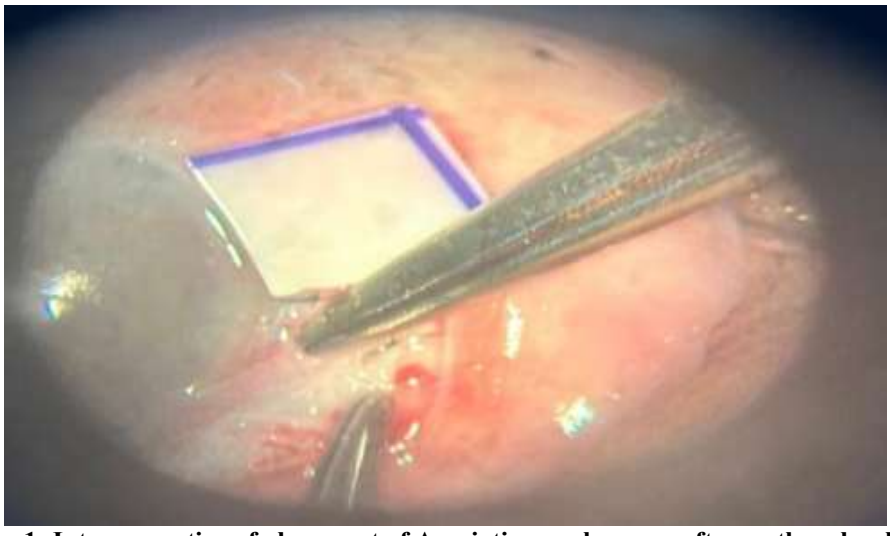


Figure 1: Intra-operative of placement of Amniotic membrane graft over the scleral flap

Postoperative Care and Follow-up:-
Postoperatively, topical antibiotics and corticosteroids were prescribed and tapered over subsequent weeks. Patients were followed up at regular intervals to evaluate intraocular pressure, bleb characteristics, visual acuity, and postoperative complications.Complete success was characterised by postoperative IOP ranging 6-18mmHg, achieved without the necessity of anti-glaucoma medications. In cases where additional medications were required postoperatively to achieve IOP ranging 6 to 18 mmHg, the outcome was characterised as qualified success. However, the outcome was considered failure if the postoperative IOP remained > 18 mmHg even after taking anti-glaucoma medications.

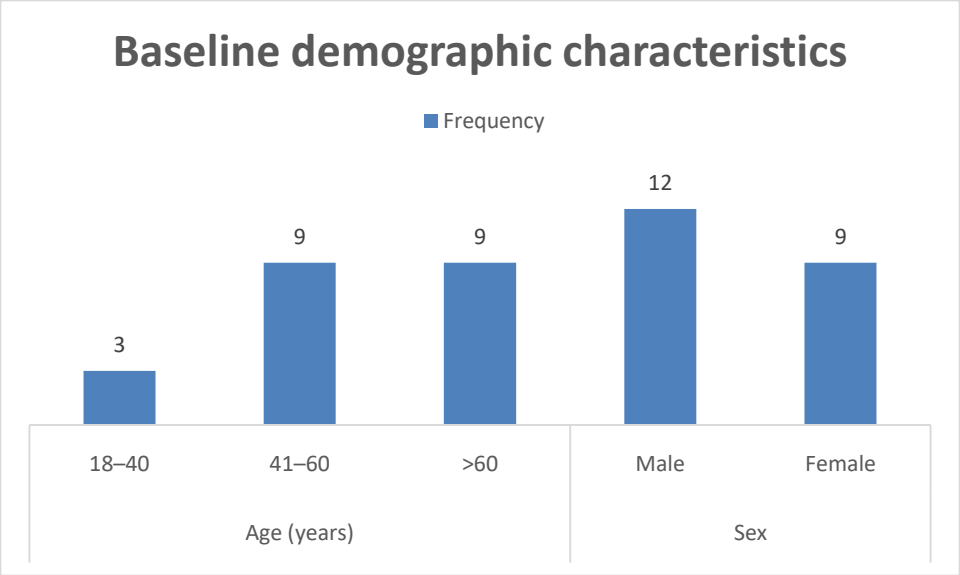
Data Analysis:-
Collected data were entered into a spreadsheet and analyzed using descriptive statistical methods to assess surgical outcomes.

