Effect on Intraocular Pressure Following Primary Trabeculectomy with and Without Mitomycin C 0.2% in Primary Open Angle Glaucoma

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Abstract-

Objective/Aim: To examine the effect of primary trabeculectomy in POAG with and without MMC 0.2%, we are comparing the IOP response to trabeculectomy with or without MMC 0.2%.

Methods: An experimental prospective study conducted at Chandka Medical College Hospital, Larkana, using the Department of Ophthalmology, was conducted between October 2015 and March 2016. There were 86 eyes of each gender, with ages ranging from 40 to 60 years. There were two groups of patients (02), which were equally divided. A total of 43 patients were involved in Group A, while 43 patients were involved in Group B as well. The test group was treated with MMC 0.2% alongside the trabeculectomy procedure as a primary procedure for three minutes, while the control group was treated with MMC 0.2% only. Both groups were followed for six months. Between October 2015 and March 2016, a study period was conducted.

Results: The total number of patients with POAG I studied was 86 eyes. In group A, trabeculectomy with MMC was carried out on all patients, while in group B, trabeculectomy without MMC was done on all patients. Approximately 25.39±2.42 mmHg of IOP was measured before surgery in Group-A, whereas 26.23±4.23 mmHg was measured in Group B. Among Group-A patients, the IOP was 13.20±3.05 mmHg on day 1, while it was 14.09±4.04 mmHg in Group-B patients. Among the 43 patients in Group A, 41 (95.3%) completed the treatment course. The treatment course was completed by 39 (90.7%) patients in Group B.

Conclusion: In POAG, we found that trabeculectomy with MMC is better at controlling IOP after surgery than trabeculectomy without MMC. The first trabeculectomy procedure with MMC seems to work better than the first trabeculectomy procedure without MMC.

Keywords: Intraocular pressure, Primary Trabeculectomy, mitomycin, primary open angle glaucoma.

I. INTRODUCTION

Slowly progressive optic neuropathy (POAG) is defined by the loss of optic nerve fibers, visual field abnormalities, and an elevated IOP in the absence of secondary glaucoma in the presence of an open anterior chamber angle. Adults usually get this condition in one of their bilateral halves. About 1% of people over the age of 40 have this form of glaucoma, making it the most frequent.[1] Often, MMC 0.2% is used in conjunction with trabeculectomy procedures to prevent postoperative scarring and improve results. Some complications, including increased inflammation and delayed wound healing, have been reported with the use of MMC 0.2%. A comparison of trabeculectomy with and without MMC 0.2% in POAG is therefore needed to determine its efficacy and safety. Anterior chamber aqueous outflow is facilitated by constructing a fistula to the Sub-Tenon space in the trabecular meshwork, which lowers intraocular pressure (IOP). Trabeculectomy has been referred to as the "gold standard" surgical treatment for uncontrolled glaucoma since its inception by Cairns nearly four decades ago. Surgical intervention is the last remaining option if medicinal and laser therapy have failed to provide the desired results.[2] Trabeculectomy has seen a high success rate and low complication rate as a result of advancements in surgical instruments, surgical methods, and the use of anti-metabolites.[3] High IOP, visual field progression, and glaucoma drug inability to manage it are all indications for trabeculectomy surgery. Both elevated IOP and hypotony have the potential to cause postoperative problems, such as: bleb leaking; shallow anterior chamber; bleeding from the wound; choroidal effusion; suprachoroidal hemorrhage; and retinal detachment following trabeculotomy. Produced through the fermentation of Streptomyces caespitose, MMC is an antineoplastic antibiotic.[4] MMC inhibits the synthesis of deoxyribonucleic acid (DNA). Cell development and fibroblast replication are halted by histological studies. Trabeculectomy is an operation that removes the corneal fibroblasts and Tenon's capsule in order to maximize the surgical success and stability of a bleb or fistula.[5] It is a major cause of failure for patients with glaucoma who undergo a trabeculectomy to develop wound fibrosis. Wound fibrosis appears to be primarily a result of fibroblasts in the conjunctiva and Tenon's capsule.[6] Trabeculectomy is being performed by ophthalmologists with the goal of avoiding this reaction so they can achieve better surgical outcomes. To determine the effect of

