

## To Study and Compare the Intra-Operative and Long Term Post-Operative Complications with Penetrating (Trabeculectomy) Vs Non Penetrating (Deep Sclerectomy) Glaucoma Surgery in Primary Glaucoma: A Comparative Study

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### Abstract:

**Purpose:** TO STUDY AND COMPARE THE INTRA-OPERATIVE AND LONG TERM POST-OPERATIVE COMPLICATIONS WITH PENETRATING (TRABECULECTOMY) VS NON PENETRATING (DEEP SCLERECTOMY) GLAUCOMA SURGERY

**Methods:** In this study, 35 eyes underwent trabeculectomy (group A) and 35 eyes underwent deep sclerectomy (group B). The unaided visual acuity, best corrected visual acuity, slit lamp examination to assess the anterior chamber depth, hyphaema, hypotony, blebitis, choroidal detachment, filtering bleb morphology and functioning, cystoid macular oedema, endophthalmitis etc. gonioscopy was performed, fundus evaluation using 78D/90D/20D indirect ophthalmoscopy, visual field examination, Applanation tonometry to evaluate the intra ocular pressure was performed at 1st day, 1 week, 1 month, 3 month, 6 month, 1 year and 7 year postoperatively

### Results:

The complications were divided into intra-operative, early postoperative and late postoperative time. 2 patients from group A suffered intraoperative hyphaema whereas none encountered the same intraoperatively in group B. In the early postoperative period, the most common complication seen with group A patients was shallow anterior chamber and hyphaema and was seen in 25% of the patients whereas the commonest early postoperative complication among group B patients was seen to be severe anterior chamber inflammation which was seen in 15% of them.

The late onset complications included loss of >1 line vision on snellen's chart in 25% of group A patients, followed by occurrence of cataract in about 20% of them, 3 patients presented with marginal increase in the IOP who were later started on one group anti glaucoma medication. 2 patients from group B had persistently elevated intra ocular pressure for which Nd Yag assisted goniopuncture was performed. Loss of >= 1 line vision on snellen's chart was also noted in 1 patient. Other late onset complications included blebitis, severely vascularised bleb, failure of the filtering bleb and hypotony maculopathy, 7 patients from group B had to undergo conventional trabeculectomy with application of MMC due to very high intra ocular pressure.

**Conclusion :** Our study observed that although both the penetrating and non-penetrating surgeries significantly lowered the IOP in patients with primary open angle glaucoma, the patients who underwent standard penetrating surgery (trabeculectomy), i.e. group A, encountered significantly more number of complications as compared to the patients falling under group B.

**Keywords:** IOP, Trabeculectomy, NPGS,

Date of Submission: 02-12-2019

Date of Acceptance: 18-12-2019

### I. Introduction

Glaucoma is a leading cause of irreversible blindness worldwide and is second only to cataracts as the most common cause of blindness overall<sup>[1]</sup>.

The penetrating surgery includes the gold standard procedure known as Trabeculectomy as the standard procedure in penetrating anti-glaucoma surgery. It was introduced by Cairns in 1968.<sup>[2]</sup> Wound healing and scar formation causing fibrosis and the obstruction of aqueous outflow remain the most common reason for the failure of trabeculectomy<sup>[3], [4]</sup>.

Adjunctive antifibrotic agents, such as 5-fluorouracil (5-FU) or Mitomycin-C (MMC), are commonly used to increase the success rate of glaucoma filtering surgery.<sup>[5][6]</sup> The non-penetrating procedures include deep sclerectomy, viscocanalostomy as the two main procedures. Both the procedures perform by enhancing the

natural aqueous outflow channels. The aqueous moves through the thin trabecular descemet membrane which in turn offers negligible resistance to its outflow by promoting very slow and maintained fall in the IOP and thus reduces the chances of sudden postoperative hypotony observed mainly post trabeculectomy.[7] Deep sclerectomy is primarily aimed to reduce the outflow resistance to aqueous. in this procedure the internal wall of schlemm's canal, juxta canalicular meshwork and the corneal stroma behind the anterior trabeculum and descemets membrane is removed, without entering the anterior chamber and thus a thin membrane is left behind[8,9].

