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Original Research Article

Risk Factors Affecting Control of Intraocular Pressure in Patients Undergoing Combined Small Incision Cataract Surgery with Trabeculectomy

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Abstract:

Introduction: Cataract and glaucoma often coexist in elderly patients, impacting the treatment and prognosis of both conditions. This study aims to identify the risk factors associated with poor intraocular pressure (IOP) control following combined small incision cataract surgery (SICS) with trabeculectomy.

Materials and Methods: Seventy five patients operated for SICS with Trabeculectomy were included in study. A detailed history, preoperative and postoperative evaluation including visual acuity, slit lamp examination, applanation tonometry, gonioscopy, automated perimetry and fundus examination was done. Patients were followed up for one year. Statistical analysis was performed by using Correlation coefficient and Relative risk

Results and Discussion: Among 81 eyes operated, 58 eyes had good IOP control and 23 eyes had poor IOP control at the end of one year. Postop IOP >10mmHg on day 5 ($p = 0.002$) and IOP >13mmHg on day 10 ($p = 0.001$) and an increase of IOP of 4 mmHg between day 1 and 1 month of surgery ($p = 0.04$) were significant risk factors for poor prognosis at one year. Complete success rate of procedure was 60.5%, and qualified success rate of procedure was 96%.

Conclusion: Combined SICS with trabeculectomy shows 96 % success in managing cataract with glaucoma in elderly patients. IOP >10 mmHg in the first week and an increase in IOP of 4 mmHg in the first month were significant risk factors for poor IOP control at 1 year. Further studies with longer follow-up periods and a larger sample size are recommended to validate these findings.

Keywords: Glaucoma; Intraocular pressure control; Risk factors; Small incision cataract surgery; Trabeculectomy.

Introduction

In elderly patients, cataract and glaucoma often coexist, and the treatment and prognosis of one condition can be affected by the other.

Combined cataract and glaucoma surgery is recommended in certain situations such as poor control of glaucoma despite maximal medical therapy (MMT), maximum tolerated therapy (MTT), intolerable drug side effects, poor affordability, non-compliance in patients to medical therapy, advanced glaucoma where postoperative intraocular pressure(IOP) spike cannot be tolerated, one-eyed patients with significant cataract and moderate glaucomatous defects with the other eye losing vision due to glaucoma[1].

The surgical options available for these patients include Phacoemulsification or small incision cataract surgery (SICS) with Trabeculectomy.

Objective

To study the intraocular pressure (IOP) control and enlist the risk factors associated with poor IOP control in patients undergoing Combined Manual Small Incision Cataract Surgery and Trabeculectomy.

Material and Methods

In this study, 83 eyes of 75 patients with moderate or severe glaucomatous damage along with cataract were enrolled as a prospective interventional cohort. The study population consisted of patients who visited the Ophthalmology Department as an outpatient or through an eye camp and undergone SICS with Trabeculectomy from March 2017 to August 2017. The patients were followed up for a period of one year.

Patients who were more than or equal to 40 years of age, both sexes, with a diagnosis of Primary open angle glaucoma(POAG), Primary angle closure glaucoma(PACG), or Secondary glaucoma were included in the study. Patients with a past history of cataract surgery, trabeculectomy, severely scarred conjunctiva (eg: Chemical burns, Steven-Johnson syndrome), patients with mild glaucomatous damage who could be managed medically, and patients with neovascular glaucoma were excluded from the study.

A detailed history regarding age, duration of glaucoma, and associated systemic illnesses was elicited. Treatment history including the nature of the Antiglaucoma medication (AGM), compliance to medication, prior laser procedures, and previous cataract surgery was elicited.

A complete ocular examination was done preoperatively. It included

a) Best Corrected Visual Acuity (BCVA) for distance using Snellen's chart in logMAR.

b) Intraocular pressure (IOP) assessment using Goldmann Applanation Tonometer.

c) Anterior segment examination using Slit-lamp Biomicroscopy and optic disc examination using a 90D lens.

d) Gonioscopy using Zeiss 4 mirror gonioscope.

e) Visual field examination using Humphrey perimeter (Glaufieldlite).