Results:-

Baseline demographic characteristics of study participants:-
The study population predominantly consisted of patients above 50 years of age, reflecting the age-related nature of glaucoma. A slight male predominance was observed among the enrolled participants(Table 1).

Table 1. Baseline demographic characteristics of study participants (n = 21)

Variable	Frequency	Percentage (%)
Age (years)		
18–40	3	14.3
41–60	9	42.9
>60	9	42.9
Sex		
Male	12	57.1
Female	9	42.9



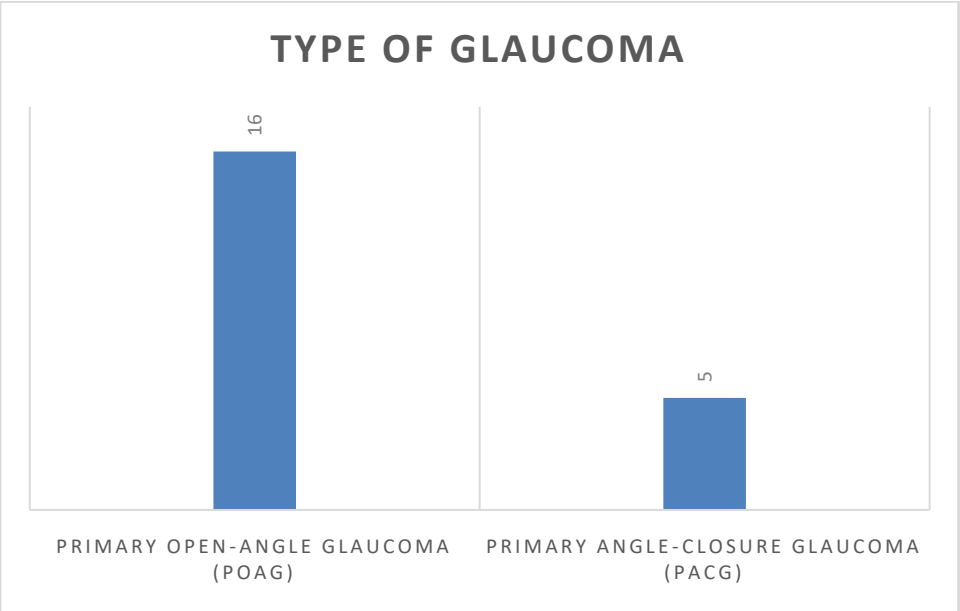
Graph 1. Baseline demographic characteristics of study participant

Distribution of glaucoma types:-

Primary open-angle glaucoma constituted the majority of cases in the study population, accounting for 76.2% of patients, while 23.8% had primary angle-closure glaucoma. This predominance of POAG is consistent with patterns typically observed in surgical glaucoma cohorts at tertiary care centers(Table 2).

Table 2. Distribution of glaucoma types (n = 21)

Type of glaucoma	Frequency	Percentage (%)
Primary open-angle glaucoma (POAG)	16	76.2
Primary angle-closure glaucoma (PACG)	5	23.8
Total	**21**	**100**

