ORIGINAL RESEARCH PAPER

Ophthalmology

STATUS OF INTRAOCULAR PRESSURE AND COMPLICATION PROFILE OF PATIENTS UNDERGOING MICRO-TRABECULECTOMY AT A TERTIARY CARE TEACHING HOSPITAL. A COHORT STUDY

KEY WORDS: Glaucoma, Intra occular Pressure, Micro-Trabeculectomy

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ABSTRACT

Background: IOP control at the early postoperative period is critical for successful Trabeculectomy. It is no exaggeration to say that long-term surgical results are determined by early IOP control. Objectives of the study was to report on the medium to long term IOP control following micro-Trabeculectomy employing a 2x2mm superficial scleral flap and 0.75 mm internal ostium in a cohort of eyes at relatively low risk for surgical failure. **Methodology:** The cohort study was conducted on patients attending Postgraduate Department of Ophthalmology Government Medical College, Srinagar. A total of 41 cases with the diagnosis of primary open angle glaucoma were included in the study and the cohort was followed postoperatively at 1 week, 2 weeks, 1 month, 2 months, 3 months, and 6 months interval. At each visit a full ocular examination was performed. **Results:** Majority of the cases were males, 30 (73.1%) and among males most of the cases 13 (43.5%) were in the age group of 60-70 years. On the pre-operative assessment of the studies cases, majority of the cases 23 (56.2%) were having a cup disc ratio between 0.7-0.8 mm, majority 23(56.2%0 had IOP between 31-40 mmHg preoperatively followed by 14 (34.2%) cases who had IOP between 21`-30 mmHg. The mean IOP at week 1` was 12.15 ± 4.20 mmHg and at 6 months it was 16.59 ± 1.91` mmHg. Moreover, the mean change in IOP measured pre-operatively and at 6 months was found to be 16.63 ± 5.84 mmHg. The association was found to be statistically significant ($p<0.001$). Majority 20 (48.3%) studied cases had thin polycystic (I) blebs followed by flat diffuse blebs among 16 (39.5%) cases. The most common complications like raised IOP was found in 3 (7.5%) cases while hyphaema and the shallow anterior chamber was found in 2 (5%) cases only. **Conclusion:** micro-Trabeculectomy is safe and effective at reducing IOP in low-risk glaucoma eyes with IOP control and complication profile similar to previous reports of filtering surgery utilizing larger scleral flaps.

INTRODUCTION:

Trabeculectomy has become the surgical procedure of choice for chronic open-angle glaucoma (COAG) for the last many years. It was Cairns, who first reported its use in humans. [1] Glaucoma is a group of ocular disorders of multi-factorial etiology united by a clinically characteristic optic neuropathy with potentially progressive, clinically visible changes at the optic nerve head (ONH). It is the second most prevalent condition after the cataract is known to cause blindness worldwide. [2-3] The estimated prevalence of glaucoma in the world was 60.5 million in 2010 and is expected to increase to 79.6 million by 2020. [4] Primary open-angle glaucoma is a chronic optic neuropathy with characteristic patterns of optic nerve injury and visual field loss. [4-5] Elevated intraocular pressure is the most important risk factor for POAG progression and is the primary therapeutic target, however, one-sixth of patients with POAG have IOP levels below 21mmHg, which is considered statistically normal in the 95th percentile range. [6]

IOP control at the early postoperative period is critical for successful Trabeculectomy. [7-9] It is no exaggeration to say that long-term surgical results are determined by early IOP control. If early postoperative IOP is too low, complications such as choroidal detachment (CD), shallow anterior chamber, and hypotony maculopathy can occur; if it is too high, surgery is unsuccessful.

Several studies on target IOP in the early postoperative period after conventional Trabeculectomy and complication patterns have been reported from other parts of the World. There have been no such reports from India. [10-12] We conducted this study intending to report on the medium to long term IOP control following micro-Trabeculectomy employing a 2x2mm superficial scleral flap and 0.75 mm internal ostium in a cohort of eyes at relatively low risk for surgical failure.

