



## STUDY OF TWO SITES PHACO TRABECULECTOMY IN CASES OF COEXISTING GLAUCOMA AND CATARACT -LONG TERM FOLLOW UP

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### ABSTRACT

**Purpose:** To study safety and efficacy of two-site phacotrabeculectomy in patients with primary open-angle glaucoma (POAG), with respect to intraocular pressure (IOP), antiglaucoma medication (AM) requirements and post-operative complications. **Study design:** Prospective clinical case series. **Methods:** Thirty patients (eyes) with co-existing visually significant cataract and POAG underwent two-site phacotrabeculectomy and reviewed with a follow-up at five years for decrease in IOP, need for AM and complications of the procedure. **Results:** All patients were followed up for five years with lost to follow up of three (10%) patient after 3 years. Pre-operatively mean (SD) IOP was 34.55 (10.08) mm of Hg. Mean post-operative IOP after five year follow up was 13.5 ( 2.7) mm of Hg, which was significant [SE (d) is 1.9]. Mean(SD) decrease in IOP at the end of five year follow up was 21.05 (3.5) mm of Hg(p=0.0005). Mean AM postoperatively were significantly less (0.66) compare to preoperatively (2.7). Intraoperative, postoperative complications occurred in nine patients who were managed to their best. **Conclusion:** Two-site phacotrabeculectomy is safe and effective in IOP control over a five year follow-up period in patients with POAG.

**KEYWORDS:** Phacotrabeculectomy, Glaucoma, IOP.

**Abbreviations-** IOP-intraocular pressure AM-antiglaucoma medicine.

### INTRODUCTION

As glaucoma and cataract both are diseases with an increasing prevalence with age one after, finds that they are co-existent in the patient population. The goal of treatment in such cases is to achieve an adequate long term control of intraocular pressure (IOP), avoid postoperative IOP spikes, which are deleterious effect on optic nerve head, optimal visual rehabilitation and improving the quality of life of patients. Patients presenting with co-existent, visually significant cataract and glaucoma those are resistant to medical therapy pose an interesting therapeutic problem. In this scenario the potential benefit of delaying cataract surgery in order to improve the success of filtering surgery must be weighed against the drawback of two separate operations and delaying visual rehabilitation. As well as the risk of trabeculectomy induced progress of cataract progression and bleb failure with subsequent cataract surgery. Conversely, performing cataract surgery to improve vision while delaying the filtering surgery may cause accelerated optic nerve damage secondary to transient or sustained elevation of post-operative IOP. Cataract surgery alone has significant effect on IOP following an

early rise in IOP; IOP tends to fall in the long run. The effect is however small averaging 2-4mm Hg and one cannot depend on this as a means of lowering the IOP. After initial controversies combine surgeries to tackle both cataract and glaucoma has become firmly established as a widely accepted modality of treatment.<sup>[1-4,15,18,19,21,22,23]</sup>

Phacotrabeculectomy is performed either with the two procedures (phacoemulsification and trabeculectomy) through the same incision (one site) or through separate incisions (two sites).

It has been argued that the phacoemulsification incision separate from the trabeculectomy incision reduces postoperative scarring of the scleral flap and conjunctiva and improved the results of the filtration surgery.<sup>[4-14]</sup>

Most glaucoma specialists currently gauge how aggressive they need to be with respect to filtering surgery and postsurgical management on the basis of a predetermined target IOP. One approach to setting a target IOP range is outlined in the Canadian consensus guidelines that have been previously published.<sup>[30]</sup>

Given the challenges reviewed above, we sought to determine the efficacy and safety of phacotrabeculectomy. However, the decision to perform phacotrabeculectomy through one site or two sites remains controversial. Although outcomes in terms of visual acuity (VA) have been similar,<sup>[5-8]</sup> there is a debate concerning which technique offers the best IOP control and reduction in glaucoma medication requirements.<sup>[9-10]</sup> In our study we did two sites phacotrabeculectomy.