primary trabeculectomy without MMC 0.2% on intraocular pressure (IOP), a primary trabeculectomy with MMC 0.2% will be compared to a trabeculectomy without MMC 0.2% on POAG. POAG is a chronic, progressive disease characterized by increased IOP, which can lead to irreversible damage of the optic nerve and visual loss. A trabeculectomy improves aqueous outflow and lowers IOP by removing a portion of the trabecular meshwork, a surgical procedure commonly used to treat POAG.

A comparison of primary trabeculectomy with and without MMC 0.2% in POAG will help to determine the optimal treatment approach for managing IOP in this patient population. A study of the two treatment strategies will provide valuable information on their short- and long-term effects on IOP, as well as any complications or additional interventions. In addition to providing evidence-based guidelines for POAG management, the study will contribute to the improvement of patient care in this disease.

II. MATERIAL AND METHODS

Study place and duration

We conducted this prospective study from October 2015 to March 2016 at the Department of Ophthalmology, Chandka Medical College Hospital, Larkana, on 86 POAG patients receiving anti-glaucoma topical medication with uncontrolled IOP. Patients either sex with age range from 40 to 60 years with diagnosed of POAG who were on anti-glaucoma topical medication but IOP was uncontrolled medically were included while Failed Trabeculectomy (Previous Trabeculectomy), Neovascular glaucoma, Juvenile glaucoma, POAG associated with vernal conjunctivitis, Primary open angle glaucoma with dry eye syndrome and Any previous ocular surgery like; Retinal Detachment, Perforated Globe, were not included in this study.

The Sampling size was calculated with proportion of efficacy 84.6% in MMC and 65.4% without MMC. The power test considers 80% and 95% confidence intervals, and the margin of error is highly significant at 0.05. A total of 86 patients were included, divided equally into two groups, each with 43 patients.

Data collection procedure:

There were two groups of patients (A and B), which were equally divided. In group A, the MMC concentration was 0.2%, while in group B, there was no MMC concentration. Each group containing 86 eyes from 86 POAG patients. 43 patients are in each group. The number of patients' present was 44 males and 42 females. Twenty-one man and twenty-two women were in group A. Twenty-three male and twenty-seven female patients were in group B, with 22 (51.2%) involving the left eye, 21 (48.8%) involving the right eye, and 23 men and 20 women in group A.

They were in the 40-60-year-old age bracket. 16 patients in Group A were under the age of 50, while 27 patients in Group A were beyond the age of 50. In Group B, there were 23 patients under the age of 50 and 20 individuals beyond the age of 50. All patients were given a thorough explanation of the procedure and the potential side effects. All patients had a thorough preoperative examination, including a biomicroscopic examination, gonioscopy, dilated fundus examination, and indirect ophthalmoscopy, to ensure that they were in good health prior to surgery, as well as a thorough systemic and ophthalmic examination. Open angle gonioscopy was found in all individuals in both groups (Grade-IV) In addition to surgery, all patients were encouraged to follow up for six months after surgery. They were to follow up on the first day after surgery, the first week after surgery, the first month after surgery, and the third month after surgery.

Data Collection Tool/ Proforma

An SPSS version 17.0 program was used to calculate the data. Numerical variables for males and females were analyzed as means and standard deviations. The effectiveness of each group was determined by its fall in IOP. Using a P value of ≤ 0.05, a Chi-Square test was carried out (highly significant). In order to determine the significance of the differences between the two groups, a standard t-test was used. There were tables and graphs presenting all the data.