METHODOLOGY:

The cohort study was conducted on patients attending Postgraduate Department of Ophthalmology Government Medical College, Srinagar. Patients with primary open angle glaucoma whose intraocular pressure was more than 21mmHg inspite of maximum tolerated medical therapy, Patients intolerable to various side-effects of anti-glaucoma medications and Patients with poor compliance to medical treatment were included in our study. A total of 41 cases with the diagnosis of primary open angle glaucoma were included in the study and the cohort was followed postoperatively for a period of six months. Eyes with uveitis, robotic eyes, eyes which have had previous Trabeculectomy, eyes in which anti-metabolites were used and aphakic eyes were excluded from the study.

Preoperatively, workup of cases included socio-demographic details, full ocular and medical history and ocular examination including visual acuity measurement, slit-lamp examination, gonioscopy, applanation tonometry, and fundus examination by slit-lamp biomicroscopy and indirect ophthalmoscopy was also performed. Repeated perimetry was done with the Humphrey visual field analyzer. After assessing the above parameters and establishing the diagnosis, cases were subjected to micro-Trabeculectomy. Cases were admitted to the hospital one day before surgery. Intraocular pressure was lowered by pharmacotherapeutic agents viz. I/V Mannitol (1-2g/kg body weight) oral glycerol (1-1.5g/kg body weight) and oral acetazolamide (250mg TID) depending upon the value of intraocular pressure. Each case was explained the objectives of the study and written informed consent were obtained from each case before their inclusion into the study.

Operative Procedure: Surgery was conducted under local anesthesia by peribulbar block. The skin of eyelids, half of the forehead, and face were cleaned with 10% povidone-iodine

and draped. Following the insertion of a lid speculum, a 4-0 silk traction suture was inserted at the superior rectus. A fornix-based conjunctival flap was made and bleeding episcleral vessels were cauterized by using wet field cautery to scleral bed. A 2x2mm partial thickness scleral flap with a crescent knife was formed. Paracentesis in the opposite superior quadrant was performed. Anterior incision into the anterior chamber at the angle of the scleral flap was given. Kelly punch trabeculectomy (0.75x0.75mm) was done. Peripheral iridectomy with de Wecker's scissors was performed. 10-0 nylon sutures to the corners of the scleral flap were applied. 10-0 nylon sutures to conjunctiva were applied. Balanced salt solution via paracentesis to produce a, bleb was injected. Subconjunctival injection of dexamethasone and gentamycin was administered 180 degrees away from the drainage site. Pad and bandage were applied for 24 hours. The bandage was removed and the eye was examined after 24 hours. Particular attention was paid to the condition of filtering bleb, cornea for striate keratopathy or edema, the anterior chamber for depth and contents, pupil for reaction, and shape. Intraoperative and postoperative complications were recorded. Topical antibiotic-steroid eye drops were given for 6 weeks and cycloplegic eye drops for 1-2 weeks postoperatively.

Postoperative follow up was done at 1 week, 2 weeks, 1 month, 2 months, 3 months, and 6 months interval. At each visit a full ocular examination was performed, including visual acuity, slit-lamp examination of anterior chamber and bleb, intraocular pressure measurement, and fundus examination. Postoperative complications were recorded.

Statistical Analysis:

Data were entered in a Microsoft Excel spreadsheet. Continuous variables were summarized as mean and standard deviation. Categorical variables were summarized as percentages. The difference between the two means was calculated using a t-test. P-value < 0.05 was considered significant at 95% confidence interval. All the statistical analysis was done using SPSS 23.0.

Ethical Issues:

The study has no ethical issues about the animal or human experimentation. The study proposal was presented before the institutional ethics committee before the commencement of the study. The institutional ethics committee approved the study proposal.

