To Compare the Effect on IOP Following Primary Trabeculectomy with MMC 0.2% versus Trabeculectomy without MMC in Primary Open Angle Glaucoma

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Authors’ contributions
This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

Objective: To determine the effect on intraocular pressure following primary Trabeculectomy with MMC 0.2% versus Trabeculectomy without MMC in Primary Open Angle Glaucoma.

Study Design: This is a prospective and experimental Study.

Setting: Study carried out at Ophthalmology Department, Shaheed Mohtarma Benazir Bhutto Medical University Larkana, from 01-03-2020 to 31-08-2020 (06 Months).

Materials and Methods: The patients with primary open angle glaucoma were selected from glaucoma clinic after taking careful history and clinical examination. Patients selected for trabeculectomy into two groups. Group A includes 43 patients while Group B also includes 43 patients. Among Group A patients adjunctive MMC 0.2mg/ml for a period of 3 minutes was used during trabeculectomy as a primary procedure (Test Group) while Group B patients were operated

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without MMC 0.2% (Control Group). Follow-up period of 06 months was observed in both groups. The span of study was from 01-03-2020 to 31-08-2020.

**Results:** The total of 86 Eyes of 86 patients of POAG were included in this study. Group A patients were operated for trabeculectomy with MMC while group B patients were operated for trabeculectomy without MMC. The mean IOP before surgery of Group-A was 25.39±2.42 mmHg while in Group-B it was 26.23±4.23mmHg. At day 1 of surgery in Group-A patients IOP was 13.20±3.05 mmHg while in Group-B patients IOP, was 14.09±4.04 mmHg. After 3 months in Group-A, IOP was 13.04±3.81 mmHg in Group-B IOP was 14.01±4.18 mmHg. Out of 43 patients in Group-A, 41(95.3%) were succeeded while in Group-B, 39(90.7%)were succeeded. Significant result was found for IOP reduction after 6 months of surgery in group-A IOP was 13.48 ± 2.86 mmHg while in group-B, IOP was 15.09 ±2.64 (P=0.754).

**Conclusion:** Trabeculectomy with MMC as a primary procedure seems to be more effective than trabeculectomy without MMC.

**Keywords:** IOP; primary trabeculectomy; MMC; POAG.

1. INTRODUCTION

Someone describe distinctly primary open angle glaucoma as a multifactorial slow progressive optic neuropathy, characterized by acquired loss of optic nerve fibers, corresponding visual field defects, and raised IOP in the presence of open anterior chamber angle with an absence of signs of secondary glaucoma. It is a bilateral disease of adult onset. It is the most common type of glaucoma, affecting approximately 1% of the general population over the age of 40 years [1].

Trabeculectomy is a glaucoma filtration surgery that lowers IOP by creating a fistula to allow aqueous outflow from the anterior chamber to the Sub-Tenon space. They labeled Trabeculectomy as the "Gold Standard" surgical management of uncontrolled glaucoma since its first introduction by Cairns about 4 decades ago. Failure of maximum tolerated medical and laser therapy leaves no option other than surgical intervention [2]. With the advance of surgical instruments, modification of surgical techniques and adjunctive use of anti-metabolites, trabeculectomy has been producing a high success rate with low complication incidence [3]. According to Bo Ram Seol that primary trabeculectomies using MMC make the surgeons comfortable with the balance of efficacy and safety [4].

The indications of trabeculectomy operation are visual field progression, high IOP not controlled with argon laser trabeculoplasty/glaucoma medication, and severe visual field defects. The postoperative complications of trabeculectomy may be because of elevated IOP or hypotony, like a bleb leakage, shallow anterior chamber, wound leakage, choroidal effusion, cystoid macular edema, suprachoroidal hemorrhage and retinal detachment.