Patients were categorized as having mild, moderate, or severe glaucomatous damage based on optic nerve head changes and visual field defects. A mean defect value of 0-6 signifies mild, up to 12 a moderate defect, and more than 12 a severe defect.[2]. Target IOP was determined based on the severity of glaucomatous damage. In mild glaucomatous damage initial target IOP was kept at 15-17mmHg, for moderate glaucoma 12-15mmHg, and in low teens for severe damage [3].

For eyes with a baseline IOP of 20 mmHg and below, the target IOP was set as 30% below the baseline value. A complete preoperative workup was done including a blood hemoglobin level, Blood sugar, Blood pressure, and Nasolacrimal duct syringing. After complete evaluation and diagnosis patients were posted for a Combined Small Incision Cataract Surgery with Trabeculectomy. Peribulbar anaesthesia containing a mixture of (2% lignocaine, 0.5% bupivacaine with hyaluronidase 5IU/ml, and adrenaline one in one lakh) was given.

Eyelids and lashes were prepared. The skin over the periocular area was painted with 5% povidone iodine for 3 minutes. A fornix based conjunctival flap was dissected superiorly, up to 5 mm and Tenon's capsule was separated. A straight line partial thickness scleral flap was made 2.5 mm away from the limbus with a crescent blade. The sclerocorneal tunnel was dissected 1-2 mm into the clear cornea and paracentesis was made at 9'O clock position. A 5-6 mm capsulorhexis was performed after filling the AC with dispersive viscoelastic. The anterior chamber was entered with a 3.2 mm keratome. The inner lip of the tunnel was enlarged to around 6 mm. After hydrodissection and delineation, the nucleus was rotated and prolapsed into the anterior chamber using a Sinsky hook and delivered by sandwich technique. Cortex was aspirated with a Simcoe 2-way-irrigation aspiration cannula. A single piece rigid posterior chamber intraocular lens (PCIOL) was placed in the capsular bag. Viscoelastic was aspirated out. Trabeculectomy was performed by excising 0.5 mm x 0.5 mm tissue from the posterior lip of the sclera tunnel using an 11-size Bard Parker blade or Kelley's punch. A broad based peripheral iridectomy (PI) was performed. Two loose interrupted 10-0 ethilon sutures were passed on either side of the punched area to close the scleral tunnel and the knots buried. The edges of the conjunctival flap were anchored tightly to the limbus with 10-0 ethilon sutures. Ringer Lactate was injected through the side port to check the trabeculectomy, observe the formation of a diffuse bleb, and ensure there was no wound leak. Intracameral moxifloxacin 0.1 ml was injected through the side port, the side port was stromal hydrated. One ml subconjunctival injection of Dexamethasone and gentamycin was given inferiorly.

Topical moxifloxacin (0.5%), dexamethasone (0.8%), and prednisolone acetate 1% suspension was applied 2 hourly during waking hours for one week. Medications were tapered over 3 months. 1% Atropine eye drop was applied thrice a day on the first five postoperative days. Tablet Acetazolamide 250 mg BD was given as required for the first five postoperative days.

The patients were followed up on Postoperative day 1, day 5, day 10, and end of one month, three months, six months, and 12 months. At each postoperative visit visual acuity, IOP, Patency of peripheral iridectomy, Anterior Chamber depth, Cup Disc ratio, and any Postoperative complications were recorded. Visual field was tested at six months and one year to rule out glaucoma progression.

Age distribution, sex, and laterality of the operated eye in the study population were tabulated. Patients were categorized into Primary open angle glaucoma, Primary Angle closure glaucoma, Secondary open angle, and Secondary angle closure glaucomas. Patients on irregular AGM were grouped with patients who had no

antiglaucoma medication for data analysis. Post-operative results were tabulated for 81 eyes as two patients were lost to followup.

Ethical approval was obtained from the Institutional Ethical Committee in Tirunelveli Medical College and Hospital located in Tamil Nadu, India (Ref-966/OPTHAL/2017) before commencing the study. And adherence to the tenets of the Declaration of Helsinki was followed.

