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Clinical Evaluation of injectable Mitomycin-C in Trabeculectomy for Glaucoma Patients

Mehvash Hussain, Sania Ishaque, Fizzah Farooq, Muhamamd Muneer Quraishy

ABSTRACT

Objective: To evaluate the efficacy of injectable Mitomycin-C (MMC) administered at the bleb site during trabeculectomy in patients with glaucoma.

Study Design and Setting: This cross-sectional study was conducted at the Department of Ophthalmology, Unit-1, Dow Medical College, Dr. Ruth K. M. Pfau Civil Hospital Karachi, and SMBB Trauma Centre from January to June 2022.

Methodology: Data were obtained through non-probability consecutive sampling. After obtaining informed consent, patients meeting the diagnostic criteria and undergoing trabeculectomy were enrolled. Demographic data, including age, gender, and eye laterality, were recorded. Efficacy was defined as a postoperative intraocular pressure (IOP) reduction of more than 30% compared to preoperative values. Ophthalmic examinations included visual acuity, refraction, slit-lamp biomicroscopy, gonioscopy, and IOP measurement. The effect of MMC across different subgroups was analyzed using an independent t-test, with a p-value =0.05 considered statistically significant.

Results: A total of 62 patients underwent trabeculectomy with injectable MMC. The mean preoperative IOP was 32.81 ± 13.13 mmHg, while the mean postoperative IOP at one month was 13.88 ± 5.90 mmHg, indicating a significant reduction (p = 0.01). Over 30% IOP reduction was achieved in the majority of cases. Only five patients developed postoperative complications, including fibrosis and flat blebs.

Conclusion: Injectable Mitomycin-C is an effective adjunctive therapy in trabeculectomy, significantly lowering intraocular pressure and enhancing surgical success while minimizing postoperative scarring and surgical failure.

Key Words: Efficacy, Glaucoma, Intraocular Pressure (IOP), Mitomycin C and Trabeculectomy

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INTRODUCTION

Glaucoma is a specific type of optic neuropathy which is defined by visual field loss, optic disc damage, and typically but not always increased IOP. Glaucoma has been a major cause of deterioration of vision especially in the developed world. Refractory glaucoma refers to glaucoma that is resistant to conventional treatment. In Karachi, Pakistan estimated 9.6% of the population have a confirmed diagnosis of glaucoma[1]. Globally, glaucoma is estimated to impact 79.6 million people till 2020.[2] Trabeculectomy is a type of filtration surgery commonly performed to reduce intraocular pressure (IOP) in glaucoma patients. It establishes an alternative pathway for aqueous fluid to drain into the subconjunctival space.[3] It is commonly believed that vision can be maintained in glaucomatous eyes if eye pressure is kept below the level at which injury to the optic nerve has previously taken place. In the past, the success rate of this surgery was restricted due to postoperative fibroblast proliferation and scarring of the filtering bleb. Various adjunctive modifications, including antimetabolites like MMC and anti-VEGF agents, have been utilized to prevent scarring.[4]

Trabeculectomy is a surgical procedure used to treat glaucoma by creating an additional channel for the filtration of aqueous humor. The success of this procedure relies heavily on the natural ocular wound healing response. Research has shown that the inhibition of fibroblast proliferation is crucial for successful filtering surgery.[5]

Mitomycin C (MMC) is an anticancer agent obtained from the soil bacterium *Streptomyces caespitosus* that acts as a

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Deoxyribonucleic acid cross-linker and leads to inhibition the cascade of fibroblast growth.[6] Mitomycin C is an antiproliferative agent that has been widely used as an adjunct in trabeculectomy surgery. By inhibiting fibroblast proliferation, Mitomycin C helps to prevent scarring and promote the formation of a functional filtering bleb.[7] Mitomycin C is commonly used in trabeculectomy to minimize episcleral fibrosis in post-operative period and prevent failure of bleb caused by scarring during the healing of wound.[8] Mitomycin C enhances the outcomes of glaucoma filtration surgery (trabeculectomy) by ensuring effective long-term intraocular pressure (IOP) control. Mitomycin C has been proven to optimize the success rate of trabeculectomy in patients with refractory glaucoma, particularly those with: African ancestry, uveitis and congenital glaucoma.[9] While Mitomycin C is an effective adjunct in trabeculectomy, its use can be associated with complications such as: thin-walled blebs, bleb leaks and scleromalacia.[10] Therefore, careful consideration of Mitomycin C dosage and exposure time is essential to minimize the likelihood of experiencing adverse effects.

