Outcomes Following Trabeculectomy Done by Conventional Method and Kelly’s Punch in Primary Open Angle Glaucoma: A Comparative Study

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ABSTRACT

BACKGROUND
Over the years, the practice of doing trabeculectomy with a Kelly’s Descemet membrane punch has become increasingly common. But literature describing its comparison to traditional trabeculectomy is few and far between. This study was therefore conducted to evaluate and compare the surgical outcomes and complications of trabeculectomy done conventionally and that done by Kelly’s punch in patients with primary open angle glaucoma.

METHODS
Patients diagnosed as primary open angle glaucoma (POAG) having bilateral involvement and unresponsive to maximal medical therapy were enrolled in this study. Sixty-eight such patients seen in a 4-year 7-month period underwent conventional trabeculectomy in one eye (Group 1) and trabeculectomy with a Kelly’s Descemet membrane punch in the other eye (Group 2). Both the groups were evaluated in terms of mean IOP reduction, sustainability for a period of next six months and post-operative complications.

RESULTS
The mean IOP reduction in Group 1 was 12 mmHg and in Group 2 was 9 mmHg from the pre-operative mean at the end of the six post-operative weeks. Sustainability at the end of six months was attained in 88% of eyes in Group 1 and in 85% of eyes in Group 2. Overall incidence of early post-operative complications was less in Group 2. The incidence of cataract formation was 13% in Group 1 and 8% in Group 2 and during the same period of time. More serious sight threatening complications like persistent hypotony, bleb infection and endophthalmitis were not encountered in either group.

CONCLUSIONS
Both the techniques offer adequate and sustainable post-operative IOP control. Early postoperative complications are however marginally higher in the conventional group.

KEYWORDS
Trabeculectomy, Conventional, Kelly’s Punch, Intra Ocular Pressure (IOP)
BACKGROUND

Of the many factors that define the disease entity of glaucoma, intraocular pressure is the only one which can be measured, monitored and modified. Therapeutic approaches available to reduce IOP include medications, lasers and surgery. Currently surgical approach is considered when the other two approaches have not yielded desired results or when compliance to medical therapy is uncertain. Of the various surgical approaches to glaucoma, trabeculectomy as described by Cairns in 1968 still remains the gold standard and perhaps the most frequently performed glaucoma surgical procedure. The basic surgical technique essentially remains the same – creating an aqueous outflow pathway beneath a scleral flap. Various minor modifications to this technique have happened over the years, which mainly involved the size, shape and the scleral flap and subsequent suturing techniques. Use of the Kelly’s Descemet membrane punch (henceforth referred to as Kelly’s punch) is one such modification.

We wanted to compare conventional trabeculectomy as done by block excision with that done by Kelly’s punch in terms of surgical outcome, sustainability and post-operative complications.

METHODS

The study was done over a period of 4 years 7 months (from January 2015 to July 2019) in a peripheral medical college in the state of West Bengal. Informed consent was obtained from all participants.

Inclusion Criteria

Only patients with primary open angle glaucoma with bilateral involvement who were between 45 and 75 years of age and had not been able to maintain IOP below 21 mmHg were included in this study. They were inducted mainly under the following circumstances- patients who were unable to maintain their IOP after maximal medical therapy. By maximal medical therapy we implied three or more medications of different genres not being able to achieve its therapeutic endpoint. Usually it meant a combination of a prostaglandin analogue, beta blockers and an alpha agonist applied for a period of two months or more. Patients who were non-compliant, who were unable to maintain their therapeutic schedule, patients with investigative evidence of progression of glaucoma as seen on Automated Perimetry. This included comparison by the Overview program and the Glaucoma Change Probability program.

Exclusion Criteria

Patients below 45 years of age (this was done because chances of post-operative fibrosis and consequent surgical failure are more in patients of this age group. Many authorities recommend routine use of mitomycin C in these patients.

We wanted to keep this variable out of our comparative protocol), patients with absolute glaucoma, blind eyes for any other cause or uncertain visual potential, patients with angle closure glaucoma (this study was restricted to POAG only), patients with past history of glaucoma surgery, patients with history of other ocular surgeries (cataract, retinal detachment, pterygium etc. pterygium surgery needs special mention because the autograft is usually harvested from the superior conjunctiva making subsequent trabeculectomy at that site unviable). Patients with other coexistent eye disease that might affect surgical outcome (mature cataract, uveitis, intra ocular neovascularisation, corneal dystrophies etc.) and patients with past history of trauma or chemical injuries that might affect bleb viability were excluded from the study.