Statistical analysis was performed by using correlation coefficient and relative risk. MedCalc statistical software was used for statistical analysis. Complete success was defined as the achievement of IOP<21mmHg without any antiglaucoma medications. Qualified success was defined as IOP<21mmHg with anti-glaucoma medications [4].

Poor control of intraocular pressure is considered when the achieved final IOP at the end of one year is 3mmHg above the target IOP.

Results

A total of 83 eyes of 75 patients underwent combined SICS with trabeculectomy.

The study patients ranged from 40 to 80 years of age, seven patients belonged to the 40-49 years age group and 68 belonged to 50 to 80 years.

Out of the 75 patients, 44 were male, 31 female. 34 (45%) patients were operated in the right eye, 33 (44%) in the left eye and 8 (11%) in both eyes. The indication for surgery was POAG in 50 eyes, PACG in 25, SOAG in 6, and SACG in 2 eyes (Figure 1).

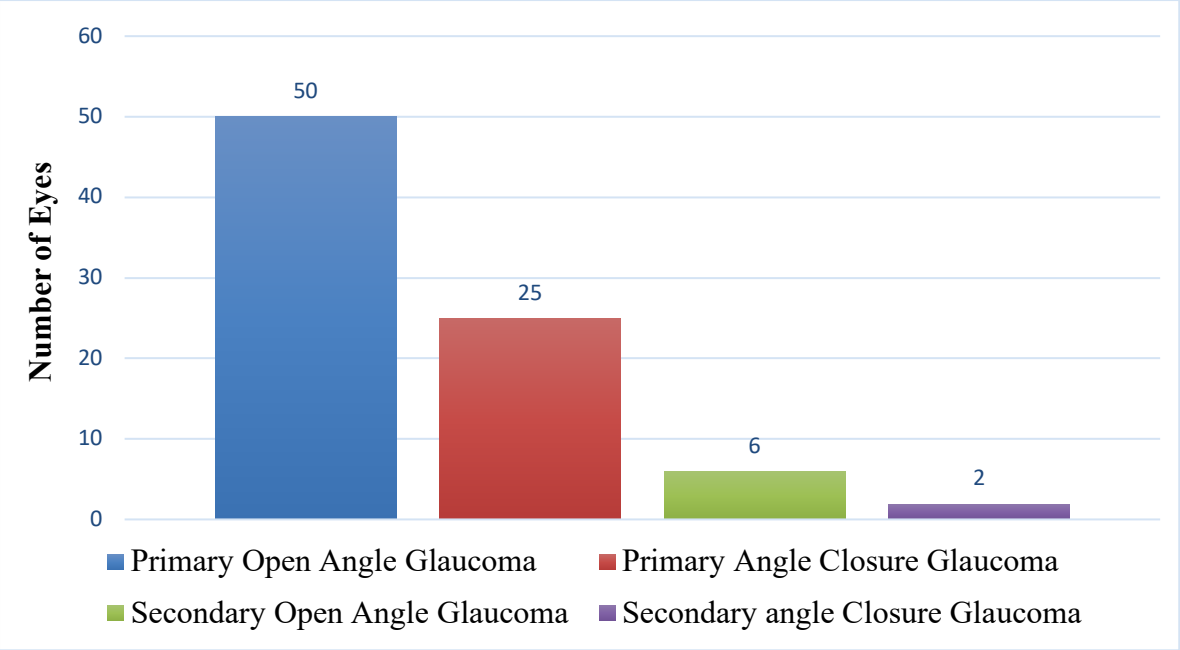

Figure 1: Shows the distribution of the various types of glaucoma in the study eyes.

One patient with POAG and one with PACG were lost to follow up. Duration of glaucoma was less than one year in 44 patients, between one to five years in 27 patients, and six to ten years in four patients. In all age groups, eyes with severe glaucomatous damage were higher (78%) than moderate damage.

