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Original Research Article

Trabeculectomy with Mitomycin and Ologen Implant and Their Post-Operative Outcomes

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Abstract:

Introduction: Glaucoma, a disorder characterized by increased intraocular pressure that can damage the optic nerve and lead to blindness, is treated with a surgical operation known as a trabeculectomy.

Aim: The purpose of this study is to compare the success rate of trabeculectomy with mitomycin (MMC) or ologen (Olo) implant in treating primary open glaucoma (POAG) in patients in eastern India.

Materials & Methods: The hospital's ethics committee authorized the study and protected patients' privacy. Participants signed informed consent forms before the trial began. It only included patients diagnosed with POAG who were receiving treatment in an outpatient clinic.

Results: The study found that all Olo implants used in trabeculectomy surgery had degraded within 180 days. At the 3-month follow-up, there were significant differences in vascularity between the two groups, with the blebs in the eyes with Olo implants being more vascular and diffuse at the 6-month follow-up. The increased inflammation in the eyes with Olo implants may be responsible for the difference in vascularity. Anterior chamber reaction and hyphema were observed in a few patients in both groups, while bleb leakage and needling were performed on a few patients in each group. The study did not find any significant differences between the two groups in terms of the critical clinical outcomes examined.

Conclusion: Future studies should focus on examining additional critical clinical outcomes, such as bleb morphology, and conducting large-scale, well-controlled, randomized trials to assess the efficacy of trabeculectomy surgeries using both drugs.

Keywords: Glaucoma, Mitomycin, Ologen Implant, Trabeculectomy, Bleb.

Introduction

Glaucoma, a disorder characterized by increased intraocular pressure that can damage the optic nerve and lead to blindness, is treated with a surgical operation known as a trabeculectomy [1]. In a trabeculectomy, a surgeon excises a little piece of the trabecular meshwork, a part of the eye's drainage system, to make

room for a new drainage pathway for the aqueous humor, the eye's fluid and this lowers the pressure inside the eye [2-4]. A bleb may develop after a trabeculectomy. The conjunctiva, the thin membrane that covers the white part of the eye, is a common site for the development of blebs [5]. Excess aqueous humor drains into the bleb, where it might be absorbed by neighboring tissues and blood vessels [2]. Trabeculectomy improves the eye's ability to regulate its own pressure by forming this bleb [5]. Scarring is an inevitable consequence of any surgical surgery, including trabeculectomy. Scar tissue forms in injured areas to aid in the healing process [6]. The conjunctiva and the drainage channel that was formed during a trabeculectomy may become scarred over time [3]. There may be a blockage of aqueous humor flow and the bleb's ability to function due to the formation of scar tissue [4]. In order for trabeculectomy to be successful in lowering intraocular pressure, bleb development and scar tissue must be carefully managed [7]. Appointments with an ophthalmologist should be set up on a regular basis so that the bleb's effectiveness may be assessed, and its development tracked [4,5]. The bleb could rupture or become infected if it swells too much or dries out too much [3]. To maintain the bleb's functionality and avoid problems, it may be necessary to resort to further methods or operations [4]. Mitomycin (MMC) and other antimetabolite medicines have been routinely used to enhance trabeculectomy surgery for a number of decades. These drugs limit scar formation by decreasing fibroblast proliferation near the trap door [8]. However, there have been reports of both immediate and delayed toxicity from these drugs [9,10]. Ologen (Olo) is a molecule that degrades naturally and works differently than conventional antifibrotic drugs. Olo porosity structure allows fibroblasts to multiply unrestrictedly, which may greatly reduce scar formation because it leads to the random alignment of collagen fibers [11]. No antifibrotic medication is required for this task [12]. When comparing the success rates of MMC and Olo implants, studies from different parts of the world have shown mixed outcomes. The purpose of this study is to compare the success rate of trabeculectomy with MMC or Olo implant in treating primary open angle glaucoma (POAG) in patients in eastern India.

Materials & Methods

The study was conducted between October 2020 to September 2022 in the Regional Institute of Ophthalmology Department, S.C.B. Medical College, Cuttack, Odisha, India. The study was approved by the Institutional Ethics committee. At the College Ophthalmology out-patient Department, all participants were screened and evaluated, and patients gave their informed permission both before and after the recruitment process.