Pre-Operative Evaluation

All patients underwent a comprehensive eye evaluation and an additional glaucoma work up. By comprehensive eye evaluation, it was meant that each patient had his best corrected visual acuity recorded, underwent a thorough slit lamp evaluation of the anterior segment, iris and the crystalline lens. The anterior chamber depth was noted both peripherally and centrally. Pupillary reactions - both direct and consensual and ocular movements were noted in all patients. The fundus was examined in all patients with a +78D lens. Glaucoma work up included 1. IOP was recorded by a slit lamp mounted Goldmann Applanation tonometer. 2. Central corneal thickness measured using an ultrasonic pachymeter. All readings mentioned in this study were that recorded after adjusting for the respective CCTs. 3. Gonioscopy performed using a Sussmann 4 mirror gonioscope. Only patients having Grade 3 angles were included in this study. 4. Optic disc evaluated by a +78D lens. 5. Automated Perimetry done on Humphrey Field Analyzer. Glaucoma was diagnosed on the basis of Heijl Anderson criteria.

Therapeutic Protocol

All patients on diagnosis of primary open angle glaucoma were started on monotherapy with a prostaglandin analogue. If IOP was not controlled, and /or there were signs of progression on perimetry, a beta blocker was added. If that did not work either, an alpha receptor agonist was added. A fourth drug was not considered because of issues related to cost and patient compliance. These patients were slated for glaucoma surgery.

Study Design

One eye of the selected patient underwent trabeculectomy by conventional technique whereas the other eye underwent the same procedure with a Kelly’s punch. They were assigned as Group 1 and Group 2 respectively. The minimum gap between two operations was four weeks. The worse eye – decided on the basis of a higher IOP and an unfavourable automated perimetry reading was operated first. To eliminate bias, the first 34 of the “first eyes” underwent conventional trabeculectomy and the next 34 underwent punch trabeculectomy.
Surgical Technique
In Group 1 patients, a fornix based conjunctival flap was made with Westcott scissors. A 4 mm equilateral triangular partial thickness scleral window was then fashioned using a #15 Bard Parker blade. Anterior dissection was continued up to the clear aspect of the cornea. A 2.5 mm full thickness scleral block was then excised beneath the pre fashioned window. Peripheral iridectomy was done and the window was closed with interrupted 10’0 mono filament nylon sutures. Conjunctiva was then sutured in a watertight manner.

In Group 2 patients, conjunctival flap and scleral window was prepared in the same way as the previous group. Anterior chamber was then entered with a 2.8 mm keratome and minimally extended to approximately 3 mm. Two buttons of size 1 mm were excised using a Kelly’s punch. This meant the overall size of the scleral ostium in this group was relatively smaller than the previous group.

Closure technique of the surgical wounds was similar to Group 1.

No anti metabolites were used in any of the patients operated. Releasable sutures were not used either. All surgeries were performed by the authors to reduce interpersonal variability.

Post-Operative Period and Follow-Up Protocol
All eyes received topical steroids in tapering doses for six weeks and cyclopregics for the first ten to fifteen days depending on the extent of uveal response. Patients were followed up on the first post-operative day, then at one week, then at three weeks and finally at the end of six weeks. Subsequently they were followed up at six weekly intervals for the next one year.

Statistical Analysis
Data were expressed in simple percentage and proportions.

RESULTS

In this study, sixty-eight eyes underwent conventional trabeculectomy and the contra lateral eye underwent trabeculectomy with a Kelly’s punch, which meant the number of eyes in both groups were the same.

1) Demographics

| Age           | Males        | Females     |
|---------------|--------------|-------------|
| 45 to 55 years| 9(13.29%)    | 7(10.29%)   |
| 56 to 65 years| 17(25%)      | 11(16.18%)  |
| Above 66 years| 14(20.58%)   | 10(14.71%)  |
| Total         | 40(58.82%)   | 28(41.18%)  |

Table 1

2) IOP reduction

The mean pre-operative IOP in both the groups were nearly the same, 26 mmHg ± 2 mmHg post anti glaucoma medication. The mean IOP reduction in Group 1 was 12 mmHg whereas in Group 2 it was 9 mmHg at the end of six weeks.

