



A randomised clinical trial comparing the outcome of trabeculectomy using triangular versus rectangular scleral flaps

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Abstract

Background: Trabeculectomy is the standard surgical procedure for management of glaucoma.

Objective: To compare the outcome of triangular and rectangular scleral flaps in trabeculectomy.

Materials and methods: This study was carried out in the Department of Ophthalmology, BPKIHS, Dharan, over a period of one year. A total of 22 patients undergoing trabeculectomy were randomized to undergo either trabeculectomy with triangular scleral flap (Group A= 11 eyes) or trabeculectomy with rectangular flap (Group B=11 eyes).

Outcome measurement: The parameters studied were intraocular pressure (IOP), anterior chamber depth (ACD), bleb characteristics and surgical complications.

Statistics: P value of <0.05 was considered significant. All calculations were executed using SPSS 11.0 software program.

Results: The age ranged between 40 to 76 years with the mean of 56.5±9.25 years. The most common pre-operative diagnosis was angle closure glaucoma. The postoperative percentage of IOP reduction (Group A=68.9%; Group B=66.51%) was statically significant in both the groups (p=0.001). Trabeculectomy was almost equally effective with complete surgical success of 91% in group A, and 82% in group B (p=0.534). Final bleb scores were almost similar in both the groups with 3.27 ± 1.5 in group A and 3.36±1.21 in group B (p=0.877). Hypotony with the IOP less than 6 mmHg was found in the first post-operative day in 2 patients in Group A and in 1 in Group B. All of them improved spontaneously within a week.

Conclusion: Both triangular and rectangular scleral flaps in trabeculectomy are equally effective in terms of post surgical IOP control, bleb characteristics and complications.

Keywords: Trabeculectomy, glaucoma, intra ocular pressure, scleral flap

Received: 05.10.2008. Accepted: 20.10.2008
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Introduction

Trabeculectomy is the most commonly performed operation for glaucoma because it produces fewer postoperative complications than any of the other surgical procedures (Shields, 1998). It is a surgical procedure that lowers IOP by creating a fistula, which

allows aqueous outflow from the anterior chamber to the subtenon space. This fistula is protected by a superficial scleral flap which can be done either by rectangular flap or triangular flap according to the surgeon's preference (Kanski, 2003).

Some surgeons believe that the size and shape of the scleral flap vary from surgeon to surgeon. There is no reported advantage of one shape over another with regard to success rate (Kanski, 2003; Vuori and Viitanen, 2001). Though the rectangular flap trabeculectomy has been the standard procedure for the last more-than-three-decades, some studies have suggested that a triangular flap trabeculectomy is equally effective, and perhaps may be better because it is easier to dissect and may filter more freely as the sclerostomy opening is closer to the edges of the scleral flap (Becker Shaffers 1999).

Subjects and methods

This study was carried out in BPKIHS, Dharan, Nepal, and included 22 eyes within a period of one year (March 2007-March 2008). All the patients with primary open angle glaucoma and angle closure glaucoma were included. Patients diagnosed with congenital glaucoma, secondary glaucoma, normal tension glaucoma, combined intraocular surgeries, failed trabeculectomy, and ocular trauma were excluded from the study. An informed written consent was obtained from all the patients included in the study. The research proposal was approved by the research committee and the ethical review board of the institute.

Study population

Sample size calculation

The sample size calculated for the expected difference of 5% in the means with the standard deviation ± 5 , allocation ratio 1:1 for 95% confidence interval, was 22 (Sahai, Kurshid 1996). Patients undergoing trabeculectomy were divided into two groups using simple computer generated randomization technique. Group A (n=11) had triangular flap, while Group B (n=11) had rectangular flap trabeculectomy.

Preoperative assessment

In all patients, baseline demographic data such as name, age, gender and history of diabetes were recorded. Ocular history included duration of glaucoma since the

time of diagnosis, number and duration of anti-glaucoma medications used in the past and present. In all cases detailed slit-lamp examination was carried out and best-corrected visual acuity was recorded. Anterior chamber depth was measured using van Herrick's method. Best-corrected visual acuity was recorded after refraction. Fundus examination was performed with both direct and indirect methods (+90 D lens) and the condition of disc and macula was recorded. Intraocular pressure was measured using Goldmann applanation tonometer, by recording an average of 3 readings. Gonioscopy was performed with Goldmann single mirror gonioscope. Visual field charting was done using Humphrey automated perimeter.

Operative procedure

All surgeries were performed by ophthalmic surgeons with more than 5 years of experience using a similar technique. Peribulbar anesthesia was used in all cases. A limbal-based conjunctival flap was prepared at 11 to 1 O'clock position by incising the conjunctiva and tenon's capsule 8 mm posterior to the limbus. The dissection was carried out to the limbal zone and superficial vessels cauterized with bipolar cautery. In group A, triangular 4x4 mm scleral flap making an angle of 60° (equilateral triangle) (Vuori & Viitanen, 2001) was created at 12 O'clock position to a depth of approximately one half of the scleral thickness. Likewise, in group B, 4x3 mm rectangular scleral flap was created until the clear cornea was exposed. Trabeculectomy was done by excising the deep rectangular block (1.5x1.5 mm) using Vannas scissors followed by peripheral iridectomy and the scleral flap was closed with 2 interrupted 10-0 nylon sutures at the apices of the rectangle and with a single suture at the apex of the triangular scleral flap (Shields 1998). Tenon's capsule and the conjunctival layer were closed in two layers with running 8-0 Vicryl suture in both the groups. Following surgery, dexamethasone sodium phosphate 2 mg and gentamicin 20 mg were injected sub-conjunctivally.