Surgical Techniques

Local anesthetic was used during the procedures. There were two injections of xylocain 2 percent (lignocain): 5cc for the face block, and 2.5cc for the Peribulbar area. The entire procedure was carried out under a microscope. A limbal-based conjunctival flap was created in all cases. A rectangular superficial scleral flap was used to perform a guarded filtering technique on each eye. Ten milliliters of water for injection were added to the vial holding 2 milligrams of MMC. A 0.2 mg/ml MMC solution-soaked surgical sponge (4x4mm) was placed between the subtenon and sclera three minutes before dissecting the flap. An irrigation sponge with 100 ml of normal saline was used to rinse and dry the surgical sponge and the entire area. Afterwards, a superficial scleral flap of 4x4 mm was excised at 120 clock and 1mm from the clear cornea. P.I. was conducted on 2 x 1mm deep trabecular blocks in front of the scleral spur. The 2 interrupted 8/0 virgin silk was used to close the superficial scleral flap. The tenon capsule and conjunctival layers were stitched together in two independent layers at 120 clock sclera with continuous 8.0 virgin silk suture. The A/C was reformed and checked for leaks using Ringer's solution fed into the system. Every patient was given topical Moxifloxacin eye drops of 0.5% and Dexamethason eye drops of 0.3% every hour for the first five days following surgery, followed by a dose reduction to 4 to 1 drops daily for the following six weeks.

After six months of follow-up without anti-glaucoma medication, the IOP level is considered stable at less than 21 mmHg.

III. RESULTS

The table 1 shows the comparison of variables between Group A and Group B. The total number of participants in the study is 86, with 43 in each group.

First, we compare the age of participants in Group A, where 27 (63%) were over 50 years of age and 16 (37%) were under 50 years. As a group, Group B has 20 participants over 50 years of age (47%) and 23 participants under 50 years of age (53%). Among the overall participants in the survey, 47 (54.6%) are older than 50, and 39 (45.3%) are under 50 years. There is no significant difference in age between the two groups based on the p-value of this comparison, which is a p-value greater than 0.05. Table 1

The second variable compared is gender, with Group A having 21 male participants (48.8%) and 22 female participants (51.2%). Group B has 23 male participants (53.5%) and 20 female

participants (46.5%). The total number of male participants is 44 (51.2%), and the total number of female participants is 42 (48.8%). The p-value for this comparison is also greater than 0.05, indicating that there is no significant difference in gender between the two groups. Table 1

The third variable compared is the type of complications. Group A has 2 participants with complications, with 1 (33.3%) having a bleb leakage, 0 (0%) having cataract formation, 0 (0%) having hyphemia, and 1 (33.3%) having scleral thinning. Group B has 4 participants with complications, with 2 (50%) having a bleb leakage, 1 (25%) having cataract formation, 1 (25%) having hyphemia, and 0 (0%) having scleral thinning. The total number of participants with complications is 6, with 3 (50%) having a bleb leakage, 1 (16.6%) having cataract formation, 1 (16.6%) having hyphemia, and 1 (16.6%) having scleral thinning. The p-value for this comparison is less than 0.05, indicating that there is a significant difference in the type of complications between the two groups. Table 1

The table 2 shows the intraocular pressure (IOP) levels of two groups (A and B) after different time intervals following surgery. The IOP values are presented as mean ± standard deviation (SD). The P-value is also provided, indicating the statistical significance of the difference between the two groups.

After 1st week of surgery, there is no statistically significant difference in IOP levels between groups A and B (P-value = 0.257, ** denotes P < 0.01). Similarly, there is no significant difference in IOP levels after 2nd week of surgery (P-value = 0.534).

After 1st month of surgery, there is still no statistically significant difference in IOP levels between the two groups (P-value = 0.214). However, after 3rd months of surgery, the difference in IOP levels between groups A and B becomes statistically significant (P-value = 0.011, * denotes P < 0.05). Group A has a mean IOP of 13.04±3.81, while group B has a mean IOP of 15.30±4.18.