Proper history and thorough clinical examination was carried out in each patient including detailed history about age, sex, symptoms, frequent change of glasses, colored halos, history of drug intake, systemic history of hypertension, diabetes mellitus and family history if any.

Ocular examination included various steps including external ocular evaluation, pupillary reactions, visual acuity which included uncorrected and best corrected visual acuity. Slit lamp biomicroscopy was then carried out to evaluate the ocular structures followed by fundus evaluation to document the RNFL and Optic disc changes.

Gonioscopy was performed in each patient and the grade and degree of angle structures visible was carefully noted. Applanation tonometry is the gold standard method of choice[10] to calculate the intra ocular pressure and thus this technique was used to measure the pre and post operative intra ocular pressure of each patient.

Humphery visual field analysis was also carried out in all the patients except the ones who were visually severely handicapped.

The above mentioned study was carried out to establish the rate of success between penetrating glaucoma surgery and non penetrating glaucoma surgery in patients with primary open angle glaucoma on the basis of the pre and post operative intra ocular pressure.

## **II. Methods**

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

The study was held at the department of ophthalmology , SMS medical college & hospitals, Jaipur . 70 patients were selected for the study who suffered from primary glaucoma. After explaining the need of the study, surgical procedures to be followed and possible complications, an informed consent was obtained from the patients and they were assigned into two groups;

Group A ( $n = 35$ ) patients who underwent trabeculectomy

Group B( $n = 35$ ) patients who underwent deep sclerectomy

### **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 of IOP altering events such as retinal detachment or prolonged corticosteroid administration , Corneal or retinal pathology , History of presence ofuveitis , 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 noted. All the patients received a complete preoperative examination, including best corrected visual acuity measurement (BCVA) on the Snellen's chart, slit lamp examination, applanation tonometry (Goldmann applanation tonometry), gonioscopy, dilated fundus evaluation, Humphrey visual field (24-2, or 30-2) examination, and specular microscopy was performed.

#### **Surgical technique:**

All surgeries were performed by the same surgeon under peribulbar anesthesia .

**In group A,** The eye was prepared with Povidone Iodine 5% solution. Controlled gentle digital massage with the hand was given. Superiorrectus bridle suture was placed, Trabeculectomy was performed in the superotemporal or superonasal quadrant trying to avoid sites of perforating scleral vessels. A fornix based

conjunctival flap was prepared. Haemostasis was achieved by adequate wet field cautery. Subconjunctival Mitomycin C 0.2 mg/ml applied for 120 seconds 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 vanna's scissor and a single toothed fine forceps. Scleral flap reapproximated with an apical 10-0 nylon suture and one releasable suture. Conjunctival flap closed water tight by 10-0 nylon suture.

### **In group B**

The eye was prepared with Povidone Iodine 5% solution. Controlled gentle digital massage with the hand was given. Superior rectus bridle suture was placed. A limbal based conjunctival flap was prepared with a conjunctival incision 8-10 mm from the limbus. Haemostasis was achieved using adequate wet field cautery. A 5x5mm rectangular one-third thickness flap was made and dissected 1-1.5mm anteriorly into clear cornea with a disposable crescent knife. A second 3x3 mm deep scleral flap (90% thickness) was dissected leaving a thin layer of sclera. The dissection was then carried further into 2mm of clear cornea. The Schlemm's canal was then identified and unroofed. The sclero-corneal dissection was further carried forward for 1-1.5mm to remove the sclero-corneal tissue in front of the anterior trabeculum and Descemet's membrane. The superficial scleral flap was then loosely sutured with two 10-0 nylon sutures. The conjunctiva and the Tenon's membrane were closed separately. A subconjunctival injection of 0.3 ml gentamycin and 0.3 ml of dexamethasone was administered after completion of the entire procedure.