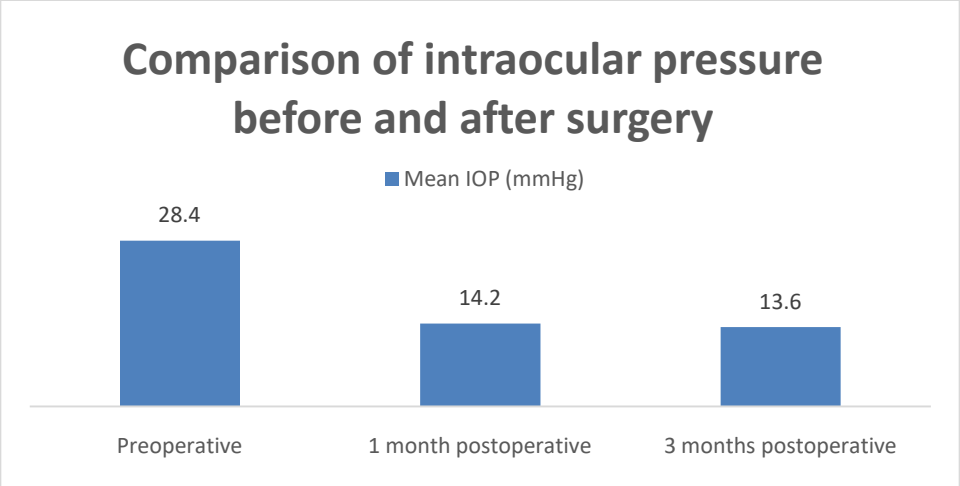


Graph 2. Distribution of glaucoma typesComparison of intraocular pressure before and after surgery:-

A substantial reduction in mean intraocular pressure was observed following surgery compared to preoperative values. The pressure-lowering effect was sustained during subsequent follow-up visits(Table 3).

Table 3. Comparison of intraocular pressure before and after surgery

Time point	Mean IOP (mmHg)	Standard deviation
Preoperative	28.4	4.6
1 month postoperative	14.2	2.8
3 months postoperative	13.6	2.4

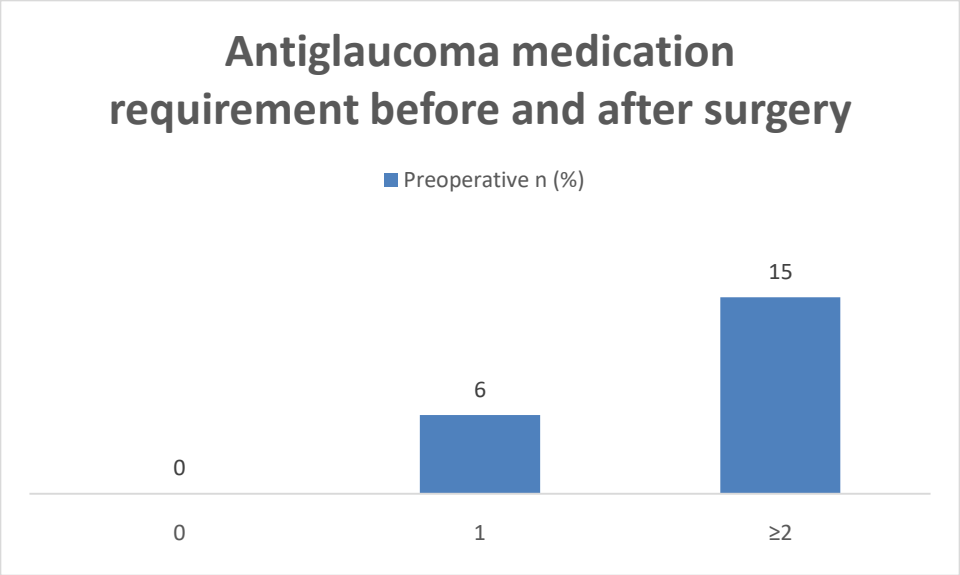


Graph 3. Comparison of intraocular pressure before and after surgery

Antiglaucoma medication requirement before and after surgery:-
There was a marked decrease in the requirement for antiglaucoma medications after the procedure. Most patients achieved satisfactory intraocular pressure control without topical therapy(Table 4).