MMC is an antineoplastic antibiotic produced from the fermentation of Streptomyces caespitosus [5]. MMC prevents deoxyribonucleic acid (DNA) synthesis. The histological investigations illustrate it suspends cell growth and fibroblast replication: Thus the aim of using this medication during trabeculectomy is to suspend fibroblasts of conjunctiva and Tenon's capsule and therefore, to increase the success of operation and stability of bleb or fistula in surgery [6]. Wound fibrosis formation is the leading cause of failure in trabeculectomy operation in patients with glaucoma. Fibroblasts of the conjunctiva and Tenon's capsule are the major cause of wound fibrosis formation [7]. That is why ophthalmologists are trying to prevent this reaction in trabeculectomy to reach the more successful operative outcomes.

2. MATERIALS AND METHODS

This was a case series study with probability consecutive sampling carried out at the Department of Ophthalmology, Chandka Medical College Hospital at Shaheed Mohtarma Benazir Bhutto Medical University Larkana.

A total of 86 eyes of 86 patients of POAG were included in this study and equally divided into 2 groups. We include each group of 43 patients.

Group-A -------- WITH MMC 0.2%
Group-B-------- WITHOUT MMC

There were a total of 44 male and 42 female patients. In Group A, there were 21 male and 22 female patients. In 22 (51.2%) patients' left eye
The treatment and its complications. All patients were followed up postoperatively as under:

- 1st day after surgery
- 1st week after surgery
- 1st month after surgery
- 3rd month after surgery
- 6th months after surgery

The collected information was entered into the predesign form and statistical analysis through SPSS version 22.0. Analysis was described in mean and standard deviation for numerical variables in each group for male and female ratio. We calculated efficacy by fall in IOP in each group. Chi-Square test was applied considering P-value <0.05 (highly significant). Standard t-test was applied to see significance between the two groups. We presented all data in the form of tables and graphs.

3. RESULTS

Trabeculectomy is considered successful if IOP level is stabilized less than 21 mmHg or at 6 months of follow-up without anti-glaucoma medication. The result showed that there were 44 male and 42 female patients. In group A there were 21 male and 22 female patients while in group B there were 23 male and 20 female patients. The mean age of study subjects in treatment Group A was 52.39±5.01 years with range of 18(42-60) years while mean age of study subjects in treatment Group B was 50.30±5.59 years with range of 19(41-60) years. The age was further specified in two groups. In treatment Group A 16 patients were aged ≤50 years and 27 patients were aged >50 years while 23 patients were aged ≤50 years and 20 patients were aged >50 years in treatment Group B. The mean IOP before surgery for study subjects in treatment Group A was 25.39±2.42 mmHg while mean IOP before surgery for study subjects in treatment Group B was 26.23±4.23 mmHg.

The mean IOP after 1 week of surgery for study subjects in treatment Group A was 13.20±3.05 mmHg while mean IOP after 1 week of surgery for study subjects in treatment Group B was 14.09±4.04 mmHg. The mean IOP after 2 weeks of surgery for study subjects in treatment Group A was 13.51±3.56 mmHg while mean IOP after 2 weeks for study subjects in treatment Group B was 14.02±4.00 mmHg. The mean IOP after 1 month of study subjects in treatment Group A was 13.13±3.64 mmHg while mean IOP after 1 month of study subjects in treatment Group B was 14.18±4.09 mmHg. The mean IOP after 3 months of study subjects in treatment Group A was 13.04±3.81 mmHg while mean IOP after 3 months of study subjects in treatment Group B was 14.01±4.18 mmHg. The mean IOP after 6 months of study subjects in treatment group A was 13.48±2.86 while mean IOP after 6 months of study subjects in treatment Group B was 15.09±2.64 please seen Table 1.

22(51.2%) Patients were diagnosed with POAG in right eye in both groups while 21(48.8%) were diagnosed with POAG in left eye. By fundoscopy, in treatment Group-A optic disc Cupping ranged from 0.5 to 0.8 cup disc ratio (CD ratio) while in treatment Group-B optic disc cupping ranged from 0.5 to 0.9 CD ratio was noted.

