To Study and Compare the Long Term Efficacy (Intra Ocular Pressure Reduction) 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 LONG TERM EFFICACY (INTRA OCULAR PRESSURE REDUCTION) WITH PENETRATING (TRABECELECTOMY) 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). Applanation tonometry was performed at 1st day, 1 week, 1 month, 3 month, 6 month, 1 year and 7 years postoperatively. The variable included was the intraocular pressure using goldmann applanation tonometer.

Results: Overall, the mean preoperative IOP in group A patients was 28.2 ± 2.70 mmHG and in group B it was 26.2 ± 2.70 mmHG. 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 at 1 year and 7 year was 42.4% and 38.6% in group A and 30.2% and 24.2% in group B respectively.

Out of 35 patients in group A, 3 patients were prescribed one group of anti-glaucoma medication postoperatively due to marginally high intraocular pressure
Out of 35 patients in group B, 7 patients had to undergo trabeculectomy with the application of MMC due to persistently high intraocular pressure

The mean reduction reduced over time in both the groups compared, which was observed more in the group B patients

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 non-penetrating surgery (deep sclerectomy) provided comparable reduction in the IOP with fewer complications.

Keywords: IOP, Trabeculectomy, NPGS,

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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[3].

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[4]. Wound healing and scar formation causing fibrosis and the obstruction of aqueous outflow remain the most common reason for the failure of trabeculectomy[5][6].

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[7][6].

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 hyptonym 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]

Appplanation 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.

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 reduction in the 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. 40 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

III. 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 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 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. Superior rectus 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 using 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 vannas scissors and a single toothed fine forceps. Scleral flap reapproximated with an apical 10-0 nylon suture and one releasable suture. Conjunctival flap closed with 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 abd 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-mydiatic 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.

Statistical analysis

The statistical analysis was thereby performed using the Statistical Package for Social Sciences software version 23 (SPSSInc., 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 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.

IV. Results

70 eyes of 70 patients were evaluated in our study with the aim to study, evaluate and compare the long term decrease in the intraocular pressure in patients undergoing trabeculectomy vs patients undergoing deep sclerectomy. The study observes postoperative status of the IOP after trabeculectomy and deep sclerectomy and compares the 2 groups.

In our study, the mean age was observed to be 62.10± 8.21 years in Group A and 59.83± 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 study assessed the reduction in the intraocular pressure using goldmann applanation tonometer at intervals of 1st day, 1 week 1 month, 3 month,6 month, 1 year and 7 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 ± 2.12mmHg 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 %, at 7 year was 38.6% in group A and 30.2 % and 24.2% at 1 year and 7 year respectively in group B. The mean reduction observed in both the groups were compared, which was observed to be more in the group B patients.

Out of 35 patients in group A, 3 patients were prescribed one group of anti glaucoma medication post operatively due to marginally high intra ocular pressure

Out of 35 patients in group B, 7 patients had to undergo trabeculectomy with the application of MMC due to persistently high intra ocular pressure

V. 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 1 year duration.

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 ± 2.12mmHg 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 reduction in the mean IOP at 7 year in group A and B was observed to be 38.6% and 24.2% respectively.

3 patients from group A were added single group anti glaucoma medication postoperatively and 7 patients from group B had to undergo conventional trabeculectomy with MMC.

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