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Mini-trabeculectomy in comparison to conventional trabeculectomy in primary open angle glaucoma

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PURPOSE. *To evaluate the safety and efficacy of mini-trabeculectomy in comparison to conventional trabeculectomy in primary open angle glaucoma (POAG).*

METHODS. *A prospective interventional study of mini-trabeculectomy versus conventional trabeculectomy was undertaken on 60 eyes of 54 medically uncontrolled POAG patients requiring glaucoma surgery. They were divided into two groups: Group I underwent mini-trabeculectomy (30 eyes of 26 patients) and Group II underwent conventional trabeculectomy (30 eyes of 28 patients). All patients were followed up for at least 15 months. Statistical analysis was carried using Student's t test and paired t test for quantitative data and Pearson's chi-square test for qualitative data.*

RESULTS. *The mean intraocular pressures (IOP) at the end of 15 months of follow-up in Groups I and II were 15.80±4.3 mmHg and 16.13±3.3 mmHg versus mean preoperative IOP of 28.63±2.74 and 28.60±2.44, p<0.0001, respectively. The difference in IOP control was significant only at 6 months of follow up (13.65±3.45 versus 15.98±4.05, p=0.041). The complications and failure were comparatively less in Group I.*

CONCLUSIONS. *Mini-trabeculectomy is a safe and effective alternative to conventional trabeculectomy in terms of IOP control. A modified tunnel incision employed in mini-trabeculectomy may be responsible for avoiding some of the complications. (Eur J Ophthalmol 2006; 16: 674-9)*

KEY WORDS. *Primary open angle glaucoma, Mini-trabeculectomy, Trabeculectomy, Progression of glaucoma, Visual fields*

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INTRODUCTION

Filtration surgery for glaucoma is undertaken to lower the intraocular pressure (IOP) so as to slow or eliminate pressure-dependent ganglion cell loss (1). Trabeculectomy was first described by Cairns in 1968, and since then is considered one of the most successful methods of permanently lowering IOP. Several serious postoperative complications are often associated with this procedure (2). These include early postoperative aqueous leak, which after surgery with a fornix-based conjunctival flap was reported to reach an incidence rate of 21%, hyphema, and cataract formation (3-5).

Hypotony is a serious and common complication and in 1–2% of cases it may even persist after standard trabeculectomy (6). Hypotony can lead to flat anterior chamber, corneal edema, cataract, maculopathy, and thus loss of vision (7, 8). Attempts have been made to reduce postoperative hypotony by tight suturing of the scleral flap (9) and modifying wound techniques (10-19). Tight suturing of the scleral flap can lead to higher pressure and poor drainage of aqueous. It needs to be combined with postoperative laser suture lysis. Suture lysis may, however, lead to conjunctival hole with aqueous leak or be unsuccessful due to a thick conjunctiva or blood over sutures (9).

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Filtering surgery should be as safe as possible and every effort should be made to reduce the incidence of postoperative hypotony. The present prospective study was made to evaluate the safety and efficacy of a modified trabeculectomy technique, mini-trabeculectomy in comparison to conventional trabeculectomy. The new technique, mini-trabeculectomy, differs from conventional trabeculectomy by a modification of scleral flap and creation of a sclerocorneal tunnel without radial incisions.

PATIENTS AND METHODS

A prospective interventional study of 60 eyes of 54 patients requiring filtering surgery for adequate control of IOP was carried out at JIPMER between August 2003 and September 2005.

Patients aged 40 years or more with the diagnosis of primary open angle glaucoma (POAG) on maximal tolerable medical therapy and/or progressive visual field loss were included in the study. Patients having undergone any intraocular or glaucoma surgery in the past and eyes with chronic inflammatory or cicatricial diseases involving superior conjunctiva were excluded from the study.

A total of 60 eyes of 54 patients were randomly assigned into two groups. Group I underwent mini-trabeculectomy (30 eyes of 26 patients) and Group II underwent conventional trabeculectomy (30 eyes of 28 patients). All patients were followed up for at least 15 months (mean 18 months, range 15 to 24 months).

Documentation of patient's age, sex, and detailed clinical history along with general physical and systemic examination findings was done.