Out of 43 patients in treatment Group A 41(95.3) patients were succeeded and 2(4.7) patients unsucceeded. While in treatment group B 39(90.7) patients were succeeded in terms of reducing IOP postoperatively < 21 mmHg and 4(9.3) patients unsucceeded (Table 2).

Independent t-test was applied to compare both treatment groups in terms of IOP control. The IOP of treatment group A was found lower than treatment group B. This mean difference was found significant p=0.011 between the two treatment groups.
Table 1. Comparison of IOP according to both groups (n=86)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Groups</th>
<th>Mean</th>
<th>SD</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>IOP After 1 Week of Surgery</td>
<td>Group-A (n=43)</td>
<td>13.20</td>
<td>3.05</td>
<td>0.257**</td>
</tr>
<tr>
<td></td>
<td>Group-B (n=43)</td>
<td>14.09</td>
<td>4.04</td>
<td></td>
</tr>
<tr>
<td>IOP After 2 Week of Surgery</td>
<td>Group-A (n=43)</td>
<td>13.51</td>
<td>3.56</td>
<td>0.534**</td>
</tr>
<tr>
<td></td>
<td>Group-B (n=43)</td>
<td>14.02</td>
<td>4.00</td>
<td></td>
</tr>
<tr>
<td>IOP After 1 Month of Surgery</td>
<td>Group-A (n=43)</td>
<td>13.13</td>
<td>3.64</td>
<td>0.214**</td>
</tr>
<tr>
<td></td>
<td>Group-B (n=43)</td>
<td>14.18</td>
<td>4.09</td>
<td></td>
</tr>
<tr>
<td>IOP After 3 Months of Surgery</td>
<td>Group-A (n=43)</td>
<td>13.04</td>
<td>3.81</td>
<td>0.011*</td>
</tr>
<tr>
<td></td>
<td>Group-B (n=43)</td>
<td>15.30</td>
<td>4.18</td>
<td></td>
</tr>
<tr>
<td>IOP After 6 Months of Surgery</td>
<td>Group-A (n=43)</td>
<td>13.48</td>
<td>2.86</td>
<td>0.754**</td>
</tr>
<tr>
<td></td>
<td>Group-B (n=43)</td>
<td>15.09</td>
<td>2.64</td>
<td></td>
</tr>
</tbody>
</table>

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

Table 2. Frequency of success after surgical procedure (n=86)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Groups</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group-A n (%)</td>
</tr>
<tr>
<td>Success</td>
<td>41(95.3)</td>
</tr>
<tr>
<td>Failure</td>
<td>2(4.7)</td>
</tr>
<tr>
<td>Total</td>
<td>43</td>
</tr>
</tbody>
</table>

Table 3. Frequency of complication

<table>
<thead>
<tr>
<th>Complications</th>
<th>Group-A n(%)</th>
<th>Group-B n(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bleb Leakage</td>
<td>1(33.3)</td>
<td>2(50)</td>
</tr>
<tr>
<td>Cataract formation</td>
<td>0(0)</td>
<td>1(25)</td>
</tr>
<tr>
<td>Hyphema</td>
<td>0(0.0)</td>
<td>1(25)</td>
</tr>
<tr>
<td>Scleral thinning</td>
<td>1(33.3)</td>
<td>0(0)</td>
</tr>
</tbody>
</table>

4. DISCUSSION

Trabeculectomy with and without antimetabolites is the most common filtering surgery performed in our region. Therefore, lot of properties of MMC are used during trabeculectomy procedure in order to modulate wound healing in the subconjunctival space as well as Tenon’s capsule. Ingrid U et al reported trabeculectomy with MMC with a success rate of 86% in reducing postoperative IOP with the concentration of 0.5mg/ml applied for 5 minutes on the sclera and Tenon flap with 14.16% postoperative complications for a follow-up period of 1 year [8,9]. The above study has higher rate of complications mostly probably due to increased concentration of MMC applied for a longer period than our study in which the success rate is 95.3% with 4.7% postoperative complications. Moreover, the MMC concentration 0.2mg/ml is also low applied with a short period of 3 minutes over the scleral flap.