### AIMS AND OBJECTIVES

1. To study post-operative reduction in IOP levels with two sites phacotrabeculectomy.
2. To study incidence of post-operative inflammation in two sites phacotrabeculectomy.
3. To study post-operative need for antiglaucoma medications.

### MATERIALS AND METHODS

It was a prospective, nonrandomized, clinical trial. Patients were recruited and enrolled at the AVBRH EYE OPD. All operations were performed by one surgeon (PS).

Thirty patients having COEXISTING GLAUCOMA AND CATARACT were selected randomly included in the study.

All the patients had a minimum preoperative follow up of more than three year in the glaucoma unit of our clinic. All patients had typical glaucoma visual field defect by automated perimetry (threshold 30.2 or 24.2) and also progression of glaucoma damage (perimetry testing and C/D ratio evaluation) during the last months preoperatively.

#### Selection criteria

1. IOP level more than 25mm of Hg.
2. Patients with visually significant cataract co-existing with primary open angle glaucoma. on gonioscopy

#### Exclusion criteria

1. Grade four cataracts.
2. Subluxated and dislocated lens
3. Secondary glaucomas
4. Previously failed trabeculectomy
5. Ocular hypertension

#### Data collection

Baseline data including IOP by Goldman appplanation tonometry, upper limit of target IOP range (established using an approach similar to that reported by a Canadian Consensus working group<sup>16</sup>), and the number of topical and oral antiglaucoma medications used by the patient were recorded before surgery. The combination of two drugs was considered to be two medications. Best-corrected VA was measured by the Snellen method. Other information collected before surgery included age,

gender, and diagnostic type of glaucoma, and history of previous laser trabeculectomy or iridotomy.

Data collected during surgery included operative time and complications.

Data were collected at each postoperative visit (included IOP, number of supplemental antiglaucoma medications, best-corrected VA, occurrence and nature of any complications). All the data (preoperative and postoperative) were analyzed at the end of the follow up. AM were started to those patients whose IOP was more than 18.9 mm of Hg postoperatively.

Primary outcome was cumulative success rate at one year determined by Kaplan –Meier analysis. Complete success rate was defined as proportion of patients meeting their target IOP ranges without any glaucoma medications. (i.e. Eyes were counted as failures if they did not meet their target IOP range or if they required 1or more medications in order to meet their target IOP range at any given time.) Qualified success rate was defined as, those who achieved their target IOP range with allowance of up to 2 or any number of glaucoma medications. Secondary outcomes included difference in mean postoperative IOP, mean IOP drop from baseline, mean number of glaucoma medications, and rates of adverse postoperative complications. These complications included IOP spike on the first postoperative day (defined as IOP > 25 mm Hg), hypotonous maculopathy (diagnosed by a drop in vision of 5 or more Snellen lines from preoperative levels, accompanied by macular striae, in the setting of hypotony), suprachoroidal haemorrhage, bleb leak (identified by a hole in the bleb wall accompanied by a Seidel-positive test), uveitis, and endophthalmitis. Hypotony was defined as IOP readings of < 6 mm Hg obtained on 2 separate days up to 2 months postoperatively or at least 1 such reading obtained more than 2 months postoperatively.

#### Procedure

##### Type of anaesthesia-Peribulbar block with 2% lignocaine

A temporal clear corneal incision was made with a 3.2-mm blade keratome was done at superotemporal limbus. Standard phacoemulsification and intraocular lens implantation then was performed. The surgeon then switched position and was seated superiorly for the trabeculectomy. A limbal-based conjunctival flap was created and a limited tenonectomy was performed in most cases. After applying light electrocautery and exposing the conjunctival insertion anteriorly at the limbus, a triangular scleral flap was dissected and with a crescent knife under the scleral flap, the dissection then was advanced into clear cornea. The anterior chamber was entered with sharp blade and a block of tissue of 3.5 by 1mm under the anterior hinge of the scleral flap was cut by Kelly's Descemet's punch. The iridectomies were done and scleral flap closure was performed by 10-0

nylon suture, with single suture. The conjunctival wound was closed with 10-0 nylon suture.