Table 4. Antiglaucoma medication requirement before and after surgery

Number of medications	Preoperative n (%)	Postoperative n (%)
0	0 (0)	15 (71.4)
1	6 (28.6)	5 (23.8)
≥2	15 (71.4)	1 (4.8)

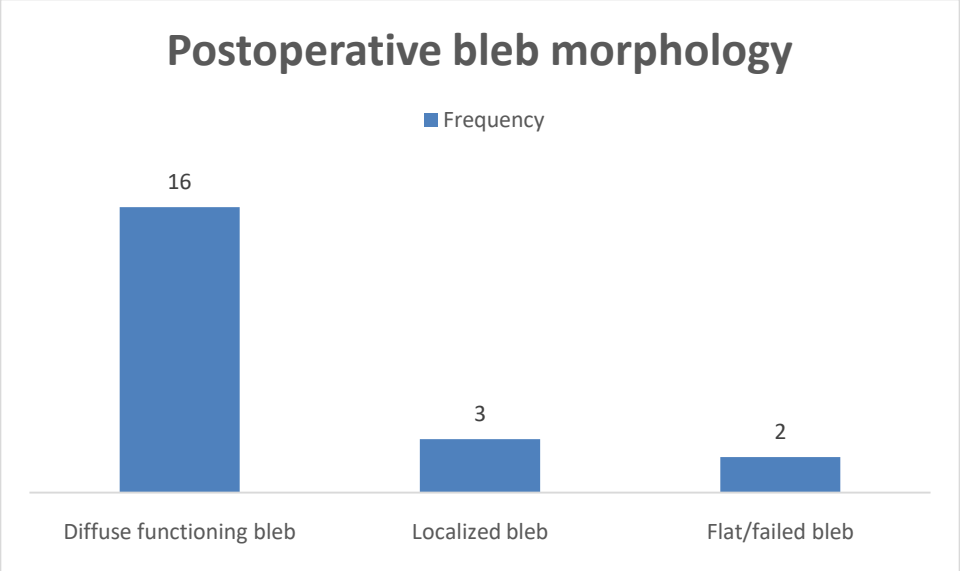


Graph 4. Antiglaucoma medication requirement before and after surgery

Postoperative bleb morphology:-
The majority of eyes developed diffuse, well-functioning blebs postoperatively, suggesting favorable modulation of wound healing. Only a small proportion demonstrated localized or failed blebs(Table 5).

Table 5. Postoperative bleb morphology (n = 21)

Bleb type	Frequency	Percentage (%)
Diffuse functioning bleb	16	76.2
Localized bleb	3	14.3
Flat/failed bleb	2	9.5

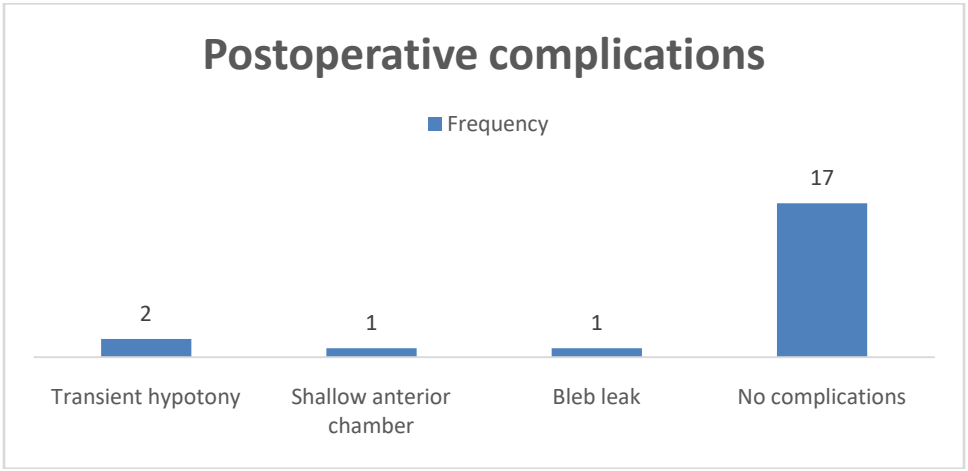


Graph 5. Postoperative bleb morphology

Postoperative complications:-
Postoperative complications were infrequent and largely self-limiting. Most patients completed follow-up without any adverse events(Table 6).