Out of the 25 eyes with Angle Closure Glaucoma, Peripheral Iridotomy (PI) was done in 19 eyes of which 3 were not patent. Regarding antiglaucoma medication, among 83 eyes, 17 eyes used beta blockers, six eyes used travoprost, one eye used alpha agonist, 14 eyes used more than one antiglaucoma medication, and 45 eyes were on no medication. Out of 83 eyes, 33 had Preoperative IOP in the range of 11-20 mmHg. 19 had IOP in the range of 21-30 mmHg, and 13 had IOP in the range of 31-40 mmHg and 12 had IOP in the range of 41-50 mmHg. Six eyes had IOP above 50 mmHg. In this study among 83 eyes 18 had arcuate field defect, 36 had double arcuate defect, and 13 had tubular vision. In 16 eyes the field could not be assessed because of poor visual acuity due to significant cataract or glaucomatous damage.

As two eyes were lost to follow-up, postoperatively among 81 eyes 58 eyes had good postoperative IOP control and 23 eyes had poor IOP control at one year. IOP distribution graph of eyes with good and poor IOP control over a period of one year follow up is depicted in Figure 2&3.

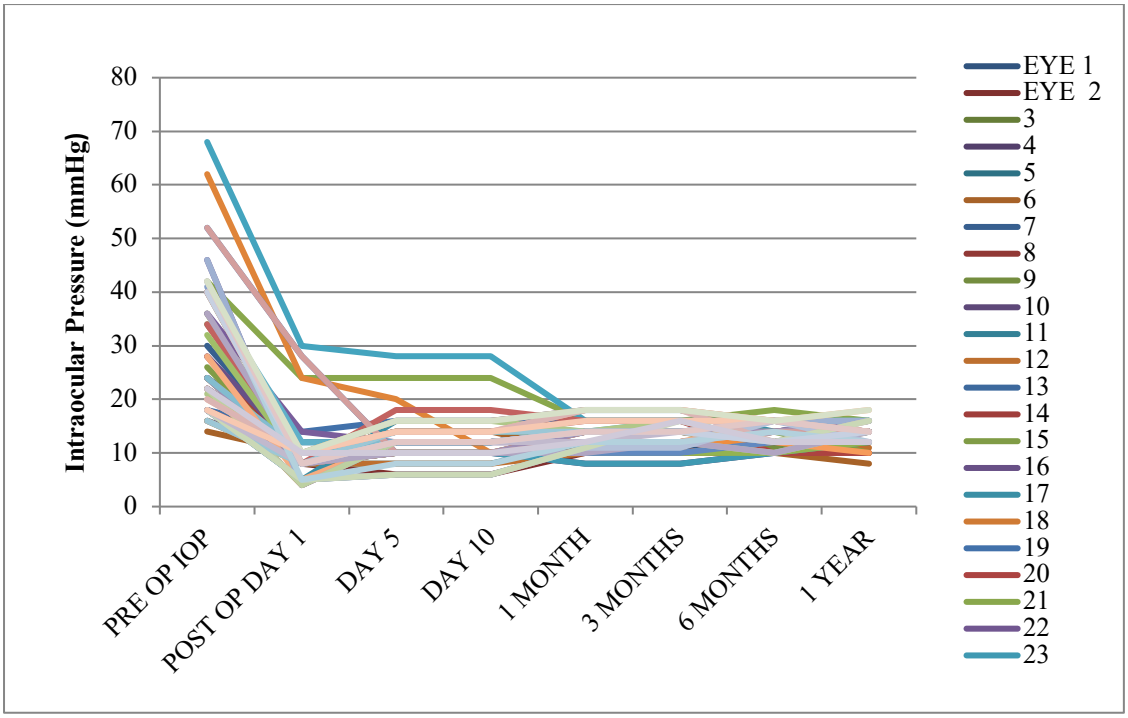

Figure 2: IOP distribution of 58 eyes with good IOP control from preop till one year follow up.