After 6th months of surgery, the difference in IOP levels between the two groups is not statistically significant (P-value = 0.754). Group A has a mean IOP of 13.48±2.86, while group B has a mean IOP of 15.09±2.64.

In summary, after 1st week, 2nd week and 1st month of surgery, there is no significant difference in IOP levels between groups A and B. However, after 3rd months of surgery, group B has a statistically significant higher IOP level compared to group A. After 6th months of surgery, the difference in IOP levels between the two groups is not statistically significant.

From the results, it can be seen that both Group A and Group B had a high success rate for the surgical procedure, with 95.3% and 90.6% respectively. However, Group A had a slightly lower failure rate of 4.6% compared to Group B's failure rate of 9.3%. Overall, both groups had a similar number of participants (43 in each group) and a similar success rate. However, Group A had a slightly lower failure rate than Group B. Table 3

Table 1: Overall frequency of patients according to age, gender and complications (n=86)

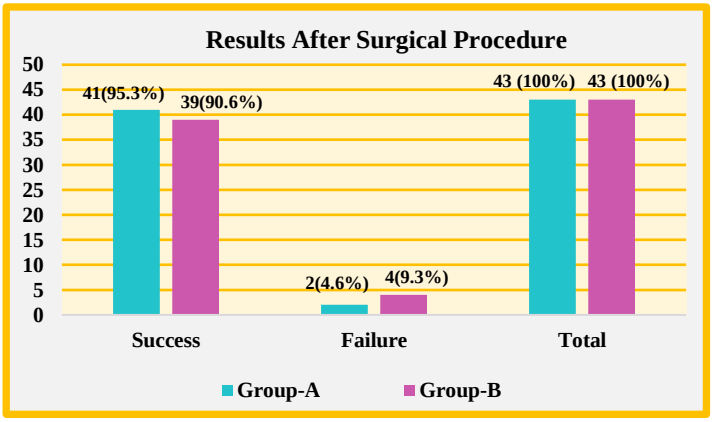
Variables	Group A (n=43)	Group B (n=43)	Total	P-Value
Age in groups				
> 50 < 50	27 (63%) 16(37%)	20(47%) 23(53%)	47(54.6%) 39(45.3%)	> 0.05
Gender				
Male Female	21(48.8%) 22(51.2%)	23(53.5%) 20(46.5%)	44(51.2%) 42(48.8%)	> 0.05
Type of complications	**(n= 2)**	**(n = 4)**	**(n = 6)**	
Bleb Leakage Cataract formation Hyphemia Scleral thinning	1 (33.3) 0 (0) 0 (0.0) 1 (33.3)	2(50) 1(25) 1(25) 0(0)	03(50.0%) 1 (16.6%) 1 (16.6%) 1 (16.6%)	< 0.05

Table 2: Comparison of IOP follow-up between the two groups (n=86)

IOP	Groups	Mean ± SD	P-value
IOP After 1st Week of Surgery	A (n=43)	13.20±3.05	0.257**
	B (n=43)	14.09±4.04	
IOP After 2nd Week of Surgery	A (n=43)	13.51±3.56	0.534**
	B (n=43)	14.02±4.00	
IOP After 1st Month of Surgery	A (n=43)	13.13±3.64	0.214**
	B (n=43)	14.18±4.09	
IOP After 3rd Months of Surgery	A (n=43)	13.04±3.81	0.011*
	B (n=43)	15.30±4.18	
IOP After 6th Months of Surgery	A (n=43)	13.48±2.86	0.754**
	B (n=43)	15.09±2.64	

Independent t-test Test was applied.
P-value ≤0.05 considered as significant
* Significant at 0.05 Levels
** Not Significant at 0.05 Levels

Graph 1: Frequency of patients according to result after surgical procedure (n=86)