A comprehensive ocular examination was carried out including recording of best-corrected visual acuity (BCVA), anterior and posterior segment examination (stereoscopic optic disc evaluation) with slit lamp biomicroscopy, IOP measurement with Goldmann applanation tonometer, gonioscopy, measurement of anterior chamber depth (ACD) by ultrasound A scan (E-Z scan^{Tm} AB 5500+; Sonomed Inc., Lake Success, NY, USA), and visual field recording using Humphrey field analyzer (Humphrey Instruments, Inc.; model HFA II 750, San Leandro, CA, USA). Assessment of blebs was done according to Migdal and Hitchings' classification of blebs (20). All surgeries were performed by the same surgeon (V.A.R.).

Surgical technique

Written informed consent was taken prior to surgery, which was performed under peribulbar local anesthesia. A 5-0 polyglactin traction suture was placed under the superior rectus muscle to rotate the eyeball downward to expose the superior quadrant.

The surgical procedure consisted of a small, 3 mm, fornix-based conjunctival flap. Light diathermy was applied to bleeding vessels and to the scleral area to be dissected. A horizontal scleral incision of 300 µm depth was made 1 mm posterior to the limbus. Using a crescent shaped diamond knife (Visitec; Sarasota, FL, USA) lamellar dissection was done through the scleral incision, advancing into the corneal stroma up to 1 mm from the limbus. The corneoscleral tunnel was then widened nasally and temporally and a sclerocorneal pocket of 3 mm in length and 2 mm in width (from scleral incision to cornea) was thus completed. Thereafter, the anterior chamber was entered centrally using the knife. Anterior camber was formed with viscoelastic material (2% hydroxy propyl methylcellulose). A 1 mm Kelly's Descemet punch (Katena; Denville, NJ, USA) was introduced into the anterior chamber and corneotrabeculectomy was carried out. Spontaneous aqueous outflow through the scleral incision was regarded as adequate; otherwise the punch was reused, posterior to its first dissection. Peripheral iridectomy was then performed following which viscoelastic material was aspirated from the anterior chamber. Sclera incision was closed by one 10-0 nylon suture allowing for minute egress of aqueous. The conjunctival flap was closed using 6-0 silk.

Postoperatively, all eyes received topical antibiotic-corticosteroid drops, which were tapered over 4 to 6 weeks. Cycloplegic eyedrops were also used for initial 1 or 2 weeks. Patients were serially followed up on day 1, at 1 week, at 1 month, and at monthly intervals for 6 months, and 3 monthly intervals thereafter. During each visit the IOP, bleb characteristics, anterior chamber depth, and cup/disc ratio were monitored. Visual field analysis was done at 3 monthly intervals postoperatively.

Subconjunctival injections of 5-fluorouracil and digital ocular compression were carried out in eyes having flat bleb with high IOP in the early postoperative period. Additional antiglaucoma medications were added if indicated. Success of the procedure was defined as an IOP 20 mmHg with no additional antiglaucoma medication or surgery. Qualified success was defined as an IOP 20

mmHg with antiglaucoma medication. IOP of more than 20 mmHg with antiglaucoma medications for 3 consecutive months with or without evidence of progressive glaucomatous optic disc cupping and/or deterioration of visual field status was regarded as failure of the surgery.

The data were compiled and statistically evaluated using Student's t-test and paired t-test for quantitative data and Pearson's chi square test for qualitative data as indicated.

RESULTS

The mean age of the patients in the study was 59.3±10.7 years. Male and female ratio was 32:28. There was no statistically significant difference in age or sex between the two groups. Other preoperative characteristics of the study population are summarized in Table I. Baseline visual acuity distribution was not significantly different between the two groups.

The mean preoperative IOP in Group I was 28.63±2.74 (range 22 to 33) mmHg and in Group II was 28.60±2.44 (range, 25 to 34) mmHg. There was no statistically significant difference between the two groups regarding preoperative IOP distribution. The average postoperative IOP at each follow-up visit is detailed in Table II.

All 60 eyes were under follow-up for 15 months or more and 47 eyes for 24 months. The mean IOP at the end of 15 months of follow-up in Group I was 15.80±4.3 mmHg (preoperative mean IOP: 28.63 ± 2.74; $p<0.0001$) versus 16.13±3.3 mmHg in Group II (preoperative mean IOP: 28.60±2.44; $p<0.0001$). IOP achieved at the end of 15 months follow-up was lower in Group I than in Group II but was not statistically significant ($p=0.656$). There was no statistically significant difference in the postoperative IOP between the two groups except at 6 months postoperatively.