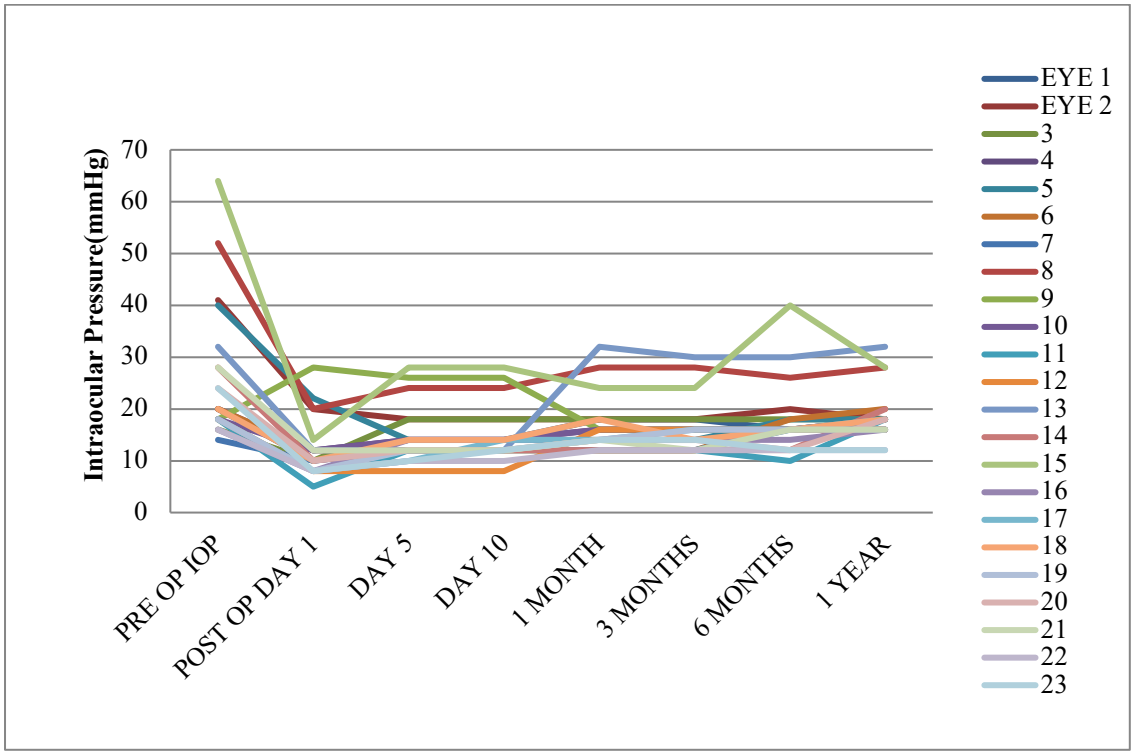

Figure 3: IOP distribution of 23 eyes with poor IOP control from preop till one year follow up.

The mean post op IOP of eyes with poor IOP control at one year was 18.9 mmHg which was higher when compared to mean post op IOP of eyes with good control (Figure 4).