3) Sustainability

Sixty of the 68 eyes (88%) of Group 1 and 58 out of 68 eyes (85%) in Group 2 were able to maintain their postoperative intraocular pressure at the end of six months. Six of the failed patients were overlaps, meaning they were both eyes of the same patient. It therefore remained unclear whether it was attributable to the respective surgical techniques or some other inherent patient factor. The other four eyes of Group 2 where IOP was de-controlled at the end of six months had surgery with Kelly’s punch whereas the contra lateral eye which had conventional surgery fared well. The results are outlined in Table 2.

| Group | Mean IOP At 1 Week | Mean IOP At 6 Weeks | Mean IOP At 6 Months |
|-------|---------------------|---------------------|----------------------|
| Group 1 | 11                  | 14                  | 14                   |
| Group 2 | 13                  | 16                  | 17                   |

Table 2

4) Complications

Complications were divided into two groups – early and late. Early complications referred to those occurring within the first two weeks of surgery. Those occurring later than that were referred to as late complications.

a) Early Complications

Table 3 shows the various early complications encountered during this study.

| Complication       | Group 1 | Group 2 |
|--------------------|---------|--------|
| Hyphaema           | 6 (9%)  | 3 (4%) |
| Uveal inflammation | 5 (7%)  | 2 (3%) |
| Shallow ant. Chamber | 6 (9%) | 2 (3%) |
| Hypotony           | 4 (6%)  | 1 (2%) |

Table 3

Transient hyphaema was noted in 6 eyes (9%) in Group 1 and 3 eyes (4%) in Group 2. Meniscus height of none of the hyphaema exceeded 2 mm. All of these resolved spontaneously within a period of seven to nine days. Uveal inflammation meant a cell count of Grade 1 or higher persisting beyond the first week, and was noticed in 5 eyes (7%) in Group 1 and 2 eyes (3%) in Group 2. None of them progressed and gradually resolved over the next 10 to 15 days. No additional medications besides topical steroids and cyclopregics were required.

Shallow anterior chamber referred to a situation where there was iridocorneal touch at any point of time and persisting for one day or more in the early post-surgical period. Incidence was 6 cases (9%) in Group 1 as against 2 cases (3%) in Group 2. Four of these eyes of Group 1 and all eyes of Group 2 responded to conservative management like pressure bandage and lower lid massage. The remaining two eyes of Group 1 were found to have hyper filtration and had to undergo surgical revision and tightening of the scleral flap.
Hypotony was affirmed when IOP was equal to or less than 6 mmHg at any point of time after surgery.\(^5\) The incidence was again more in Group 1- four (6%) against one (2%) in Group 2. All incidents were noted within the first 72 hours of surgery. All of these eyes however responded to conservative management and did not require surgical intervention.

b) Late Complications
Cataractogenesis was accepted when there was definite bio microscopic evidence of the same and a drop of one line or more in visual acuity as seen on the Snellen's chart.\(^3,4\) Nine eyes of Group 1 (13%) and 5 eyes of Group 2 (8%) reported cataract development in a period between seven and nine months following surgery. They were subsequently managed on the merit of each individual case.

**DISCUSSION**

As we have already said, the technique of trabeculectomy as described by Cairns way back in 1968 still remains one of the most preferred techniques of filtration procedure,\(^1\) and our institution is no exception. Several minor modifications and variations have been made; including use of mitomycin C. Use of Kelly’s punch was first reported by Suzuki\(^2\) in 1997, nearly thirty years after conventional trabeculectomy was first described. Literature regarding comparison of the efficacy of these two variations is unfortunately insufficient in number. This prompted us do a study of our own.

As it was a comparison of surgical techniques, other variables were kept to a minimum. Only a single disease entity was therefore chosen – namely primary open angle glaucoma. Angle closure cases were purposefully excluded. As POAG mostly has bilateral and symmetric involvement, doing two variations in two eyes of the same patient resolved other issues of inter patient variability.

