

Bleb Morphology and Related Complications: Ologen Versus Mitomycin - C in Primary Trabeculectomy: A Comparative Study

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Abstract: ***Aim:** To assess and compare bleb morphology and its related complications in trabeculectomy with ologen implant and trabeculectomy with MMC. **Methods:** In this study, 21 patients of POAG underwent trabeculectomy with ologen implant (group A) and 21 patients of POAG underwent trabeculectomy with MMC (group B). Blebs were graded clinically with moorfields bleb grading system at 6 months. Early and late bleb related complications were noted at day 1 and 7, 4 week, 12 week and 6 month. **Results:** The mean post operative bleb scoring was 4.38 ± 0.67 in group A and 4.47 ± 0.68 in group B. No significant difference between the two groups was found ($p = 0.668$ with 40 degrees of freedom). Early Bleb related complications were found in 14.28% Patients in group A and 28.5% patients in group B which was found to be non significant. ($p = 0.786$). Postoperative mean ACD (OCT) in group A and group B was 3.00 ± 0.16 and 3.14 ± 0.15 respectively and was found to be significant. ($p = 0.006$) **Conclusion:** Bleb morphology and its complications were similar in both ologen implant and MMC in trabeculectomy.*

Keywords: Ologen, MMC, Bleb, Trabeculectomy

1. Introduction

Trabeculectomy [Filteration surgery] is the most commonly performed surgical treatment in dealing with POAG worldwide. Fibrosis of the sub-conjunctival tissue may lead to bleb failure, decreasing the long term success of trabeculectomy[1].

With the introduction of anti-metabolites, such as mitomycin C (MMC), which significantly decreases the post-operative sub-conjunctival scarring, has improved the long term success of trabeculectomy[2]. However, using of adjunctive anti-metabolites during surgery have increased the incidence of bleb-related complications like thin avascular blebs, hypotony maculopathy, blebitis, and endophthalmitis[3].

Ologen (OLO) is a biodegradable, porous, collagen implant, was designed aiming to improve the long term success of trabeculectomy by decreasing the sub-conjunctival scarring but with less bleb-related complications. At the end of the trabeculectomy, the collagen implant is placed sub-conjunctivally over the scleral flap. The implant helps to facilitate the formation of loose connective tissue matrix by acting as a scaffold for growth of fibroblast into the pores of the implant and thus aims to help tissue remodeling and decrease the scar formation. The implant not only acts as a reservoir but also helps to mechanically separate the conjunctiva and episcleral surface and prevent adhesions between them.

The present study was undertaken to assess and compare bleb morphology and its related complications in trabeculectomy with ologen implant and trabeculectomy with MMC.

2. Methods

This study was conducted in compliance with the tenets of declaration of Helsinki and Institutional ethics committee approval had been obtained ahead of the study.

This prospective randomised comparative case study included patients scheduled for trabeculectomy at anand hospital and eye centre jaipur. 42 adult patients were enrolled in the study. After explaining the study, surgical procedures and possible complications, an informed consent was obtained and patients were assigned to two groups;

Group A ($n = 21$) who underwent trabeculectomy with ologen implant

Group B ($n = 21$) who underwent trabeculectomy with MMC.

Eligibility Criteria

Inclusion Criteria

Patients with an IOP >20 mmHg with maximal tolerated anti glaucoma drugs, Patients having intolerable side effects of anti glaucoma drugs, Patients with POAG and having poor compliance for anti glaucoma drug use, Patients who couldn't afford anti glaucoma medicine, Patients willing for surgery, Patients willing for follow ups were included in study.

Exclusion Criteria

Age less than 18 years, Any glaucoma other than primary glaucoma, Recent ocular infection or inflammation, Previous intraocular surgery, anterior segment laser surgery, History

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of IOP altering events such as retinal detachment or prolonged corticosteroid administration, Corneal or retinal pathology, History of presence of uveitis, Those who were not willing to participate, Those who were not able to come for follow up were excluded.

Pre operative evaluation

Baseline information, such as, age, gender, number of anti-glaucoma medications and medical history were recorded. All patients received a complete preoperative examination, including best corrected visual acuity measurement (Snellen chart), slit lamp examination, tonometry (Goldmannapplanation tonometry), gonioscopy, dilated fundus examination, a Humphrey visual field (24-2, or 30-2) examination

3. Surgical Technique

All surgeries were performed by the same surgeon under peribulbaranesthesia.

Group A: The eye was prepared with Povidone Iodine 5% solution Controlled gentle digital massage with the hand was given. Trabeculectomy was performed in the superotemporal or superonasal quadrant trying to avoid sites of perforating scleral vessels. The conventional superior rectus bridle suture placed. A fornix based conjunctival flap was prepared. Haemostasis was achieved by adequate wet field cautery. A 4 x 4 mm triangular scleral flap one third of the thickness dissected to within 1 mm of clear cornea with a Bard Parker knife. After creating a paracentesis opening, inner sclerostomy block was dissected out with the blade in the dimensions 2mm x 3 mm, at the base of the hinge of the superficial scleral flap. Peripheraliridectomy performed through the inner sclerostomy with a vannasscissor and a single toothed fine forceps. Scleral flap closure with an apical suture using 10-0 nylon and one releasable suture at one side. A 6 mm x 2 mm Ologen implant was placed on top of the sclera and the conjunctiva was then closed water tight by 10-0 nylon suture.