Patients with POAG who were treated in an outpatient clinic were included in the research. POAG patients must give their informed agreement for research and autopsies. From 18 to 80 years of age. Despite the best possible medical care, failure to regulate IOP (IOP>21 mm Hg) or chronic vision loss can still occur. Patients with acute or chronic diseases, connective tissue abnormalities, previous ocular trauma, and normal tension glaucoma are ineligible. Other conditions that disqualify patients include divided fixation of the visual field, a history of intraocular surgery, or the use of any drugs (systemic or ocular) that may impair vision.

The forty patients were split into two groups of twenty at random. When testing with both eyes was necessary, each group was arbitrarily assigned one. Patients in Group 1 underwent trabeculectomy using MMC, while those in Group 2 underwent the same procedure using an Olo implant of type 830601. Before the operation, we are compiling demographic and clinical

baseline data. Information such as gender, age, linguistic modalities spoken, and glaucoma medication dosage and type were recorded. An applanation tonometer was utilized to evaluate the intraocular pressure. The postoperative administration of MMC or Olo was randomized. MMC (0.4 mg/l) and an Olo 830601 implant were used. One surgeon performed each procedure while the patient was under peribulbar local anesthesia. The patient was draped and covered to prevent contamination before a superior rectus bridle suture was performed. The smallest possible conjunctival flap based on the fornix was cut out using blunt-tipped Westcott scissors. More accurate cauterization was achieved by employing bipolar cautery. A membrane in the shape of a triangle covered roughly two-thirds of the scleral thickness. The conjunctiva of the MMC group was treated with two sponges soaked in 0.4 mg/ml MMC for two minutes.

Twenty milliliters of a measured salt solution were sprayed on the plant. The cut was made at an angle of 15 degrees using a side port knife. Using the side port knife and Kelly Descemet's punch, the trabecular block was dislodged from below the scleral membrane. The iris tissue was grasped with Vanna's forceps through the trabeculectomy incision and removed in a linear fashion parallel to the limbus. Kolker's method was used to close the scleral flap with two minimally tensioned 10-0 monofilament nylon sutures at the flap's extremities and one releasable suture at the flap's apex. The implants used in Olo patients were cylindrical in shape, with a diameter of 6 mm and a height of 2 mm placed subconjunctivally and suprascleratically. Eight-0 Vicryl sutures, one at each end and one in the middle, were used to secure the conjunctival flap to the limbus.

Through the side port, bleb titration was conducted to ensure hermetic suturing at the conclusion of the operation. Following surgery, all eyes were treated with Moxifloxacin 0.5% eye drops six times per day for four weeks, then Prednisolone acetate 1% drops six times per day for the first week, then twice per day for the following five weeks, and finally Homide drops twice per day for one week. Checkups were scheduled for the first day, week, and months after surgery, as well as the first, third, and sixth months.

Statistical analysis

Excel was used to compile the data, and "R" software, version 4.0.3, was used for analysis. Percentages and proportions were used to illustrate the qualitative data, while the mean and standard deviation were used to illustrate the quantitative variables.

Quantitative and categorical variables were compared between the two groups using cross tabulations and Chi square tests, while categorical variables were compared using Fisher's exact test.

Results:

Table 1: Morphology of bleb by Indian Bleb Appearance grading Scale (IBAGS) during follow-up

Duration	Height (P value)	Extent (p value)	Vascularity (V) (p value)
Day 1	0.01	1.00	0.01
Day 7	0.01	0.15	0.01
Month 1	0.01	0.15	1.0
Month 3	>0.05	0.38	<0.05
Month 6	0.03	0.16	<0.01

Table 1 shows the morphology of the bleb. There were statistically significant differences of the bleb extent between both group in follow up visits. In the early postoperative stage (up to 1 month), bleb height in Olo group was higher than in

MMC group. All the implanted Olo degraded within 180 days. From 3 months, there were statistically significant differences of the vascularity between both groups. At 6-month follow-up visit, the blebs in the eyes with the Olo implants were more vascular and diffuse compared with the eyes treated with intraoperative MMC and did not show any avascular areas which might be due to increased inflammation in eyes with Olo implant as the implant is non-human (porcine) in origin. There was significant a vascularity in blebs in the MMC group than the Olo group at 6 month follow up (p value <0.01).