Table 6. Postoperative complications

Complication	Frequency	Percentage (%)
Transient hypotony	2	9.5
Shallow anterior chamber	1	4.8
Bleb leak	1	4.8
No complications	17	81.0

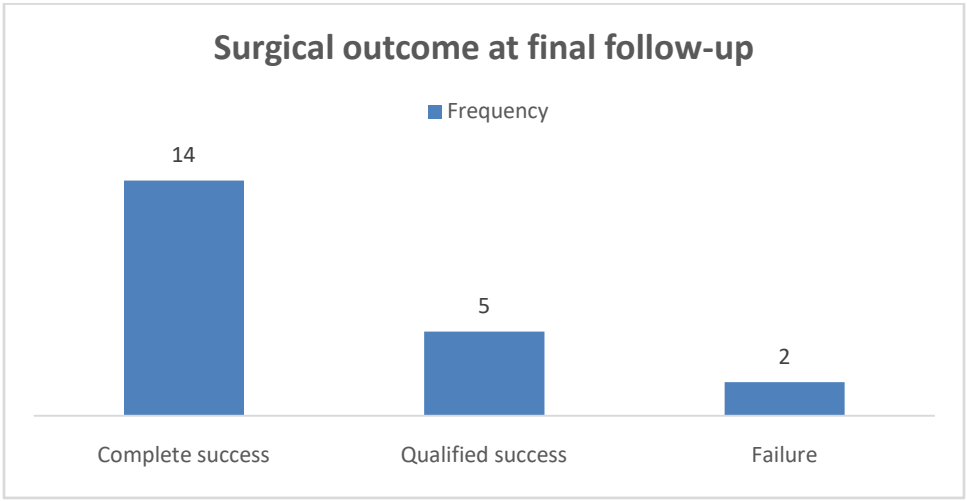


Graph 6. Postoperative complications

Surgical outcome at final follow-up:-
A high rate of complete surgical success was achieved at final follow-up. Failure was observed in only a small subset of patients(Table 7).

Table 7. Surgical outcome at final follow-up

Outcome category	Frequency	Percentage (%)
Complete success	14	66.7
Qualified success	5	23.8
Failure	2	9.5



Graph 7. Surgical outcome at final follow-up

Discussion:-

Glaucoma remains one of the leading causes of irreversible blindness worldwide, and reduction of intraocular pressure (IOP) remains the only proven strategy to slow disease progression [11]. Trabeculectomy is considered the gold standard surgical procedure for glaucoma when medical therapy fails to achieve adequate pressure control. However, postoperative fibrosis and scarring of the filtering bleb remain major causes of surgical failure. To overcome this limitation, antifibrotic agents such as Mitomycin-C (MMC) and biological adjuncts like amniotic membrane transplantation (AMT) have been increasingly used to improve surgical outcomes. The present study evaluated the outcomes of sub-tenon MMC-augmented trabeculectomy with amniotic membrane transplantation in glaucoma patients and demonstrated significant reduction in IOP, decreased requirement of antiglaucoma medications, favorable bleb morphology, and a high rate of surgical success.In the present study, most patients were above 50 years of age, with a slight male predominance. This finding is consistent with the known epidemiology of glaucoma, which is more prevalent among older individuals due to age-related degeneration of the optic nerve and trabecular meshwork changes. Similar demographic patterns have been reported in many clinical studies evaluating surgical outcomes in glaucoma patients, where the majority of individuals undergoing trabeculectomy belong to middle-aged or elderly age groups.