A. Hye et al conducted study on effect of two different concentrations 0.2mg/ml and 0.4mg/ml of MMC on IOP postoperatively revealed the success rate of 85%. Adequate IOP decreased postoperatively with the concentration of 0.2mg/ml with insignificant frequency of complication[10] above study supports our study regarding the success rate of 95.3% in trabeculectomy with MMC, the dose, time of MMC application intraoperatively, with low incidence of complication.

Hector Fontana et al revealed in retrospective research study about the long-term outcomes of trabeculectomy with adjunctive MMC reveals
85% success rate in terms of IOP reduction postoperatively with MMC concentration of 0.3mg/ml applied for 3 minutes under the scleral flap with low incidence of postoperative complications [11]. Keeping in view the above parameters present study is at par with above study regarding postoperatively success rate 95.3% low concentration 0.2mg/ml of MMC with insignificant postoperative complication rate 4.7%. Tsai J.-C et al: Mentioned about the control of IOP postoperatively with a success rate of 73% with greater incidence of Hypotony maculopathy 20% amongst the MMC 0.2% group [12]. Although this study showed a reduction of IOP postoperatively at desired level <21 mmHg but postoperative complications are more as compare to present study which reveals 4.7% of complication rate postoperatively in MMC group.

P.S Mahar et al revealed a significant drop of IOP from 22.93 mmHg preoperatively to 10.63 mmHg postoperatively with 0.2 mg/ml for duration of 3 minutes [13]. With high rate of postoperatively complications 60%. Above study supports our study regarding the control of IOP with MMC but with low occurrence of postoperative complications 4.7%. Ching-Ya Huang: conducted retrospective research study trabeculectomy with MMC got a 60.6% complete success and 95.4% qualified success rate with 58.5% complication rate of MMC concentration from 0.1 to 0.27mg/ml for 2 year follow-up period [14]. Although above study supports the postoperative reduction of IOP but different in complication rate than our study which is lower 4.7% with low concentration 0.2mg/ml of MMC with short period of 3 minutes. Probably the higher complication rate of above study is due to high concentration of MMC.

M. Afzal et al revealed 88% of success rate postoperatively IOP has reduced significantly in MMC group than control group: from 34.6mmHg preoperatively to 17.4 mmHg postoperatively with concentration of MMC 0.04% for duration of 3 minutes with no significant complications for a follow-up period of 06 months [15]. This study favours our study regarding the use of MMC intraoperatively with trabeculectomy for significantly reducing the IOP with insignificant frequency of complication with concentration of 0.2mg/ml than the higher concentration 0.4mg/ml with higher complications.

J. Singh et al has concluded 85% success rate of trabeculectomy with MMC with 15% postoperative complications. The MMC concentration was 0.2mg/ml for a period of 5 minutes [16]. Above study favours our study regarding the postoperative reduction of IOP with the exception of high postoperative complication rate 15% while our study has the low postoperative complication rate 4.7% higher complication rate is perhaps due to longer application period of MMC to the scleral flap than our short period of MMC application.

5. CONCLUSION

Our study concluded that trabeculectomy with adjunctive MMC is more effective in controlling IOP postoperatively as compare to trabeculectomy without MMC in POAG. Moreover, there are less chances of postoperative complications with low dose of MMC applied intraoperatively for a shorter period of time. Therefore, I fully recommend the use of MMC 0.2% with trabeculectomy as a primary procedure.

CONSENT AND ETHICAL APPROVAL

An informed consent was taken after properly explaining the procedure of study and getting approval from the ethical committee.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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