Mitomycin-C is applied to the tissues using surgical sponges during the procedure, but alternate method of application is also used in which Mitomycin C can be given in injectable form.

Mitomycin C is applied using a sponge, which is soaked in the medication and placed on the eye in subconjunctival space for 5 minutes. Both the dose and time for sponge can be altered. Hence, this method is still widely used, but it can be associated with issues like: varying concentrations and sizes of sponges[11], inconsistent dosing, increased risk of complications and difficulty in determining the exact amount of medication delivered.

Injectable Mitomycin C is a relatively new approach that offers a more precise and controlled delivery of the medication. It also proves to assist in better IOP control and lesser surgical complication. Injectable method involves injecting Mitomycin C directly into the subconjunctival space, allowing for: precise dosing and reduced risk of overdose[11], targeted delivery to the specific area of the eye and reduced risk of complications associated with sponge application.[12]

Mitomycin C injectible is prepared with dilution in dose of 0.1ml of 0.2mg/ml MMC with 0.1 ml of 1% lidocaine. Subtenon injection of Mytomycin C hydro dissects the conjunctiva off the sclera, aiding in flap dissection[11].

Qualitative and quantitative analysis using optical coherence tomography (OCT) revealed blebs arising after MMC enhanced trabeculectomy had optimal functionality, characterized by a low reflectivity index and a cystoid pattern. Conversely, trabeculectomies performed without MMC exhibited mixed OCT patterns (layered or diffuse), which correlated with high infrared reflectivity and reduced functionality.

Rationale of this study is that injectable Mitomycin C is alternate method which is less time consuming, easier to inject in the desired tissue and can be spread to make a uniform bleb. Dose of MMC used is less than sponge method resulting in less harm to the adjacent tissues due to controlled delivery.

METHODOLOGY

A cross-sectional study was undertaken within the facility of Department of Ophthalmology and Visual Sciences, Dr Ruth K.M.Pfau, Civil Hospital Karachi, Shaheed Mohtarrma Benazir Bhutto (SMBB) Trauma Center, Dow Univeristy of Health Sciences (DUHS), Karachi. Study period was from January 2022 to June 2022. Ethical approval for the study was granted by the Institutional Review Board (IRB) of Dow University of Health Sciences (IRB/DUHS/Approval /2022/2118). All participants were provided with written consent to get it signed before registering in the research study process. Confidentiality of the data of participants was ensured. Men and women aged 20–70 years with primary or secondary glaucoma were included if they were scheduled for trabeculectomy (alone or with cataract surgery), especially if they were not taking medicines regularly or wanted surgery only to control eye pressure. Patients were not included if they had other health problems like asthma, high blood pressure, or diabetes, if they had eye surgery for reasons other than glaucoma, or if they had previous glaucoma operations such as valve, shunt, or goniotomy procedures.

Sample size of this study was determined using open EPI sample size calculator. Taking treatment success rate of trabeculectomy augmented with MMC reported to be 78.7% according to study by Qin ZX et al, margin of error 5%, confidence level 95%, sample size was calculated to be 65. Hence we enrolled 62 patients for our study.[13]