IV. DISCUSSION

In our area, the most common filtering surgery is trabeculectomy, which can be done with or without antimetabolites. MMC characteristics are therefore used in trabeculectomy to control Tenon's capsule wound healing and sub conjunctival space wound healing. As reported by Ingrid U et al.,[7] 0.5 mg/ml MMC applied over the sclera and tenon flap achieved an 86% success rate with only 14.16 postoperative

complications.[7] Compared to our study, which had a success rate of 95.3% and 4.7% postoperative problems, the preceding study had a greater rate of complications, most likely because the concentration of MMC was applied for a longer period. An additional benefit is the short application time (three minutes) combined with the low MMC concentration (0.2mg/ml). Rekha Khandelwal et al. studied the effects of two different MMC concentrations on IOP postoperatively and found an 85 percent success rate with both 0.2 mg/ml and 0.4 ml. With a dosage of 0.2mg/ml and a low incidence of complications, the IOP was adequately reduced following surgery.[8] We found that 94.3% of patients who underwent trabeculectomy with MMC had successful outcomes with no complications associated with the dose and timing of its application intraoperatively. This study validates our findings." Using a 0.3mg/ml MMC concentration applied for 3 minutes under the scleral flap, Hector Fontana et al. found an 85 percent success rate in terms of IOP reduction following trabeculectomy with supplementary MMC, with a minimal incidence of postoperative sequelae.[9] According to the aforesaid parameters, the current study is on par with the previous study in terms of postoperative success (95.3%) and low concentration 0.2mg/ml of MMC (4.7%). There was a higher prevalence of Hypotony maculopathy in the 0.2% MMC group (up to 20%) for controlling IOP postoperatively, according to Tsai J.-C et al.[10] although IOP was reduced to the intended level of 21 mmHg following surgery in this trial, the rate of postoperative complications was higher than in the current study, which found that the MMC group experienced a complication rate of 4.7% after surgery.

Based on the study of P.S. Mahar el al., IOP decreased from 22.93mmHg preoperatively to 10.63mmHg postoperatively with 0.2mg/ml for 3 minutes.[11] Postoperative problems occur at a rate of 60 percent. Although the surgical complication rate was modest (only 4.7%), the above study confirms our findings about the effectiveness of MMC in controlling intraocular pressure. MMC trabeculectomy by Ching-Ya Huang et al.[2] had a 60.6% full success rate and a 95.4% qualifying success rate with a 58.5% complication rate during a two-year follow-up period with MMC concentrations between 0.1 and 0.27 mg/ml. In our research, we found a decreased complication rate of 4.7% with MMC concentrations as low as 0.2mg/ml over a three-minute period, despite the fact that the aforementioned study supports the postoperative lowering of IOP. The greater complication rate in this study may be attributable to the elevated MMC content. M. Afzal et al.,[12] observed that over a six-month follow-up period, 88% of this group's IOP had decreased dramatically from 34.6 mmHg preoperatively to 17.4 mmHg postoperatively after a 0.04% MMC concentration was applied three minutes after surgery. If you're looking to reduce your IOP during surgery, you'll want to consider using MMC intraoperatively, rather than the higher dose (0.4 mg/ml) that comes with more risks.

According to J.Singh et al.[13] Trabeculectomy with MMC had an 85% success rate and a 15 % postoperative complication rate,. For five minutes, the MMC concentration was 0.2mg/ml.13 Postoperative complications in our study were lower, reducing IOP by 4.7%, as MMC was applied to the scleral flap for a longer period than in the above study, which favored our study in terms of IOP reduction after surgery.

V. CONCLUSION

In POAG, we found that trabeculectomy with adjunctive MMC is superior to trabeculectomy without MMC in terms of managing IOP postoperatively. Furthermore, a lower intraoperative dose of MMC administered for a shorter length of time reduces the risk of postoperative problems. As a result, I strongly suggest starting with MMC 0.2% and trabeculectomy.

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