Post-operatively, all patients were treated with 1% prednisolone acetate 1 hourly (waking hours), 1% tropicamide 8 hourly and 0.3% ciprofloxacin eye drops 4 hourly for a week. The dosage of steroids was tapered according to the anterior chamber inflammatory response within three weeks after the surgery. Patients were evaluated on the first postoperative day, after 1

week, 6 weeks, then at three months. Outcome measures studied were IOP, bleb characteristic and need of post-operative anti-glaucoma medications. Other variables incorporated best-corrected visual acuity, slit lamp examination, visual field examination and fundus examination.

Intraocular pressure was determined at a fixed time (11:00 am-1:00 pm) and an average of 3 readings was taken. Eyes having IOP of less than 6 mmHg were classified as having hypotony. Shallow anterior chambers were graded according to the description of Costa ET al Hyper filtering bleb and grade 3 shallow anterior chamber (AC) were formed with viscoelastic (2% hydroxymethyl cellulose) material within the first 4 days and if the AC did not form with overnight pad and bandage. Bleb scoring was done according to Migdal and Hitching's classification (Migdal et al 1983).

Surgical success

Intraocular pressure of 21 mmHg or lower with or without medication was considered a success.

Statistical analysis

Chi square test, Student's t- test and Fisher exact test were used to find out the probability values between the groups. P value of <0.05 was considered significant. All calculations were executed using SPSS 11.0 software program.

Results

The demographic characteristics of both the groups are provided in Table 1. Angle closure glaucoma was more common in both the groups.

Post-operative IOP

The post-operative mean \pm SD IOP on the first post-operative day was 11.91 ± 5.5 mmHg in group A and 12.36 ± 6.74 mmHg in group B. IOP was lowest during the first week in both the groups which later on was seen to rise to 12.64 ± 4 mmHg in group A and 13.82 ± 2.44 mmHg in group B on the last visit (Table 4). The IOP in both the groups on day 1, 1st week, 6 weeks and the final follow up were approximately the same and the difference was not statistically significant (Table 4). The IOP reduction following surgery was more in group A, i.e. 68.9%, as compared to 66.51% in group B. In both the groups the IOP reduction following surgery

was statistically significant as compared with the preoperative status.

Anterior chamber depth

Median grade of post-operative anterior chamber depth in both the groups was similar compared to the pre-operative anterior chamber depth (Group A=2; Group B=2), and the final AC depth in all the groups was similar (Group A=2; Group B=2).

The mean bleb score on day 1 in group A was 1.91 ± 1.14 and that in group B was 2.45 ± 1.13 (Table 5). The final bleb score in group A was 3.27 ± 1.5 and group B was 3.36 ± 1.21 , which was statistically insignificant ($p=0.87$). Grade 6 bleb was observed in 1 patient in group A.

Success following surgery

The complete surgical success rates were 91% and 82% in groups A and B respectively ($p=0.534$). The qualified success, i.e. IOP < 21 mmHg on anti-glaucoma drug, was noted in 9% of patients in group A, and 18% in group B. No case of failure (IOP > 21 mm Hg on anti glaucoma drugs) was noted in both the groups.

Complications

One patient in group A and 2 patients in group B had immediate post-operative hypotony ($p=0.534$). Hyphema was seen in 2 patients in group A and in 1 in group B ($p=0.534$). Bleb leak was present in one patient in group A and none in group B ($p=0.306$) in the immediate post operative period. Cataract progression was seen in 1 patient in group B. None of the patients had corneal complications. Though hypotony was common in the early post-operative period in both the groups, none had hypotony maculopathy.

Visual acuity at the last follow-up

Post-operative visual acuity in log MAR in most of the patients in the group A was from 0.0 to + 0.2 and that in group B was from + 0.3 to + 0.6. Visual acuity was seen to improve in some patients in each group. In group A, 1 patient had improved visual acuity by 2 lines in Snellen's Chart after the surgery, 2 had a decrease in vision, while 8 had no change. While in group B, 1 had improved vision, 3 had decreased vision, while 7 had no change. The decrease in vision in those patients was due to progression of cataract.