Non probability consecutive sampling was taken into account. Patients were usually diagnosed in out patient department (OPD) where they were assessed for screening of glaucoma. Later gonioscopy was done in investigation room. They were booked for surgery. After the pre requisite pre op assessment of lab tests apart from ocular assessment they were given a date for augmented trabeculectomy. Pre op lab tests included complete blood count (CBC), blood pressure monitoring, random blood sugar (RBS) and screening for viral markers (Hepatitis B and Hepatitis C). All participants had to go through extensive and crisp ophthalmic assessments of vision, refraction, slit lamp bio microscopy, gonioscopy, IOP measurement using applanation tonometry and fundoscopy. All surgeries were performed by a single experienced surgeon in the same surgical center under topical anesthesia to rule out surgeon factor. Several steps were ensured to improve the effectiveness of the surgical procedure. In order to avoid the leakage to the surface, incision for trabeculectomy was made small. A blunt 30-gauge cannula was advanced 7 to 8 mm from the limbus and the MMC solution was delivered subconjunctivally in a calculated dose on 0.2mg/ml, behind the intended site of the surgical flap. The conjunctival entry site was delicately compressed using a surgical sponge (free of MMC) to prevent any escape of the injected MMC. Afterwards, the blunt cannula was removed and a sponge soaked in normal saline was used to spread the solution more widely over the area. The conjunctival periotomy was then completed. Hemostasis was achieved with bipolar cautery. Generous irrigation with balanced salt solution was followed by.

Trabeculectomy was carried out using the standard technique. A 3 × 3 mm scleral flap was outlined with a diamond knife preset to a depth of 300 ìm. Dissection of the partial-thickness scleral flap was performed using a 57 blade. A paracentesis was made in the temporal cornea using a 1-mm side-port blade. A sclerotomy was created with a Kelly punch, followed by the formation of a peripheral iridectomy using DeWecker scissors. The scleral flap was then secured in position with two fixed 10-0 nylon sutures (non-releasable) at its corners.

Balanced salt solution was introduced into the anterior chamber, and the surgeon confirmed flow through the trabeculectomy site using surgical sponges. If the flow appeared excessive, additional sutures were applied. Once a satisfactory flow was established and the anterior chamber remained stable, the conjunctiva was closed with a continuous 9-0 nylon suture on a vascular needle. At the end of the procedure, the conjunctival incision was carefully inspected to ensure it was watertight.

Patients were followed in out patient department a day after surgery for assessment. In the post op assessment intraocular pressure was measured weekly, after 15 days and then after one month for final outcome. Pre operatively intraocular pressure was recorded. While taking IOP each time several precautionary measures were taken. Intraocular pressure was taken after instilling anesthetic drops (lignocaine) and waiting for 1-2 min for the effect of anesthesia to start. Fluorescein strip was used to stain cornea and intraocular pressure measured under blue cobalt filter. It was ensured that pupil is not dilated. Each time same consultant took intraocular pressure so that extend of compression while place applanation prism was homogenous. A total of three readings were taken on different intervals and mean calculated. This is a universally accepted criterion of measuring to eliminate any human error on part of patient and consultant both. Excessive pressure, squeezing and abnormal tear film can change the values in one reading A reduction of more than 30% between preoperative and postoperative intraocular pressure was defined as efficacy as proven by study by Do JL et al which concluded mean change of pre and post operative intraocular pressure of greater than 30% after use of mitomycin-C as effective success measurement tool.[14]

The mean preoperative intraocular pressure (IOP) in this study was 32.81±13.13mmHg, while the mean postoperative IOP at one month after surgery was 13.88±5.90mmHg. The p-value was 0.01, as shown in Table 1. Stratification of gender concerning efficacy showed that among males, 40 (70.2%) achieved efficacy, while 1 (20%) did not. Among females, 17 (29.8%) achieved efficacy, whereas 4 (80%) did not. The p-value was 0.04, as tabulated in Table 2

Stratification of age in relation to efficacy revealed that 21 patients (36.8%) in the 20-45 years age group and 36 patients (63.2%) in the 46-70 years age group achieved efficacy. In contrast, 3 patients (60%) in the 20-45 years age group and 2 patients (40%) in the 46-70 years age group did not achieve

Figure-1: Efficacy Distribution (n=62)