RESULTS:

The age and sex distribution of the studied cases have been described in Table 1.Majority of the cases were males, 30 (73.1%) and among males most of the cases 13 (43.5%) were in the age group of 60-70 years, followed by 11 (36.5%) in the age group of 51-60 years. Among females, most of the cases were in the age group of 50-60 years. On the pre-operative assessment of the studied cases, majority of the cases 23 (56.2%) were having a cup disc ratio between 0.7-0.8 mm, majority 23(56.2%0 had IOP between 31-40 mmHg preoperatively followed by 14 (34.2%0 cases who had IOP between 21`-30 mmHg. On the pre-operative assessment of visual acuity among the studied cases, majority 17 (41.5%) had visual acuity ranging from 6/6-6/9 while very few % (12%) had visual acuity less than 6/60. Table 3 describes post-operative IOP measurement and follow up among the studied cases. The mean IOP at week 1` was 12.15 ± 4.20 mmHg and at 6 months it was 16.59 ± 1.91` mmHg. Moreover, the mean change in IOP measured pre-operatively and at 6 months was found to be 16.63 ± 5.84 mmHg. Using a t-test to determine the difference between the two means, the association was found to be statistically significant (p<0.001). Bleb formation and complication among the studied cases during treatment and follow up are described in Table 5. Majority 20 (48.3%) studied cases had thin polycystic (I) blebs followed by flat diffuse blebs among 16 (39.5%) cases. In our study, we had only 8 (19.5%) cases who reported complications. The most common complications like raised IOP was found in 3 (7.5%) cases while hyphaema and the shallow anterior chamber was found in 2 (5%) cases only. [Table 5] The overall success of Micro-Trabeculectomy among the studied cases at the end of follow up is shown in Table 6. Absolute success; IOP <21 mmHg without antiglaucoma medication was achieved among 38 (92.5%) cases while qualified success; IOP <21 mmHg with or without antiglaucoma medication was achieved among all the studied cases. There were no failures rates in our procedure during and at the end of 6 months follow up.

Table 1: Age And Sex Distribution Of Studied Subjects

Age Group	Male		Female		Total	
	No.	%	No.	%	No.	%
40-50	5	16.5	3	27.5	8	19.5
51-60	11	36.5	5	45.0	16	39.0
60-70	13	43.5	3	27.5	16	39.0
>70	1	3.5	0	0	1	2.5
Total	30	100	11	100	41	100

Table 2: Preoperative Assessment Of The Studied Cases

Preoperative C: D Ratio		
Cup Disc Ratio	**Cases (n)**	**(%)**
0.5 to 0.6	15	36.5
0.7 to 0.8	23	56.2
>0.8	3	7.3
Preoperative Intraocular Pressure		
IOP (mmHg)	**Cases (n)**	**(%)**
21-30	14	34.2
31-40	23	56.2
41-50	4	9.6
51-60	0	0
Preoperative Visual acuity		
Visual acuity	**Cases (n)**	**(%)**
6/6 to 6/9	17	41.5
6/12 to 6/18	10	24.5
6/24 to 6/36	9	22
6/60 or less	5	12
Total	41	100

Table 3: Postoperative IOP Measurement And Followup Among The Studied Cases Over The Period Of 6 Months

IOP mmHg	1 week		2 week		1 monthS		2 months		3 months		6 months	
	(n)	(%)	(n)	(%)	(n)	(%)	(n)	(%)	(n)	(%)	(n)	(%)
<10	19	46.35	14	34.16	2	4.88	1	2.44	1	2.44	1	2.44
11-20	19	46.35	24	58.54	34	82.96	34	82.96	36	87.8	36	87.8
>21	3	7.30	3	7.30	5	12.16	6	14.6	4	9.76	4	9.76
Mean± S.D	12.15± 4.20		12.5± 3.31		13.3± 2.36		13.9± 1.41		14.5± 1.18		16.59± 1.91	

Table 4: Mean Change In IOP Among The Studied Cases During The Course Of Treatment And Follow-up