Postoperatively, patients were prescribed a combination of antibiotic-steroid (tobramycin 0.3% + dexamethasone 0.1%) eye drops every 2 h for 1 week which tapered over the following 5 weeks. Cycloplegic-mydratic drops (homatropine 2%) eye drops or atropine 1% eye drops were used when signs of early inflammation appeared and shallow A/C or hypotony was observed.

Follow up examination was conducted 1st and 7th day, 1 month, 3 months, 6 months and 1 year postoperatively with applanation tonometry performed at all the visits.

Evaluation of the complications was done by observing different parameters on each visit as follows:

Unaided visual acuity, best corrected visual acuity, slit lamp biomicroscopy, grading of the filtering bleb, applanation tonometry, gonioscopy, funduscopy, visual field examination

### **Statistical analysis**

The statistical analysis was thereby performed using the Statistical Package for Social Sciences software version 23 (SPSS Inc., Chicago, Illinois, USA). Analysis of variance (ANOVA) was used to analyze intragroup changes in continuous variables pre and postoperatively. In cases of Normal distribution of data, mean and SD were used while in cases where variable are not normally distributed then median were used. The Mann Whitney U test was used to compare mean values of intergroup continuous variables. Categorical data was evaluated using the Chi square test. For all measurements, a two tailed test was used, and  $P < 0.05$  was considered as significant for measured variables.

### **III. Results**

70 eyes of 70 patients were evaluated in our study with the aim to study, evaluate and compare the intra operative and postoperative complications in patients undergoing standard trabeculectomy vs patients undergoing deep sclerectomy.

The study observes intra and postoperative complications occurred in the procedure of trabeculectomy and deep sclerectomy and compares the 2 groups.

In our study, the mean age was observed to be  $62.10 \pm 8.21$  years in Group A and  $59.83 \pm 9.91$  years in Group B. There were no significant differences in terms of mean age ( $P = 0.44$ ). No significant difference was observed according to gender i.e. groups were comparable according to gender. ( $P = 0.476$ ).

The complications were divided into intra-operative, early postoperative and late postoperative time. 2 patients from group A suffered intraoperative hyphaema whereas none encountered the same intraoperatively in group B. In the early postoperative period, the most common complication seen with group A patients was shallow anterior chamber and hyphaema and was seen in 25% of the patients whereas the commonest early postoperative complication among group B patients was seen to be severe anterior chamber inflammation which was seen in 15% of them.

The late onset complications included loss of >1 line vision on Snellen's chart in 25% of group A patients, followed by occurrence of cataract in about 20% of them. 2 patients from group B had persistently elevated intra ocular pressure for which Nd Yag assisted goniotomy was performed. Loss of  $\geq 1$  line vision on Snellen's chart was also noted in 1 patient. Other late onset complications included blebitis, severely

vascularised bleb, failure of the filtering bleb and hypotony maculopathy. 3 patients from group A were started on single drug anti glaucoma medication due to increase in the IOP and 7 patients from group B underwent conventional trabeculectomy with MMC due to raised IOP.

The study also assessed the reduction in the intra ocular pressure using goldmann applanation tonometer at intervals of 1st day, 1 week, 1 month, 3 months, 6 months and 1 year and observed that the mean preoperative IOP in group A patients was 28.2 ± 2.70 mmHG and in group B it was 26.2 ± 5.70 mmHG which was statistically not significant. The mean post operative IOP on day 1 was 9.1 ± 2.12 mmHG and 8.2 ± 1.76 mmHG in group A and group B respectively. A reduction of 68.2% in group A and a reduction of 69.6% in group B was observed.

Reduction in the mean IOP in group A at 1, 3 and 6 months was 50.2%, 48.1% and 44.6% respectively. Whereas reduction in the mean IOP in group B was found to be 34.8%, 32.55% and 31.87% respectively.

Reduction in the mean IOP at 1 year was 42.4% in group A and 30.2% in group B. The mean reduction reduced over time in both the groups were compared, which was observed to be more in the group B patients.