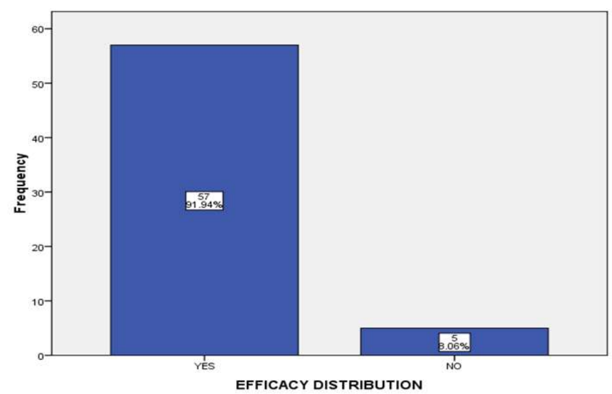

Table-1 : Mean Preoperative And Postoperative Intraocular Pressure (N=62)

Intra ocular pressure at 1 week		
Pre- Operative IOP	Post-Operative IOP	p-Value
25.1±10.34	19.78±6.20	0.32
Intra ocular pressure at 2 weeks (mmHg)		
28.1±9.19	16.42±10.2	0.01
Intra ocular pressure at 1 month (mmHg)		
32.81±13.13	13.88±5.90	0.01

Table-2: Efficacy According To Gender

GENDER	**EFFICACY**		**TOTAL**
	YES	NO	
MALE	40 (70.2%)	01 (20%)	41 (66.1%)
FEMALE	17 (29.8%)	04 (80%)	21 (33.9%)
TOTAL	57 (100%)	05 (100%)	62 (100%)
p-VALUE	0.04		

Table-3: Efficacy According To Age Groups (n=62)

AGE	**EFFICACY**		**TOTAL**
	YES	NO	
20-45	21 (36.8%)	03 (60%)	24 (38.7%)
46-70	36 (63.2%)	02 (40%)	38 (61.3%)
TOTAL	57 (100%)	05 (100%)	62 (100%)
p-VALUE	0.28		

efficacy. P-value was 0.28. Results of stratification according to age groups are tabulated in Table 3. Stratification of laterality in reference to efficacy showed that among patients with right eye involvement, 34 (59.6%) achieved efficacy, while 2 (40%) did not. In contrast, among those with left eye involvement, 23 (40.4%) achieved efficacy, whereas 3 (60%) did no. P-value was 0.34.

further stratification was also for outcome efficacy in relation to the socio economic status, concluding that no statistical significance was found as p value = 0.76. Amongst the 5 patients which didn't achieve efficacy 2 patients (3.2%) had flat, a-vascularized bleb and hence were kept on anti-glaucoma drugs for 2 months with close monitoring. Plan for re surgery will be done in future. 2 patients(3.2%) reported to have fibrosis while one patient had siedel test positive on the first post op day. He/she was taken to operation theater the very next day and sutures applied to re secure the bleb. Stratification via t-test showed no significant result for complications as p value of greater than 0.05 was noted.

DISCUSSION

Our study showed that overall efficacy of pre and post op Intra ocular pressure was 91.9%. Multiple clinical trials and research studies have validated the efficacy and safety of mitomycin-C application in sponge soaked and place at the scleral site rather than the injectable form during trabeculectomy. Hence there is shortage of comparative literature especially locally.

et al conducted a retrospective study on 35 and 36 eyes of angle closure and open angle glaucoma respectively that underwent trabeculectomy.[15] Our study evaluated prospectively on a similar comparative sample size of 62 eyes in total.

A study conducted in San Diego, USA, compared sub conjunctival mitomycin C with direct scleral mitomycin C application.[14] The mean age reported was 69.9 ± 13.4 years in the injection group. Results of our study concluded that mean age of inectable group was reported to be 55.14±8.49 years. The comaprison of both studies showed roughly equal mean age in years.

A comprehensive Cochrane review by Wilkins et al., analyzing 11 clinical studies with a total of 698 patients, demonstrated that Mitomycin-C significantly lowers the risk of surgical failure in both primary trabeculectomy and in eyes considered at high. [16] Research on primary trabeculectomy using low-dose MMC showed that intraocular pressure (IOP) remained at or below 15 mmHg in greater than 80% of patients after one year and in 60% after six years. This study followed patient for 12 months. While our study followed patients with post op Intra ocular pressure after only one month of surgery hence results cannot be comparable.