After postoperative follow-up of at least 15 months, the mean intraocular pressure was 15.80±4.3 mmHg. Twenty-nine eyes (96.7%) in Group I and 28 eyes (93.3%) in Group II had IOP 20 mmHg or less. Out of these, 28 eyes

TABLE I - PREOPERATIVE CHARACTERISTICS OF STUDY POPULATION

	Group I (mini-trabeculectomy) mean (SD)	**Group II (conventional trabeculectomy) mean (SD)**
Age, yr	60.2 (11.2)	58.3 (10.1)
IOP, mmHg	28.63 (2.74)	28.60 (2.44)
Anterior chamber depth, mm	3.11 (0.29)	3.05 (0.26)
Number of antiglaucoma medications	2.50 (0.30)	2.50 (0.75)
Primary open angle glaucoma diagnosis, no. of eyes	30	30

IOP = Intraocular pressure; SD = Standard deviation

TABLE II - VARIATION OF POSTOPERATIVE INTRAOCULAR PRESSURE (IOP) WITH TIME

Time	**Group I (mini-trabeculectomy)**	**Group II (conventional trabeculectomy)**	
	Mean IOP (SD)	**Mean IOP (SD)**	**p Value**
Day 1	13.34 (4.52)	14.05 (4.24)	0.280
Week 1	13.40 (4.27)	14.30 (4.12)	0.245
Month 1	13.83 (3.80)	14.59 (4.20)	0.310
Month 3	13.40 (4.60)	14.34 (4.46)	0.287
Month 6	13.65 (3.45)	15.98 (4.05)	0.041*
Month 9	15.02 (3.78)	16.89 (4.10)	0.055
Month 12	15.18 (3.80)	16.06 (4.16)	0.059
Month 15	15.80 (4.30)	16.13 (3.30)	0.656

Statistically significant
SD = standard deviation

in Group I and 27 eyes in Group II did not require antiglaucoma medications; 18 eyes (60%) and 15 eyes (50%) had IOP 16 mmHg or less in Groups I and II, respectively.

Subconjunctival 5-fluorouracil injections (1 to 4, mean: 2.8) along with digital ocular compression were given in 2 eyes in Group I and 3 eyes in Group II, having flat bleb with high IOP. All the five eyes responded initially but on subsequent follow-up had high IOP requiring additional antiglaucoma medications. The characteristics of the one failed eye in Group I and two failed eyes in Group II are shown in Table III. It is noteworthy that all fail cases had advanced glaucomatous optic neuropathy.

At the end of 15 months of follow-up, the average number of antiglaucoma medications decreased significantly from their preoperative values ($p<0.05$). It was 2.50±0.30 and 2.50±0.75 preoperatively for Group I and Group II, respectively, which decreased to 0.33±0.58 for Group I and 0.29±0.55 for Group II postoperatively. However, the difference of postoperative medication was not significant in the two groups ($P_{I-II} = 0.484$).

The blebs following mini-trabeculectomy were qualified as a pale diffusely elevated conjunctiva (Grade 5) in 28 eyes (93.3%) and cystic blebs (Grade 6) in 2 eyes (8%) (20). The blebs formed following conventional trabeculectomy were of Grade 4 in 25 eyes (83.3%) and cystic blebs were observed in 5 eyes (16.7%) (20). No definite correlation was observed between the appearance of blebs and the final IOP.

The mean postoperative anterior chamber depth (ACD) values were 3.01±0.35 mm (preoperative mean ACD: 3.11±0.29 mm; $p=0.112$) for Group I and 2.75±0.20 mm (preoperative 3.05±0.26 mm; $p<0.0001$) at 1 week postoperatively ($P_{I-II} = 0.002$). The mean ACD values showed no significant change in either group until the last follow-up.

Early postoperative side effects included hypotony and shallow anterior chamber with iridocorneal touch in one eye (3.3%) in Group I and 5 eyes (16.7%) in Group II on the first postoperative day. Out of these, 2 eyes in Group II required anterior chamber reformation with balanced salt solution during the second postoperative week; others resolved spontaneously at the end of the first postoperative week.

Cataract progression was seen in 1 eye (3.3%) of Group I and 3 eyes (10%) of Group II as assessed by slit lamp examination and visual acuity. None of the other patients in either group had a decrease of more than one line on Snellen's visual acuity.

Postoperative complications included blebitis in one eye of Group II (Tab. IV) which became apparent during the second postoperative month and was treated aggressively with topical antibiotic and corticosteroid drops. Endophthalmitis was not seen in any patient in this series.