Table 1
 Demography

Characteristic		Group A	Group B	P-Value
Mean Age ± SD		55.36±8.34	57.63±11.19	0.595
Gender	Male	5	6	0.500
	Female	6	5	

Table 2
 Diagnosis

Diagnosis	Group A	Group B	P-Value
ACG	7	8	0.817
POAG	4	3	

Table 3
 Pre-operative Mean Intraocular Pressure in two groups

Group	Mean ±SD	P-Value
A	40.64 ± 12.18	0.908
B	41.27 ± 13.36	

Table 4
 Post-operative Mean IOP in two groups

Mean ±SD	Period	Group A	Group B	P-Value
	Day 1	12.36±6.74	11.91±5.49	.864
	1st week	9.91±4.11	11.09±6.04	.598
	6th week	11.64±3.67	12.64±3.32	.511
	3rd month	12.64±3.98	13.82±2.44	.411

Table 5
 Mean bleb score in two groups

Mean ±SD	Period	Group A	Group B	P-Value
	Day 1	1.91±1.14	2.45±1.13	0.272
	1st week	2.09±1.22	2.55±0.93	0.339
	6th week	2.73±1.49	2.73±1.01	1.00
	3 months	3.27±1.49	3.36±1.21	0.877

Discussion

The age of the patients ranged from 40 years to 76 years. Though the primary glaucomas in adults have been reported to be more common after 60 years of age, it is not uncommon for glaucoma to occur before the age of 60 years as other factors like gender and race also attribute to the occurrence of glaucoma (American Academy of Ophthalmology 2003-2004). In the present study, there were equal numbers of male and female in each group. Most studies have reported that primary angle closure glaucoma occurs 2 to 3 times more commonly in women than in men (Becker-Shaffers, 1999), whereas in several studies, males had a higher prevalence of primary angle closure glaucoma (Starita et al 1985).

The most common type of glaucoma diagnosed in our study population was angle closure glaucoma. The incidence of angle closure glaucoma in Caucasians has been reported as 0.1-0.2% and in East Asians as 0.3-3.2% (Cairns, 1968). This difference could be because of the difference in study design and/or due to the small sample size in our study. The prevalence of POAG varies according to the study population. In most studies, in Europe and the US, the prevalence is reported as 0.5 to 1% above the age 40 (Becker-Shaffers, 1999). Acute angle closure glaucoma patients were also included in our study population.

Though trabeculectomy is not considered to be the first line of management for acute angle closure glaucoma, it has been recommended that some eyes with pupillary block eventually require filtration surgery for control of IOP, particularly those presenting late (Costa, 1993). Therefore, after reducing the IOP with systemic and topical anti-glaucoma drugs, such patients were treated by trabeculectomy in the present study. Moreover, considering the financial status and difficulty in following up of the patients in our part of the world, trabeculectomy is preferred primarily.

In all the groups, most patients had visual acuity between +2.0 or less in log MAR. Decrease in visual acuity in cases of glaucoma is attributed to corneal edema in cases of acute angle closure glaucoma, optic nerve atrophy in all forms of the glaucomas and associated cataract. Almost all the patients who had angle closure glaucoma had better visual acuity following surgery. The overall visual acuity in the two groups was

comparable ($p=0.943$). In both the groups, the pre-operative mean IOP was higher in angle closure glaucoma than in primary open angle glaucoma, but the difference was not statistically significant. The IOP reduction in both the groups following surgery in the 1st post-operative day as compared to the preoperative status was statistically significant ($p=0.001$), but the difference in IOP between the two groups was not statistically significant. The mean postoperative IOP was higher in primary open angle glaucoma as compared to angle closure glaucoma in both the groups, but the difference was not statistically significant. The level of IOP in the 1st week, 6 weeks and final visit in the two groups were significant compared to the pre-operative IOP, but the difference in IOP within the groups were not statistically significant at any point. The percentage reduction in IOP was more in angle closure glaucoma as compared to primary open angle glaucoma in both the groups. The higher reduction in IOP in angle closure glaucoma could be due to anti-glaucoma medications the patients were on prior to the surgery. Median AC depth was significantly lower in patients with angle closure glaucoma than in primary open angle glaucoma throughout the post-operative period. The median final AC depth in both the groups was similar ($p=1.00$). Bleb scores were given according to the Migdal and Hitching's classification. Significant difference in the type of bleb was not noted. Cataract progression has been reported frequently after trabeculectomy (Mycek, 2000). One patient in group B had decreased vision which was due to progression of cataract. The improvement in visual acuity in some patients was probably due to the resolving of the pre-operative corneal edema following surgery and control of IOP. Immediate post-operative hypotony was noted in some of the patients in both the groups. Associated shallow AC was not present in any patients. Hypotony without shallow AC could have been due to the systemic anti-glaucoma medications most of the patients were on for IOP control in the other eye. The final IOP in all the patients was >6 mmHg. Hyphema was seen in 3 of the patients in the 1st post-operative day which resolved by 1st week. None of the patients in this study developed a bleb-related infection such as blebitis or endophthalmitis. Moreover, as our follow-up duration was 3 months, perhaps a long term follow-up of over 1-5 years would be required to comment on such complications.

Conclusion

Both the triangular and the rectangular scleral flaps in trabeculectomy are equally effective in terms of post-operative IOP control, bleb characteristics and complications. There is no significant statistical difference vis-à-vis the success of trabeculectomy using either of these two techniques.

It is, however, recommended that a study be carried out in a larger sample size with a longer duration of follow up.

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