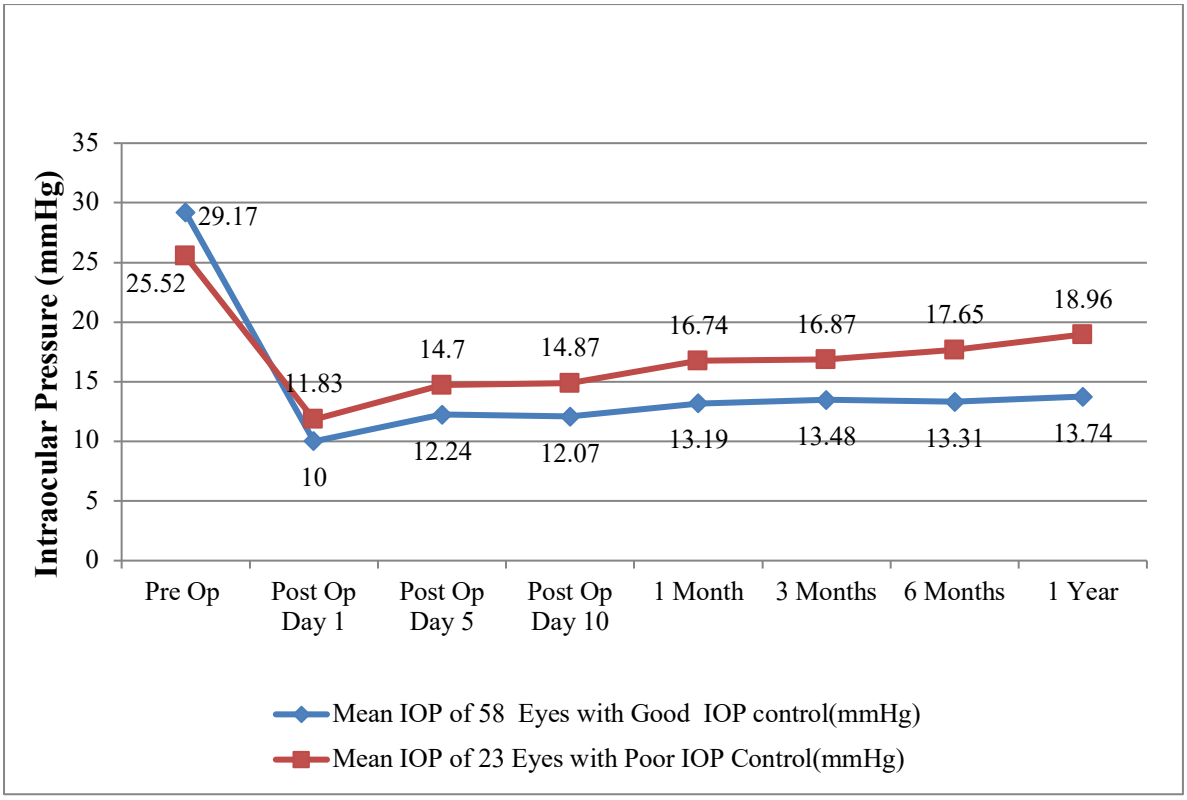

Figure 4: Comparison of Mean IOP of eyes with good and poor IOP control from preop till one year.

Majority of postoperative complications were managed conservatively. The most common postoperative complication was corneal edema. Others were hypotony, iritis, and transient increase in IOP, shallow anterior chamber, hyphaema, field progression and peripheral anterior synechiae. Age, Type of glaucoma, Pre op IOP, Pre op AGM, Extent of glaucomatous damage, and Post op IOP at each visit were analysed as probable risk factors for Poor IOP control following the surgery. Insignificant and significant risk factors were depicted in (Table 1 & 2) respectively.

Table 1: Insignificant risk factors for poor postoperative control of intraocular pressure with corresponding relative risk and p-values.

Risk factors	Eyes with Poor control of postoperative IOP(23)	Eyes with Good control of postoperative IOP(58)	Relative risk	p -value
POAG present	15	34		
POAG absent	8	24	1.22	p =0.58
PACG present	5	19	0.65	
PACG absent	18	39		p = 0.34
< 50 years	2	5	0.3	
≥ 50 years	21	53		p =0.99
Beta Blocker used	3	14	0.56	p =0.3
Beta Blocker not used	20	44		
Pre op IOP ≥ 30 mmHg	6	22	0.66	p= 0.32
Pre op IOP < 30 mmHg	17	36		
Severe damage	18	45	1.02	p= 0.94
Moderate damage	5	13		

Table 2: Significant risk factors for poor control of postoperative IOP, with corresponding Relative risk and p-values

Risk factors	Eyes with Poor control of postoperative IOP (23)	Eyes with Good control of postoperative IOP(58)	Relative risk	p - value
Postop IOP > 10mmHg On day 5	10	8	2.6	**p =0.002**
Post op IOP ≤ 10 mmHg on day 5	13	50		
Postop IOP >13mmHg on day 10	14	13	3.1	**p =0.001**
Postop IOP ≤ 13 mmHg on day 10	9	45		
IOP Difference > 4mmHg between postop day 1 and 1 month	15	23	2.12	**p=0.04**
IOP Difference ≤ 4mmHg between postop day 1 and 1 month	8	35		

Risk factors found to be significantly associated with poor control of postoperative IOP were, IOP of more than 10mmHg on Postoperative day five associated with a relative risk of 2.6, IOP of more than13mmHg on Postop Day 10 associated with a Relative risk of 3.1. Both had significant p-values of p = 0.002, and p = 0.001 respectively. IOP rise of more than 4 mmHg between postoperative day one and one month was a risk factor for poor control of intraocular pressure with a Relative risk of 2.12 and p = 0.04 (Figure 4). This study showed a weak positive linear relationship between preoperative IOP and postoperative IOP with a correlation coefficient of 0.25. The qualified success rate of the procedure in our study was 96% and the complete success rate was 60.5%.

