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COMPARISON OF EFFICACY AND SAFETY OF 0.2 MG/ML AND 0.4 MG/ML OF MITOMYCIN-C IN EYES UNDERGOING TRABECULECTOMY

Ophthalomology

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ABSTRACT

Background: Trabeculectomy is the standard surgical treatment for glaucoma. Adjunctive Mitomycin-C improves outcomes, but the optimal concentration remains debated.**Aim:**To compare the efficacy and safety of 0.2 mg/ml and 0.4 mg/ml Mitomycin-C in trabeculectomy. **Materials and Methods:**This observational comparative study included 100 glaucoma patients divided into two groups of 50 each. Group 1 underwent trabeculectomy with 0.2 mg/ml Mitomycin-C and Group 2 with 0.4 mg/ml. Preoperative assessment included intraocular pressure (IOP), visual acuity, and optic disc evaluation. Postoperative follow-up was done up to 6 months. Outcomes assessed were IOP reduction, bleb morphology, and complications.**Results:** Both groups showed significant IOP reduction. On day 1, IOP was significantly lower in Group 2 ($p < 0.05$), while no significant difference was observed at 1 week, 1 month, and 3 months. At 6 months, Group 1 showed significantly lower IOP ($p < 0.05$). The 0.4 mg/ml group had more elevated blebs and higher incidence of complications such as hypotony and bleb leaks, though not statistically significant. **Conclusion:** Both concentrations are effective; however, 0.2 mg/ml provides more stable long-term IOP control with fewer complications and may be preferred in routine practice.

KEYWORDS

Glaucoma, Trabeculectomy, Mitomycin-c, Intraocular Pressure, Bleb Morphology, Antifibrotic Agents

INTRODUCTION

Glaucoma is a progressive optic neuropathy characterized by irreversible damage to the optic nerve head and corresponding visual field loss. It remains one of the leading causes of irreversible blindness worldwide. Elevated intraocular pressure (IOP) is the most significant modifiable risk factor in the development and progression of glaucoma, and its reduction forms the cornerstone of management.[1]

When medical and laser therapies fail to achieve adequate IOP control, surgical intervention becomes necessary. Among the various surgical options, Trabeculectomy remains the gold standard procedure for lowering intraocular pressure in patients with glaucoma.[2] The procedure involves the creation of a guarded fistula that allows aqueous humor to drain from the anterior chamber to the subconjunctival space, forming a filtering bleb.[3]

Despite its effectiveness, the long-term success of trabeculectomy is often limited by postoperative wound healing and subconjunctival fibrosis, which can lead to bleb failure and inadequate IOP control. Fibroblast proliferation and extracellular matrix deposition at the surgical site play a critical role in this scarring process.[4] Therefore, modulation of wound healing has become an essential component in improving surgical outcomes.Antimetabolite agents, particularly Mitomycin-C, have been widely used as adjuncts in trabeculectomy to inhibit fibroblast proliferation and reduce postoperative scarring.[5] Mitomycin-C is an alkylating agent that suppresses DNA synthesis, thereby preventing fibroblast replication and enhancing bleb survival.[6] Its intraoperative application has been shown to significantly improve surgical success rates, especially in high-risk cases.[7]

Fig 1: Mitomycin-C

However, the use of mitomycin-C is not without complications. Higher concentrations and prolonged exposure have been associated with adverse effects such as hypotony, bleb leaks, thin avascular blebs, choroidal detachment, and increased risk of late-onset endophthalmitis.[8] These complications necessitate careful selection of dosage and exposure time to achieve an optimal balance between efficacy and safety.

Various concentrations of mitomycin-C have been employed in clinical practice, most commonly ranging from 0.2 mg/ml to 0.4 mg/ml. While higher concentrations may provide better IOP control by more effectively inhibiting fibrosis, they may also increase the risk of complications. Conversely, lower concentrations may offer a safer profile but with potentially reduced efficacy.[9] [10]

Given these considerations, there remains ongoing debate regarding the optimal concentration of mitomycin-C that provides maximum efficacy with minimal complications. Therefore, the present study was undertaken to compare the efficacy and safety of 0.2 mg/ml and 0.4 mg/ml mitomycin-C in patients undergoing trabeculectomy, with the aim of determining the most appropriate concentration for achieving favorable surgical outcomes.

Aims and Objectives

To compare the efficacy and safety of two concentrations of Mitomycin-C (0.2 mg/ml and 0.4 mg/ml) in eyes undergoing Trabeculectomy.

Materials and Methods

Study Design and Setting

This observational comparative study was conducted at the Regional Institute of Ophthalmology, Government Medical College, Amritsar, over a period of 12 months after obtaining approval from the Institutional Ethics Committee.