Group B: The eye was prepared with Povidone Iodine 5% solution. Controlled gentle digital massage with the hand was given. Trabeculectomy was performed in the superotemporal or superonasal quadrant trying to avoid sites of perforating scleral vessels. The conventional superior rectus bridle suture placed. A fornix based conjunctival flap was prepared. Haemostasis was achieved by adequate wet field cautery. SubconjunctivalMitomycin C 0.2 mg/ml applied for 3 minutes with 3 merocel sponges. Subconjunctival space copiously irrigated with 30 ml Ringer Lactate. A 4 x 4 mm triangular scleral flap one third of the thickness dissected to within 1 mm of clear cornea with a Bard Parker knife. After creating a paracentesis opening, inner sclerostomy block was dissected out with the blade in the dimensions 2mm x 3 mm, at the base of the hinge of the superficial scleral flap. Peripheral iridectomy performed through the inner sclerostomy with a vannas scissor and a single toothed fine forceps. Scleral flap re-approximated with an apical 10-0 nylon suture and one releasable suture. Conjunctival flap closed water tight by 10-0 nylon suture.

Postoperatively patients were prescribed combination of antibiotic-steroid [Tobramycin 0.3%+Dexamethasone 0.1%] eye drops every 2 hours for one week and tapered over the following 5 weeks. Cycloplegic-mydratic [Homatropine 2%] eye drops used when signs of early inflammation, shallow A/C, hypotony were present. The number, frequency and duration of the anti-glaucoma drugs, if required, was carefully noted down and compared in the above two groups.

Postoperatively subjects examined at days 1 and 7 then at 4weeks, 12 weeks and 6 months for:

- Intra ocular pressure (Applanation tonometry)
- Unaided visual acuity
- Best corrected visual acuity
- Slit lamp examination to asses : condition of filtering bleb
- Anterior chamber depth, Inflammatory reaction, Hyphaema etc.
- Gonioscopy
- Fundoscopy :

Any change in cup disc ratio postoperatively

Cystoid macular edema

- Bleb scoring: Height, area, vascularity (**Moorfield's**). There are six criteria to assess- 2 describing area, 1 describing height and 3 describing vascularity.
- Seidel's test
- Complications (if any)

Outcome Analysis:

Post operative ACD and Bleb scoring (Moorfield's) of both the groups will be assessed in mean +/- SD. Post operative complications of both the groups will be expressed in Percentage and Proportions. Significance of difference in means will be inferred by unpaired 't' test. Significance of difference in proportions will be inferred by chi-square test. For significance P value equal to or less than 0.05 will be considered significant.

4. Result

42 eyes of 42 patients were evaluated in our study with the aim to study and assess the bleb morphology and its related complications in patients undergoing trabeculectomy with ologen implant (group A) and trabeculectomy with MMC (group B).

The mean age of patients in group A was 56.05 years and in group B was 54.0 years (p = 0.000).

Male to Female ratio in group A is 2:1 and in group B is 1:1.62 which was found to be non significant, hence both the groups were comparable.

Postoperative mean ACD (OCT) in group A and group B was 3.00 +/- 0.16 and 3.14 +/- 0.15 respectively and was found to be significant. (p=0.006)

Postoperative mean bleb scoring (moorfield's) at 6 month in group A and group B was 4.38±0.67 and 4.47±0.68 and was found to be non significant. (p=0.668)

In our study we observed shallow AC, hyphaema, choroidal detachment, bleb leakage as early complications. In group A (trabeculectomy with ologen) three patients (14.28%) had complications during first week of post operative follow up. Two patients had shallow AC with hypotony and one patient had hyphaema.

In group B (trabeculectomy with MMC) out of six patients (28.5%) who had complications, shallow AC with hypotony and hyphaema was seen in two patients each respectively. One patient had choroidal detachment and another had bleb leakage in first week of follow up with positive seidel's test.

The comparison of post operative complications in both the groups was found to be not significant statistically (chi square = 1.725 with 4 degrees of freedom, p=0.786).

5. Discussion

The present study was undertaken with the aim to assess and compare bleb morphology and its related complications in MMC versus Ologen implant in trabeculectomy for the management of POAG. There was no significant difference in pre-operative parameters of the two groups in terms of age, sex and average number of anti glaucoma drugs being used.

In our study the mean post operative bleb scoring was 4.38 ± 0.67 in group A and 4.47 ± 0.68 in group B. No significant difference between the two groups was found (p = 0.668 with 40 degrees of freedom).

Dada T et al (2013)^[4] in their study noted that during first week two eyes had shallow AC with hypotony. Both cases demonstrated a positive seidel's test. The mean overall post operative bleb scoring at sixth month was observed in group A (4.38 ± 0.67) and in group B (4.47 ± 0.68). the study of variation in the bleb scoring was not significant statistically (t = -0.432 with 40 degrees of freedom, p = 0.668), however more avascular bleb was observed in group B.

Rosentreter A et al (2010)^[5] in their study after one year noted filtering blebs developed significantly more avascular area in the MMC group than Ologen group (p < 0.01)

Papaconstantinou D (2010)^[6] in their study after SD-OCT analysis denied differences in bleb height between MMC and Ologen (140.5 ± 20.3 with 129.2 ± 19.3) respectively, (p = 0.079).

Post operative complications were observed more in group B. Shallow AC (two in each group), hyphaema (one in group A and two in group B), choroidal detachment (one case in group B), bleb leakage (one case in group B). The difference in post operative complications in the two groups was found to be not significant (p = 0.198).

Stalmans et al. (2006)^[7] in their study reported flat AC (1.8%), choroidal detachment (8.9%), wound leakage (0.5%) in trabeculectomy.

Sirisha Senthil et al (2013)^[8] studied 39 eyes of 33 subjects who underwent trab with ologen (19 eyes) and trab with MMC (20 eyes). The incidence of early post operative complications were similar in the two groups except hyphaema, which was significantly more in ologen group (p = 0.02) which probably occurred because of the loose apical suture.

Since MMC is observed to have late post operative bleb related problems, we believe a longer duration follow up will be more informative in deciding whether Ologen is superior to MMC in the long term management of glaucoma.

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