Preoperative IOP (Mean IOP±SD	Last Postoperative IOP- 6 months (Mean IOP±SD)	Change in IOP (mmHg)	Significance level (p-value)
33.22±5.62	16.59±1.91	16.63±5.84	P<0.001

Table 5: Bleb formation and complications among the studied cases during the course of treatment and follow-up

Type of bleb	No. of cases	Percentage
Thin polycystic (I)	20	48.3
Flat diffuse (II)	16	39.5

Vascularized nonfiltering (III)	2	4.9
Encapsulated (IV)	2	4.9
No bleb	1	2.4
Total	41	100
Complications	**Cases**	**Percentage**
Hyphaema	2	5
Shallow Anterior Chamber	2	5
Raised IOP	3	7.5
Cataract progression	1	2.5
Total	8	19.5

Table 6: Success Of Micro-trabeculectomy Among The Studied Cases At 6 Months Follow-up

Success of Micro-Trabeculectomy	Cases (n)	Percentage (%)
Absolute	38	92.5
Qualified	41	100
Failure	0	0

NB: Absolute success: IOP <21mmHg without antiglaucoma medication; **Qualified success:** IOP <21mmHg with or without antiglaucoma medication; **Failure:** IOP >21mmHg with antiglaucoma medication.

DISCUSSION:

The cohort study was conducted on patients attending the Postgraduate Department of Ophthalmology Government Medical College, Srinagar. The mean age of the cases in our study was 59.0 ± 9.0 years, and this coincides with the mean age reported by Thimmarayan SK et al [13] in their study, (60.2±11.2 years), however, it is lower than the mean age of glaucoma patients reported by Ang GS et al. [14] (69.6±10.9 years) in the micro-Trabeculectomy group and (68.4±9.0 years) in standard Trabeculectomy group and Stephen A. Vernon et al. [15] (70.1± 9.3years). It is also lower than the mean age of glaucoma patients reported by SA Vernon et al. [16] (69.8±7.5 years). The majority of the patients (80%) were above the age of 50 years. Most of the studies that have studied the relationship of primary open-angle glaucoma and age have confirmed that older the individual, the greater the prevalence of glaucoma. The results of our study are in accordance with the other published studies.

In the present study, the mean preoperative IOP was 33.22 ± 5.62mmHg, which is almost of the same value as reported by SA Vernon et al. [16] who reported mean preoperative IOP of 33.7 ± 7.5, it is also following mean preoperative IOP noted by SA Vernon et al. [16] who reported mean preoperative IOP of 33.4 ± 8.8mmHg. It is slightly higher than the preoperative IOP reported by Thimmarayan SK et al. [13] who reported a mean preoperative IOP of 28.63 ± 2.72 mmHg.

The mean final IOP at the end of 6 months in our study was 16.59 ± 1.91mmHg (p<0.001) which is near the values reported by SA Vernon et al. [16] who reported a mean IOP of 13.4 mmHg at the last recorded outpatient visit (mean follow up 13.4 ± 7.4 months, minimum 3 months). It also coincides with mean postoperative IOP of 15.80 ± 4.3 reported by Thimmarayan SK et al. [13] It is slightly higher than the mean IOP reported by AK Negi et al. [17] who reported a mean IOP of 12.6mmHg, 8.8mmHg, and 12.7 mmHg in superior (12'O clock), superonasal and supero-temporal groups respectively at the end of 6 months.