Study Population

The study included patients diagnosed with glaucoma and scheduled for trabeculectomy with Mitomycin-C.

Inclusion Criteria

Patients aged ≥18 years diagnosed with primary open-angle glaucoma or primary angle-closure glaucoma, or those showing evidence of pressure-induced optic nerve damage (progressive optic disc cupping or visual field loss) despite controlled intraocular pressure, were included. Both sexes were considered.

Exclusion Criteria
Patients with secondary, congenital, or developmental glaucoma; prior ocular surgery or laser procedures; active or chronic inflammatory eye disease; conjunctival scarring; and those unwilling or unable to comply with follow-up were excluded.

Sample Size and Grouping
A total of 100 patients were enrolled and randomly allocated into two groups of 50 each:
- **Group 1:** Trabeculectomy with 0.2 mg/ml Mitomycin-C
- **Group 2:** Trabeculectomy with 0.4 mg/ml Mitomycin-C

Preoperative Evaluation
All patients underwent detailed history taking and general physical examination. Comprehensive ocular examination included slit lamp evaluation, visual acuity assessment, fundus examination, gonioscopy (Shaffer's grading), intraocular pressure measurement using Goldmann applanation tonometer, visual field analysis using Humphrey Visual Field Analyzer, and central corneal thickness measurement.

Surgical Technique
After obtaining informed consent, standard trabeculectomy was performed under peribulbar anesthesia. A fornix-based conjunctival flap and partial thickness scleral flap were created, followed by trabeculectomy and peripheral iridectomy.

Mitomycin-C was applied subconjunctivally using a soaked sponge for 2 minutes:
- 0.2 mg/ml in Group 1
- 0.4 mg/ml in Group 2

The area was irrigated with Ringer lactate, and the scleral flap and conjunctiva were sutured with 8-0 vicryl.

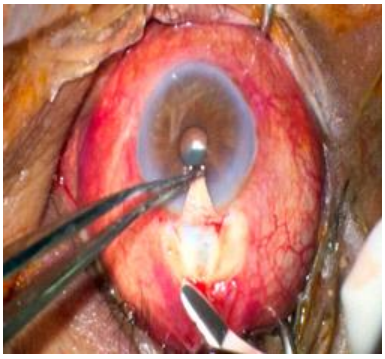


Fig 2 Partial-thickness triangular scleral flap being fashioned with a crescent knife

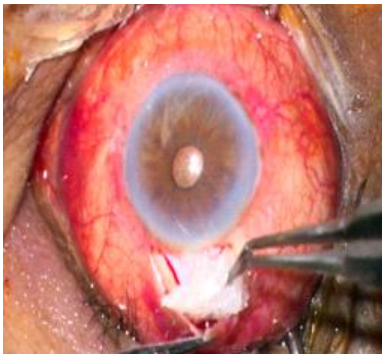


Fig 3 Mitomycin-C soaked sponge being applied to the scleral bed (bleb area)

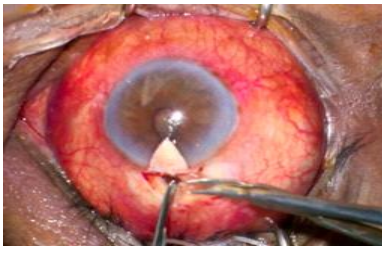


Fig 4: Surgical iridectomy being performed using Vannas scissors

Postoperative Management and Follow-up
Postoperatively, patients received topical antibiotic-steroid combination for 6 weeks and cycloplegics for 1 week. Follow-up was conducted on day 1, day 7, 1 month, 3 months, and 6 months.

At each visit, visual acuity, intraocular pressure, and slit lamp examination findings (including bleb morphology and anterior chamber depth) were recorded. Bleb assessment was performed using the Indiana Bleb Appearance Grading System.

RESULTS
The majority of patients in both groups were above 50 years of age, with the highest proportion in the 51–60 years age group (46.0% in Group 1 and 38.0% in Group 2), followed by those older than 60 years (40.0% and 42.0%, respectively). Gender distribution showed a male predominance in both groups (68.0% in Group 1 and 62.0% in Group 2). There was no statistically significant difference in age or gender distribution between the two groups ($p > 0.05$), indicating comparable baseline demographic characteristics.(Table 1)

Primary open-angle glaucoma (POAG) was the most common type in both groups, accounting for 70% of cases in Group 1 and 66% in Group 2, while primary angle-closure glaucoma (PACG) constituted 30% and 34%, respectively. Preoperative best corrected visual acuity (BCVA) showed that most patients had moderate to severe visual impairment, with a similar distribution across both groups. The difference in glaucoma type distribution was statistically insignificant ($p = 0.668$), suggesting comparable clinical profiles.(Table 2)