#### **IV. Discussion**

Seventy eyes of seventy patients suffering from primary open angle glaucoma were included in our study. These were divided into two groups. Group A underwent penetrating surgery (trabeculectomy) and group B patients underwent non-penetrating glaucoma surgery (deep sclerectomy). All the surgeries were performed by the same surgeon to minimize the variability in the results. The post operative followup was for 7 year duration.

Both the procedures undertaken were associated with some complications which included intra operative, early onset post operative and late onset post operative.

Only 2 patients from group A suffered from intraoperative hyphaema whereas no intraoperative complication was noted in group B. 25% of the patients from group A suffered shallow anterior chamber depth and hyphaema as early onset complications as compared to 15% of group B patients who encountered severe anterior chamber reaction.

25% of the patients in group A suffered from a fall of >1 line of vision on snellen's chart and about 20% presented with cataract as a late onset complication as compared to 2 patients who experienced persistently raised intra ocular pressure and 1 patient who had loss of >1 line of vision on snellen's chart as a late onset complication in group B patients.

The mean preoperative IOP in group A was 28.2 ± 2.70 mmHG and in the group B was 26.2 ± 5.70 mmHG. The mean IOP was slightly higher in group A but the difference in the mean IOP of the two groups was not statistically significant (p=0.06)

The mean post operative IOP on day 1 was 9.1 ± 2.12 mmHG and 8.2 ± 1.76 mmHG in group A and group B respectively. A reduction of 68.2% in group A and a reduction of 69.6% in group B was observed. Reduction in the mean IOP in group A at 1, 3 and 6 months was 50.2%, 48.1% and 44.6% respectively. Whereas reduction in the mean IOP in group B was found to be 34.8%, 32.55% and 31.87% respectively. Reduction in the mean IOP at 1 year was 42.4% in group A and 30.2% in group B.

It was observed that both trabeculectomy and deep sclerectomy are quite efficient at lowering the mean IOP and are comparable in terms of the IOP achieved over the time in patients with primary open angle glaucoma nevertheless the mean IOP reduction gradually reduced over time more in group B (deep sclerectomy) as compared to group A (trabeculectomy) patients.

#### **References**

- [1]. Quigley HA. Number of people with glaucoma worldwide. *Br J Ophthalmol.* 1996;80(5):389-393 Quigley HA, Broman AT. The number of people with glaucoma worldwide in 2010 and 2020. *Br J Ophthalmol* 2006;90:262-7
- [2]. Cairns JE : Trabeculectomy : preliminary report of a new method. *Am J Ophthalmol* 66:673, 1968
- [3]. W. Wang, M. Zhou, W. Huang, and X. Zhang, "Ex-PRESS implantation versus trabeculectomy in uncontrolled glaucoma: a meta-analysis," *PLoS ONE*, vol. 8, no. 5, Article ID e63591, 2013. View at Publisher · View at Google Scholar ·
- [4]. Husain R, Clarke JC, Seah SK, Khaw PT (2005) A review of trabeculectomy in East Asian people—the influence of race. *Eye (Lond)* 19: 243–252
- [5]. Palmer SS. Mitomycin as adjunct chemotherapy with trabeculectomy. *Ophthalmology.* 1991;98:317–321
- [6]. Wu KY, Hong SJ, Huang HT, Lin CP, Chen CW. Toxic effects of mitomycin-C on cultured corneal keratocytes and endothelial cells. *J Ocul Pharmacol Ther.* 1999;15:401–411.
- [7]. Chiseltia D. Non penetrating deep sclerectomy versus trabeculectomy in primary open angle glaucoma. *Eye* 2001; 15:131-2
- [8]. Fyodorov SN, kozlov Vi, Timoshkina et al. non penetrating deep sclerectomy in open angle glaucoma. *IRTC, eye microsurgery, Moscow* 2001.
- [9]. Kozobolis VP, christodoulakis EV primary deep sclerectomy in primary open angle glaucoma *J glaucoma* 2002;11; 287-93
- [10]. Perkins ES: applanation tonometer *Br J. Ophthal* 1965; 49; 590-591