In the present study, at 6 months postoperatively, visual acuity remained unchanged in 39 (95%) cases and deteriorated in 2(5%) patients by two Snellen lines (one from cataract progression and other from the progression of optic nerve damage). Alan Rotchford et al. [18] reported deterioration in visual acuity in the micro-Trabeculectomy group by a mean 0.17 logMAR equivalent at the final follow up. Visual acuity deteriorated by at least one Snellen line in 35.1% (13/37) eyes. Loss of vision was most often attributable to cataract. Ang GS et al. [14] in their comparative study of standard Trabeculectomy versus micro-Trabeculectomy showed a decrease in the average log MAR BCVA from 0.15 ± 0.27 at baseline to 0.29 ± 0.50 at 24 months in the standard Trabeculectomy group, this was not statistically significant (p=0.29). Similarly in the micro-Trabeculectomy group, the decrease in average logMAR BCVA from 0.29 ± 0.64 at baseline to 0.41 ± 0.66 at 24 months did not achieve statistical significance (p=0.54). Higher rates of visual deterioration in the above studies as compared to our study may be due to longer follow-ups in these studies as compared to our study.

The mean final IOP at the end of 6 months in our study was 16.59 ± 1.91mmHg (p<0.001) which is near the values reported by SA Vernon et al. [16] who reported a mean IOP of 13.4 mmHg at the last recorded outpatient visit (mean follow up 13.4 ± 7.4 months, minimum 3 months). It also coincides with mean postoperative IOP of 15.80±4.3 reported by Thimmarayan SK et al. [13]

Success Rate:

In our study, the absolute success rate was 92.5% which is very close to the success rates noted by Thimmarayan SK et al. [13] (93.3%) and Ang GS et al. [14] (90.5%). Our success rates are higher than those noted by SA Vernon et al. [16] (78%). Our success rate of 92.5% supports the view of micro-Trabeculectomy as an effective and safe alternative to conventional Trabeculectomy.

COMPLICATIONS

Postoperative Shallow Anterior Chamber: Postoperatively shallow anterior chamber occurred in 2 patients (4.8%). It is lower than reported by Stephen A. Vernon et al. [15] (14%). It is also lower than reported by SA Vernon et al. [16] (19.6%). It is near to that reported by Thimmarayan SK et al. [13] (3.3%) respectively.

Postoperative Hyphaema: In our study, it occurred in 2 patients (4.8%). It is near to that reported by Thimmarayan SK et al. [13] (3.3%). It is lower than that reported by Stephen A. Vernon et al. [15] (25%) and SA Vernon et al. [16] (33%) respectively.

Postoperative Cataract Progression: It was seen in one patient (2.4%). It is lower than that reported by SA Vernon et al. [16] It is near to that reported by Thimmarayan SK et al. [13] (4%) respectively.

CONCLUSION:

The first Trabeculectomy described by Cairns involved a 5 × 5 mm partial-thickness scleral trapdoor and a 4 × 1 mm tissue block excision as far as the scleral spur. Our scleral trapdoor of 2 × 2 mm is approximately one-sixth of the area of the Cairns' procedure, and the 0.75 × 0.75 mm internal opening is just one-seventh of the area of the original ostium. Thus the relative sizes of the flap and the internal ostium in "small flap" Trabeculectomy are similar to the operation from which it is derived. Such a marked reduction in the size of the surgical incisions might be expected to result in an increased rate of "filtration failure" with time as has been found to occur following holmium laser ab externo laser sclerotomy. The results of this study indicate that reducing the size of the scleral flap does not, however, appear to lead to an increased medium to long term failure rate. This reassuring fact permits the surgeon to take advantage of the potential benefits of a procedure which occupies a smaller area on the surface of the eye. .Micro-Trabeculectomy allows the surgeon to perform a controlled procedure with less tissue disruption and a chance of success that is at least the equivalent of conventional surgery. It is of particular advantage when 'virgin' conjunctiva at limbus due to previous surgeries is in short supply, allowing the operation to be performed superiorly when otherwise an inferior approach would be required. From this study, it is concluded that the micro-Trabeculectomy is safe and effective at reducing IOP in low-risk glaucoma eyes with IOP

control and complication profile similar to previous reports of filtering surgery utilizing larger scleral flaps.

Conflict of Interest: None

Source of Funding: None
Acknowledgement: Authors are highly grateful to the Head of Department, Postgraduate Department of Ophthalmology for his unending support during this work.

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