The majority of patients in both groups had a cup–disc ratio between 0.6 and 0.7 (64.0% in Group 1 and 58.0% in Group 2), followed by those with a ratio greater than 0.7. The mean cup–disc ratio was 0.69 ± 0.10 in Group 1 and 0.63 ± 0.12 in Group 2. The difference between groups was not statistically significant ($p = 0.653$), indicating similar optic nerve damage at baseline.(Table 3)

Both groups demonstrated a significant reduction in intraocular pressure (IOP) following surgery. On postoperative day 1, mean IOP was significantly lower in Group 2 (15.2 ± 2.52 mmHg) compared to Group 1 (16.8 ± 2.12 mmHg) ($p < 0.05$). At 1 week, 1 month, and 3 months, IOP values were comparable between the groups with no statistically significant differences ($p > 0.05$). However, at 6 months, Group 1 showed significantly lower IOP (11.1 ± 2.32 mmHg) compared to Group 2 (12.6 ± 2.6 mmHg) ($p < 0.05$). Overall, both concentrations were effective in reducing IOP, with significant differences observed at early and late follow-up. (Table 4)

Postoperative complications were observed in both groups, with a slightly higher incidence in Group 2. Hypotony was the most common complication (8.0% in Group 1 vs 14.0% in Group 2), followed by shallow anterior chamber and bleb leaks. Rare complications such as hyphema and choroidal detachment were seen only in Group 2. However, the overall difference in complication rates between the groups was not statistically significant ($p = 0.383$), indicating comparable safety profiles. (Table 5)

Fig 2:Post op day 1
Bleb grading H2 E3 V2 S0
Group 1 (Mitomycin-C 0.2mg/ml)

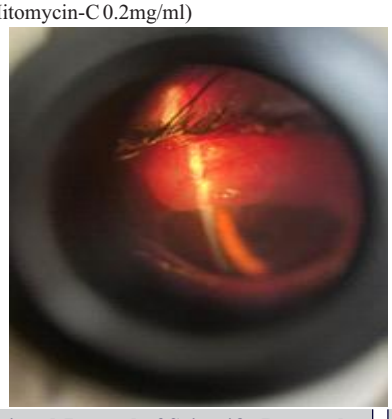


Fig 3:Post op day 1
Bleb grading H1 E2 V3 S0
Group 1 (Mitomycin-C 0.2mg/ml)

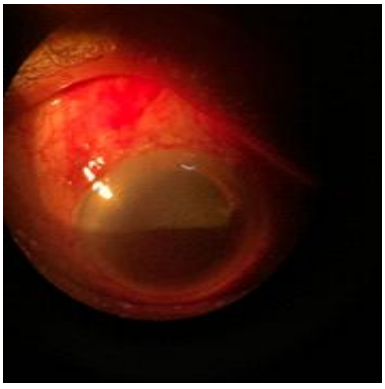
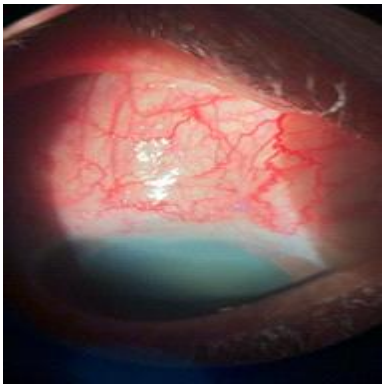


Fig 4:Post op day 1
Bleb grading H1 E2 V3 S0
Group 1 (Mitomycin-C 0.2mg/ml)



DISCUSSION

The present study evaluated and compared the efficacy and safety of two concentrations of Mitomycin-C (0.2 mg/ml and 0.4 mg/ml) as an adjunct to Trabeculectomy in patients with glaucoma.

The majority of patients in both groups were above 50 years of age, with a male predominance, which is consistent with previous studies highlighting increasing prevalence of glaucoma with advancing age.[11] [12] Primary open-angle glaucoma (POAG) was the most common type observed, in agreement with global epidemiological trends.[13] Baseline clinical parameters, including preoperative intraocular pressure (IOP), best corrected visual acuity (BCVA), and cup–disc ratio, were comparable between the two groups, indicating homogeneity of the study population.[14]

Both concentrations of Mitomycin-C resulted in significant reduction of IOP postoperatively. The 0.4 mg/ml group showed a significantly lower IOP on day 1, suggesting a stronger early antifibrotic effect. However, during subsequent follow-ups at 1 week, 1 month, and 3 months, the difference between groups was not statistically significant. At 6 months, the 0.2 mg/ml group demonstrated significantly lower IOP compared to the 0.4 mg/ml group, indicating better long-term stability. This suggests that while higher concentrations may provide rapid early IOP control, lower concentrations may offer more sustained outcomes by allowing a more balanced wound healing response.