Regarding the type of glaucoma, primary open-angle glaucoma (POAG) constituted the majority of cases (76.2%) in this study, followed by primary angle-closure glaucoma (PACG). This distribution is comparable with previously published surgical series where POAG represents the most common indication for trabeculectomy. The chronic progressive nature of POAG often leads to inadequate control with medications alone, necessitating surgical intervention.One of the key findings of the present study was the significant reduction in intraocular pressure following surgery. The mean preoperative IOP of 28.4 mmHg decreased to 14.2 mmHg at one month and further to 13.6 mmHg at three months postoperatively. This substantial reduction demonstrates the effectiveness of trabeculectomy combined with MMC and amniotic membrane transplantation in controlling IOP. Similar outcomes have been reported in earlier studies. A prospective study reported that trabeculectomy augmented with MMC and AMT reduced mean IOP from 41.9 mmHg to approximately 12.1 mmHg, indicating a reduction of more than 70% [12]. Another clinical study evaluating trabeculectomy with MMC and AMT also demonstrated significant reduction in IOP from around 30.2 mmHg preoperatively to 11.6 mmHg postoperatively [11]. These findings support the results of the present study and highlight the strong pressure-lowering effect of MMC-augmented trabeculectomy with AMT.

Another important outcome observed in this study was the reduction in the need for antiglaucoma medications following surgery. Preoperatively, most patients required two or more medications to control IOP, whereas postoperatively 71.4% of patients required no medications. This reduction indicates successful establishment of a functioning filtration pathway and adequate aqueous humor drainage. Similar findings have been reported in previous studies where trabeculectomy with MMC significantly reduced the need for postoperative medications while maintaining effective IOP control [13]. Furthermore, a systematic review concluded that the addition of amniotic membrane transplantation to trabeculectomy may enhance surgical success and reduce postoperative medication requirements [9].Bleb morphology is another critical factor influencing the long-term success of trabeculectomy. In the present study, diffuse functioning blebs were observed in 76.2% of cases, indicating favorable wound healing and effective filtration. Only a small number of patients developed localized or failed blebs. Previous studies have demonstrated that amniotic membrane acts as a biological scaffold with anti-inflammatory and antifibrotic properties, which help regulate wound healing and prevent excessive subconjunctival scarring. A clinical study reported that eyes undergoing trabeculectomy with AMT developed healthier and more diffuse blebs compared to conventional trabeculectomy [12]. Similarly, another study showed that AMT reduced the incidence of avascular cystic blebs and improved overall bleb survival [14].

Postoperative complications in the present study were minimal. Transient hypotony was observed in two patients, while shallow anterior chamber and bleb leak occurred in one patient each. The majority of patients (81%) did not develop any complications. This low complication rate is comparable with findings from previous studies. Evidence suggests that the use of AMT during trabeculectomy may reduce certain postoperative complications such as flat anterior chamber and excessive fibrosis, thereby improving overall surgical safety [9]. Additionally, amniotic membrane provides anti-inflammatory and wound-healing properties that help stabilize the filtration site and promote favorable postoperative outcomes [15].In terms of surgical outcomes, complete success was achieved in 66.7% of patients, while qualified success was observed in 23.8%, resulting in an overall success rate exceeding 90%. These findings are comparable to earlier studies reporting success rates between 85% and 94% for

trabeculectomy combined with amniotic membrane transplantation (Moon & Lee, 2020); (Kim et al., 2022) [11,14]. These comparable outcomes further validate the effectiveness of the surgical technique used in the present study.
The findings of this study demonstrate that sub-tenon MMC-augmented trabeculectomy combined with amniotic membrane transplantation is an effective and safe surgical approach for the management of glaucoma. The procedure provides significant IOP reduction, reduces medication dependence, promotes favorable bleb morphology, and achieves high surgical success with minimal complications.

Conclusion:-

Trabeculectomy augmented with sub-tenon mitomycin-C and amniotic membrane transplantation demonstrated effective and sustained intraocular pressure reduction with a high rate of complete surgical success and minimal postoperative complications. The combined approach resulted in favorable bleb morphology and significant reduction in antiglaucoma medication dependence. These findings suggest that this technique offers a safe, reproducible, and biologically advantageous modification of conventional trabeculectomy. Larger studies with longer follow-up are required to confirm long-term efficacy and durability.

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