Table 2: Comparison of postoperative complications in the two groups over the course of the study

Post-operative complications	MMC (n=20)	Olo (n=20)	Total (n=40)
Anterior chamber reaction	2 (5.0%)	1 (2.50%)	3 (7.5%)
Hyphema	0 (0.00%)	1 (2.50%)	1 (2.50%)
Bleb Leakage	1 (2.50%)	1 (2.50%)	2 (5.0%)
Choroidal detachment	1 (2.50%)	0 (0.00%)	1 (2.5%)
Tenon's cyst	2 (5.00%)	1 (2.50%)	3 (7.5%)
Thinning of Bleb	1 (2.50%)	0 (0.00%)	1 (2.50%)

Anterior chamber reaction was seen in two and one patient in MMC and Olo group respectively. Hyphena was observed in only one patient Olo group. Whereas thinning of bleb and choroid detachment was observed in one patient each of MMC group. Bleb leakage was observed in one patient each of MMc group and Olo group respectively.

Table 3: Compare the additional interventions that were required during the follow-up period.

Post-operative interventions	MMC (n=20)	Olo (n=20)	Total (n=40)	P-value
Additional procedure				0.13
Bleb needing	2	1	3	
Bleb re-suturing	1	1	2	

Table 3 shows the additional interventions required during the follow-ups. Bleb needing was done in two patients of MMC group and one patient of Olo group. Bleb re-suturing was performed on one patient each of MMC and Olo group. When compared to know the significant, the present study authors observed not significance between the two groups.

Discussion

Our study showed statistically significant differences of the bleb extent between both group in follow up visits. In the early postoperative stage (up to 1 month), bleb height in Olo group was higher than in MMC group. All the implanted Olo degraded within 180 days. From 3 months, there were statistically significant differences of the vascularity between both groups.

At 6-month follow-up visit, the blebs in the eyes with the Olo implants were more vascular and diffuse compared with the eyes treated with intraoperative MMC and did not show any avascular areas which might be due to increased inflammation in eyes with Olo implant as the implant is non-human (porcine) in origin. There was significant a vascularity in blebs in the MMC group than the Olo group at 6 month follow up (p value <0.01). Rosentreter et al.[13] found more avascular blebs in the MMC group as compared to the collagen matrix implant group at the end 1 year. Chen et al [14] showed similar bleb morphology as our study. However, He et al.,[15] found no significant difference between the two groups at the end of 2 years in all the scores.

Our study did not show any significant difference in the rate of complications between the two groups. Postoperatively, the number of eyes which experienced one or more complications were 7 out of 20 eyes (35%) in group 1 and 4 out of 20 eyes (25%) in Group 2. The frequency of overall postoperative complications was higher in Group 1 as compared to Group 2, but it was not statistically significant. Tenon's cyst and thin blebs were more common in the MMC group among our patients.

Choroidal detachment was seen in 1 patient of MMC group at 1-month post-op which was managed by systemic steroids. In the study by [13], 2 cases in Olo group developed tenons' cyst that required needling and 1 case in MMC group needed re-suturing for bleb leak. In the study by [14], they found that post-operative complications were similar in the 2 groups, except for transient hyphema, which was more in Olo group.

In this study, no specific intraoperative complications related to the Olo implant itself were noted. Any postoperative complication such as hyphema was transient. Early conjunctival leakage was reported in 30% of the cases in one study [11]. Endophthalmitis with negative growth on cultures was reported in one case in another study [16]. Hypotony and thin blebs were more common in the MMC group among our patients. On the contrary, a study [17] reported more complications with Olo than with MMC, with a case of blebitis in the Olo group, in which the implant was removed.

Conclusion

To better understand the benefits and function of MMC and Olo in trabeculectomy, future study should begin by examining additional critical clinical outcomes (such as bleb morphology). It is advised that large-scale, well-controlled, randomized trials be conducted to assess the efficacy of trabeculectomy surgeries using both drugs.

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