These findings are consistent with earlier studies by Chen et al. and Kitazawa et al., which demonstrated improved surgical success with Mitomycin-C but did not show clear long-term superiority with higher concentrations. [15] [16] Additionally, excessive inhibition of fibroblast activity at higher doses may lead to suboptimal bleb function over time. [17]

The present study showed that higher concentration (0.4 mg/ml) was associated with more elevated and extensive blebs, whereas the 0.2 mg/ml group demonstrated more moderate and stable bleb characteristics. Increased avascularity observed in the higher concentration group reflects stronger antifibrotic action.

Postoperative complications such as hypotony, shallow anterior chamber, and bleb leaks were more frequent in the 0.4 mg/ml group, although the difference was not statistically significant. These findings are in agreement with previous studies reporting higher complication rates with increased Mitomycin-C concentrations due to impaired wound healing and formation of thin, avascular blebs. [18,19]

The findings of the present study suggest that both concentrations of Mitomycin-C are effective in enhancing trabeculectomy outcomes. However, while 0.4 mg/ml provides a stronger early effect, 0.2 mg/ml appears to offer a better balance between efficacy and safety, with sustained IOP reduction and fewer complications.

CONCLUSION

Both 0.2 mg/ml and 0.4 mg/ml concentrations of Mitomycin-C are effective adjuncts in trabeculectomy for reducing intraocular pressure. The higher concentration (0.4 mg/ml) demonstrates a more pronounced early IOP reduction but is associated with a relatively higher incidence of complications and less favourable bleb morphology. In contrast, 0.2 mg/ml provides more stable long-term IOP control with a better safety profile. Therefore, 0.2 mg/ml Mitomycin-C may be preferred in routine clinical practice for achieving an optimal balance between efficacy and safety.

CONFLICT OF INTEREST: NIL
FUNDING: NIL

TABLES

TABLE 1 Baseline Demographic Characteristics

Parameter	Category	Group 1 (0.2 mg/ml) n (%)	Group 2 (0.4 mg/ml) n (%)	p-value
Age (years)	18–30	0 (0.0%)	1 (2.0%)	0.798
	31–40	3 (6.0%)	4 (8.0%)	
	41–50	4 (8.0%)	5 (10.0%)	
	51–60	23 (46.0%)	19 (38.0%)	
	>60	20 (40.0%)	21 (42.0%)	
Gender	Male	34 (68.0%)	31 (62.0%)	0.529
	Female	16 (32.0%)	19 (38.0%)	

TABLE 2 Clinical Profile of Patients

Parameter	Category	Group 1 n (%)	Group 2 n (%)	p-value
Type of Glaucoma	POAG	35 (70%)	33 (66%)	0.668
	PACG	15 (30%)	17 (34%)	—
BCVA	<6/60	16 (32.0%)	15 (30.0%)	
	6/60–6/36	14 (28.0%)	16 (32.0%)	
	6/24–6/18	12 (24.0%)	14 (28.0%)	
	6/12–6/6	8 (16.0%)	5 (10.0%)	

TABLE 3 Preoperative Optic Nerve Status

Cup–Disc Ratio	Group 1 (0.2 mg/ml) n (%)	Group 2 (0.4 mg/ml) n (%)
<0.3	1 (2.0%)	1 (2.0%)
0.3–0.5	4 (8.0%)	8 (16.0%)
0.6–0.7	32 (64.0%)	29 (58.0%)
>0.7	13 (26.0%)	12 (24.0%)
Total	50 (100%)	50 (100%)

Mean ± SD:
Group 1: 0.69 ± 0.10
Group 2: 0.63 ± 0.12
p = 0.653 (Insignificant)

Table 4: Postoperative Outcomes

Follow-up	Group 1 (Mean ± SD)	Group 2 (Mean ± SD)	p-value
Day 1	16.8 ± 2.12	15.2 ± 2.52	0.00*
1 Week	15.2 ± 2.1	14.6 ± 2.5	0.080
1 Month	14.4 ± 2.5	13.5 ± 2.6	0.060
3 Months	12.5 ± 2.3	12.2 ± 2.7	0.554
6 Months	11.1 ± 2.32	12.6 ± 2.6	0.00*

Table 5: Postoperative Complications

Complication	Group 1 n (%)	Group 2 n (%)
Hypotony	4 (8.0%)	7 (14.0%)
Hyphema	0 (0.0%)	1 (2.0%)
Shallow AC	3 (6.0%)	5 (10.0%)

Bleb Leak	2 (4.0%)	4 (8.0%)
Choroidal Detachment	0 (0.0%)	1 (2.0%)

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