Lester M et al in his study, discussing post operative intraocular pressure after subconjunctival mitomycin-C injecting in non penetrating glaucoma surgeries, concluded that average intraocular pressure before the application of mitomycin-C injections was 17 ± 6.6 mmHg while post operatively intraocular pressure after injectable mitomycin-C after 6 month was 13.9 ± 2.9 mmHg.[17] In our study the mean post operative intraocular pressure came out to be 13.88±5.90 mmHg. This is quiet close to the earlier discussed study.

Annen DJ et al conducted a retroepcetive pilot study that included a majority of high-risk patients reported 84% achievement rate at a one-year follow-up when low dose injectable mitomycin-C of 0.2 mg/mL was applied for five minutes.[18] While our study reported that 57 (91.1%) patients acheived >30% efficacy within 1 month using 0.2mg/ml injectable mitomycin-C. Annen and Stürmer, who used the same mitomycin-C concentration for one minute, found that 88% of cases maintained an intraocular pressure below 21 mmHg after about a year, with 8.8% of cases exhibiting an avascular bleb. Hence the dose of this study was same as the inectable dose that we used and our study results showed avascular bleb in 3.2%.

Singh et al analyzed a consecutive series of 20 eyes that underwent trabeculectomy with intraoperative application of 0.02 mg/mL mitomycin-C, reporting an overall success rate of 85%.[19] Among these cases, two experienced recurrent leaks, while another two developed scleral necrosis, resulting in ciliary body exposure. The authors warned that although rare, such complications can still arise even with lower mitomycin-C doses. They recommended that using reduced mitomycin-C concentrations or placing mitomycin-C in the Sub-Tenon's space without the need for scleral dissection could help mitigate the risk of scleral necrosis. Similarily 2 (3.2%) of our patients had fibrosis and 1 (1.6%) had bleb leak with the adjunctive use of 0.2mg/ml injectable mitomycin-C.

There are other studies too that reported complications with the use of mitomycin C in injectable form. Akova YA et al documented incidence of scleromalacia in two pediatric patients treated with 0.4 mg/cc mitomycin-C for five minutes.[20] Likewise, Fourman described a group of five patients who experienced scleritis within 3 to 24 weeks after receiving mitomycin-C during inferior trabeculectomy.[21] These complications were not found in our study.

Choosing mitomycin injection during trabeculectomy allows ophthalmologists to accurately determine the exact amount of antimetabolite delivered to the surgical site, ensuring consistent dosing for each patient. Additionally, intraoperative injections offer the benefit of broader mitomycin distribution through subconjunctival dissipation, resulting in a wider area of application. There were few shortcomings of our study. Our study is single centered with a smaller sample size. We looked for a single drug augmented in trabeculectomy with a shorter post op assessment of only 1 month. Hence, a multi centered study of a larger population is a necessity in future to interpret surgical complications on a broader aspect. There is also a need of studies to comapare effectiveness of mitomycin with other drugs like 5-fluorouracil that can be augmented in tabeculectomy too. Evaluation of productiveness of standardized pre-configured kits of mitomycin formulations, such as Mitosol is a necessity of future.

LIMITATIONS

There were few shortcomings of our study. Our study is single centered with a smaller sample size. We looked for a single drug augmented in trabeculectomy with a shorter post op assessment of only 1 month. Hence, a multi centered study of a larger population is a necessity in future to interpret surgical complications on a broader aspect. There is also a need of studies to comapare effectiveness of mitomycin with other drugs like 5-fluorouracil that can be augmented in tabeculectomy too. Evaluation of productiveness of standardized pre-configured kits of mitomycin formulations, such as Mitosol is a necessity of future.

CONCLUSIONS

Our study results concluded suggest that the augmentation of injectable Mitomycin-C during trabeculectomy is required for improving surgical outcomes. It enhances the bleb survival and provides better intraocular pressure control, reducing the risk of surgical failure. Injectable Mitomycin-C form also allows for more uniform drug distribution, potentially minimizing complications compared to traditional sponge-applied methods.

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Fizzah Farooq: Writeup
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