Discussion

In this Study, 59% of the patients were male and 41% female which is opposed to the study by Khurana et al [5] in which 43% were male and 57% female. No significant age wise sex preponderance was noted. Among 75 patients operated, 45% were operated in the right eye, 44% in the left eye, and 11% in both eyes as opposed to a study by David L et al [6] in which 18% underwent bilateral surgery. This study showed that 60% of the study population had POAG, 30% PACG, 7% SOAG, and 3% SACG which is similar to the study by David L et al[6] in which 56% of the study population had POAG, 23% had PACG, 7% had SOAG.

In this study, 13% of peripheral iridotomy were not patent in angle closure glaucoma patients. 55% of the patients were on no antiglaucoma medication, 20% were on beta blockers, 7% were on prostaglandin analogue, 1% were on α-agonist, and 17% were using more than one antiglaucoma medication as opposed to the study by Vinita R et al[7] in which 94.6% of eyes were using more than one antiglaucoma medication. The mean preoperative medication used was 1.36 ± 0.4 which is similar to the study by Harsha et al [4] which used 1.6 ± 0.6 medications in the preoperative period.

The mean preoperative intraocular pressure was higher in the group of patients who were on irregular antiglaucoma medication than those on regular medication irrespective of the duration of glaucoma. In this study, Beta Blocker was not a significant risk factor for failure of trabeculectomy which is similar to the study by Johnson et al [8] which described that there was no significant difference in the success rate of trabeculectomy between eyes that previously used beta blockers and eyes that did not use beta blockers. In this study out of 78% of eyes that had severe glaucomatous damage, 20% of the field could not be documented due to severe glaucomatous damage to the optic disc and 22% had moderate field defects which is similar to the study by Usha et al[9] in which 29% had moderate field defect.

This study showed a weak linear relationship between preoperative and early postoperative control of intraocular pressure with a correlation coefficient of 0.25, which is comparable to a study by Lochhead et al [10] which showed a linear relationship between preoperative and postoperative intraocular pressure in trabeculectomy and phaco trabeculectomy.

In this study, eyes with early postoperative intraocular pressure of >10 mmHg on day five or >13 mmHg on day ten were associated with poor control of intraocular pressure at the end of one year with Relative risk of 2.6 and 3.1 and a significant p-value of 0.002 and 0.001 respectively. This is comparable with a study by Rong SS et al [11] which described that IOP>10.5 mmHg on day one or >13.5 mmHg on postoperative day seven, the relative risk of failure was 4.2. Similarly, Okimotos et al [12] concluded that an IOP under 8 mmHg at 2 weeks after surgery was found to maintain postoperative IOP of either ≤11 mmHg or ≤15 mmHg for an extended period.

In this study a rise of pressure more than 4mmHg from the initial post-operative IOP within one

month has a risk factor for poor postoperative control of IOP at the end of one year, Relative risk was 2.12, p-value 0.04 which is similar to study by Hamed Esfandiariet al [13] which concluded that IOP change during the first month rather than each visit was a good predictor of failure and increase in more than 3 mmHg during the first 30 days was a good predictor of failure.

Overall the qualified success rate of the procedure in this study was 96% and the complete success rate was 60.5%. The qualified success rate in POAG was 98% and complete success rate was 53%, whereas in PACG the qualified success rate was 100% and complete success rate was 71%, which was similar to the study by Harsha et al[4] in which PACG had better postoperative IOP control than POAG.

Limitations of our study were short term follow up and surgery by a single surgeon.

Conclusion

When performed with technical precision and vigilant postoperative care, SICS combined with trabeculectomy even without antimetabolites can lead to successful surgical outcomes in management of glaucoma. High IOP in early postop period is a significant risk factor for poor control of IOP at one year. In this study, eyes with PACG have a higher success rate than eyes with POAG, which may be due to angle widening after lens removal resulting in better IOP control.

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