The extent of IOP reduction following surgical procedure was slightly more in Group 1 than in Group 2; with a mean of 12 mmHg against 9 mmHg in the latter. This was however slightly less than a study done by Zhody\(^3\) who reported a mean reduction of 13 mmHg of IOP following trabeculectomy done by Kelly’s punch. Also 88% of the patients of Group 1 and 85% patients of Group 2 maintained their post-operative IOP levels through a six-month period which in turn was indicative of their respective success rates. This was better than a study done by D’Ermo et al\(^5\) who showed a success rate of 76%. A separate study done by Jacob et al\(^6\) however had a comparable success rate of 82.3%.

Transient uveal reaction as is often noted after surgical trauma resolved uneventfully by the end of the first post-operative week. Inflammation extending beyond that period of time was noted in 5 eyes (7%) in Group 1 and 2 eyes (3%) in Group 2. Similar result was also reported by Behera et al.\(^9\)

Certain studies namely one done by Edmunds et al\(^5\) reported the incidence of hyphaema up to 24.6% in conventional trabeculectomy. In our series the incidence was 10% in Group 1 and 4% in Group 2. As the meniscus height all of the hyphaema was low, none of them were associated with any rise of intra ocular pressure. Furthermore, all of them resolved spontaneously by the end of the first week and no additional medication or procedure were necessitated.

Shallow anterior chamber – as defined by iridocorneal touch persistent for more than 24 hours\(^5\) – was noted in 9% eyes in Group 1 and 3% eyes in Group 2. Mills et al\(^10\) reported an incidence of 13% whereas Edmunds et al\(^5\) showed an incidence of 23% in patients undergoing conventional trabeculectomy. The relatively low incidence of shallow anterior chamber in our study may partly be due to the fact that only open angle glaucoma cases were operated in this study. Other mentioned studies had both open and closed angle glaucomas as their study population, which might have added to the number of patients with pre-existing shallow anterior chambers.\(^9,11\)

The incidence of hypotony as noted across various studies showed wide variability. This was perhaps due to the absence of a universally accepted definition of hypotony which gave rise to individual standardisation.\(^5,11\) We followed prescript mentioned in the study by Edmunds et al\(^5\) which defined hypotony as IOP less than 6 mmHg at any point of time in the post-operative period. Seah et al\(^12\) found the incidence to be as high as 70% whereas Edmunds et al\(^5\) found it to be around 24% in conventional trabeculectomy. Behera et al\(^9\) reported 6.6% in patients with conventional trabeculectomy and 3.3% in patients undergoing surgery with a Kelly’s punch, which was similar to our results of 6% and 2% respectively. All these eyes fortunately responded to conservative management, and none progressed to hypotonic maculopathy.

Like hypotony, rates of cataractogenesis showed a wide variation across studies. One important factor was the length of the study – longer the period, more was the incidence of cataract formation.\(^5,6\) Molteno et al\(^12\) reported an incidence of 42.9% of cataract formation in a 15 year follow up period. Watson et al\(^14\) in his 20 years survey reported the incidence at 30%. In this study which had a one year follow up period, the incidence was 13% in Group 1 and 8% in Group 2. This was in concurrence with the study of Edmund et al\(^5\) where the incidence had been reported at 14.2% at the end of one year following conventional trabeculectomy.

To summarize, it was noted that although Group 1 patients had a slightly better control of IOP both in early and long-term basis, the overall incidence of post-operative complications are marginally lower in Group 2. Those perhaps made trabeculectomy with a Kelly’s punch a relatively safer procedure.\(^3\)

This study was singular in the fact where two variations of the same surgical technique were compared keeping other variables at a minimum. An extensive search of the available literature showed paucity of a comparative study of an exactly similar nature. The authors felt that a similar but larger series with a longer period of follow up would certainly be befitting.
CONCLUSIONS

Both these techniques of trabeculectomy offer practicable alternatives to the glaucoma surgeon. Conventional trabeculectomy achieved a better control of intraocular pressure in both early and late phases of follow up. The technique using Kelly’s punch compensated by offering a relatively lower complication rate which included a lower rate of cataractogenesis as well. The choice would best be left to surgeon concerned.

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