TABLE III - CHARACTERISTICS OF CASES REGARDED AS FAILURE OF SURGERY

Serial number	Preop. IOP mmHg	Preop. drugs, n	Preop. cup/disc ratio	Time of failure, wk	Final IOP reduction (%)
Group I, 1st	33	4	0.8	6	24
Group II, 1st	30	4	0.8	6	14
Group II, 2nd	31	3	0.9	10	20

IOP = Intraocular pressure

TABLE IV - COMPLICATIONS

Complications	Group I (mini-trabeculectomy), n (%)	Group II (conventional trabeculectomy), n (%)
Hypotony	1 (3.3)	5 (16.7)
Shallow anterior chamber with iridocorneal touch	1 (3.3)	5 (16.7)
Hyphema	1 (3.3)	4 (13.3)
Cataract progression	1 (3.3)	3 (10)
Blebitis	—	1 (3.3)

Optic disc cupping and visual field loss did not progress during the course of this study.

DISCUSSION

Although trabeculectomy is regarded as the gold standard filtering surgery, it is associated with many serious complications (2, 15). Various studies have reported a number of modifications on the original technique. These include change of size (21), shape (22), and position of sclerostomy (23, 24). Modifying the wound techniques or the use of a scleral punch has also been attempted to decrease the complication of conventional trabeculectomy (10-19, 25). This underscores the absence of a single universally accepted procedure in terms of IOP control and avoiding any significant complications. None of the modifications described so far have a significant advantage over any other (15).

We report in this study the safety and efficacy of mini-trabeculectomy, a modification of standard Cairns trabeculectomy that has been designed to avoid some of the complications of conventional trabeculectomy. The mean IOP of 20 mmHg or less was obtained in 29 eyes (96.7%) in our study, 28 of which were not being treated with antiglaucoma medications.

In two prospective studies done by Ophir, mini-trabeculectomy as an initial surgery achieved planned target IOP in 95.1% and 97.2% of eyes (mean IOP 16±2.8 mmHg) with significant reduction in number of antiglaucoma medications after at least 6 and 12 months of follow-up (10, 11). In an another prospective study performed on 26 eyes with high risk of bleb scarring, mini-trabeculectomy was found to effectively reduce IOP (20 mmHg or less) in 90% of eyes (mean IOP 17.4±2.9 mmHg) after at least 12 months of follow-up (12). Das et al compared small incision trabeculectomy avoiding Tenon capsule and trabeculectomy with mitomycin-C (MMC) on 60 eyes and reported the final success rate (IOP 22 mmHg) in 93.3% and 90% of eyes, respectively (14). Our results of mini-trabeculectomy are comparable to the above studies.

The relatively high rate of eyes that had IOP 20 mmHg or less after 15 months follow-up may be attributed to several factors, which possibly include the relatively limited surgical area and lesser manipulations (10, 11). A sclerocorneal tunnel of 3 by 2 mm, reduced conjunctival dissection, and avoiding radial incisions may reduce bleeding, diathermy, and postoperative inflammation, and thus decrease the risk of filtering bleb scarring. Small peritomy of approximately an hour of limbal arc leaves enough room for subsequent filtering surgery through the same quadrant if required or any other additional surgical procedures. A sclerocorneal pocket, rather than a scleral flap, eliminates the need to grasp a scleral flap and pull it anteriorly. This manipulation is occasionally risky, especially for a thin, friable scleral flap.

Regarding postoperative complications, the low incidence of hypotony with mini-trabeculectomy in comparison to conventional trabeculectomy may be attributed to the lack of scleral radial incisions and the three plane sclerocorneal wound that would contribute to guarded aqueous filtration. The use of 1 mm Kelly's punch to cut a smaller, rounded, more anterior portion of trabeculum may contribute to the low incidence of postoperative hyphema.

The purpose of our study was to evaluate the safety and efficacy of mini-trabeculectomy in POAG. Although a more rigorously controlled study with a longer follow-up and larger sample size is desirable, the present study demonstrates the efficacy and safety of mini-trabeculectomy in primary open angle glaucoma. The results were comparable with conventional trabeculectomy but with lesser complications.

In conclusion, based on the surgical outcome after 15 months of follow-up, mini-trabeculectomy as an initial surgery for medically uncontrolled primary open angle glaucomatous eyes appears to be equivalent to conventional trabeculectomy in terms of efficacy and safety. A modified tunnel incision is a good alternative method of significantly reducing the risk of over filtration after trabeculectomy.

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