Post-operatively subconjunctival injection of antibiotic and steroid was given. Pad and bandage given. A topical antibiotic were given three times daily for two weeks. Topical corticosteroids and nonsteroidal anti-inflammatory medication were used six times daily for the first month, reduced gradually to three times daily for two weeks and then were tapered slowly. Adjunctive topical and oral antiglaucoma medications were used as needed for the first one or two weeks.

Post operatively patients were followed on first day, three months, six months, twelfth months, three years and five years. All patients contacted telephonically.

## RESULTS

All patient demographics were listed.

### Patients Demographics

No. Of eyes -30

Sex- Females – 16

Males - 14

Average age at surgery -53.4years

Glaucoma type-

Primary open angle glaucoma - 30

The majority of patients requiring surgery had advanced glaucoma (cup-to-disc ratio > 0.8 or visual field loss within 15 degrees of fixation, or both) that was resistant to medical or laser intervention, or both. One eye of each subject included in the study was randomized and underwent surgery according to the study protocol. All patients are followed up for 12 months. Lost to follow-up were two (6.6%) in six months and total 3 patients in 1 (10%) year. All patients had statistically significantly less IOP postoperatively at 12 months follow-up compared to baseline ( $p=0.0005$ ). Pre-operatively mean (SD) IOP was 34.55 (10.08) mm of Hg. Mean post-operative IOP after one year follow up was 13.5 (2.7) mm of Hg.

(Table 1).SE (d) was 1.9 which was statistically significant.

## TABLES WITH CAPTIONS

**Table 1: Mean IOT before surgery and during five year follow –up.**

TIME	IOP( SD) (mm of Hg)
Pre-operative	34.71(10.23) (n=30)
1 <sup>st</sup> month	17.45 (4.71) (n=30)
6 <sup>th</sup> month	14.69 (3.48) (n=24)
12 <sup>th</sup> month	13.85 (2.9) (n=28)
3 years	13.85 (2.64) (n=28)
5 years	13.5 (2.78) (n=27)

Mean decrease in IOP at the end of five year follow up was 21.05 (3.5) mm of Hg (Table 2).

The most commonly recorded complications of surgeries were early hyphema, uveitis and early hypotony. All other complication rates were very low. (Table 3).

Intra-operatively one patient had posterior capsular rupture and managed by anterior vitrectomy with PC IOL implantation. (Table 3).

Post operative complications occurred in 8 (26.66%) patients, 1 patient had bleb leak in the first week, 2 patient had hyphaema which were treated by giving antiglaucoma and subconjunctival injections of steroids, 2 patients had iridocyclitis, which were treated by giving subconjunctival injections of steroids and oral prednisolone. 2 patients had early pot-op. hypotony and 1 patient had PCO after 6 months and undergone Nd – YAG laser capsulotomy. Topical MMC was given to four patients.

A statistically significant proportion of patients achieved their target IOP range at 1 year. The complete success rate at 1 year was (64.30%) and 5 year was (62.90%) without add-on glaucoma therapy, and (35.70%) in 1 year and (37.03%) in 5 years with the use of up to two antiglaucoma medications, in phacotrab.(Table 4).

The mean postoperative number of medications was decreased, requiring a substantially lower number of medications than preoperatively at all follow-up times up to five year. (Table 5).

Post-operatively total sixteen patients (53.3%) needed anti glaucoma. Out of them, two for three months (6.66%) and four (13.3%) for six months and ten subjects (33.3%) for 5 years and onwards. Three patients required only one drug (10%) and rest thirteen patients (43.3%) required two drugs.

Significant improvement in visual acuity was found in all patients. Three patients (10%) had lost to follow up after 3 years and rest could be followed for complete five years.

**Table 2: Decrease in mean IOP from preoperative levels.**

Post-operative Time	IOP (SD)	p-value < 0.05
1 <sup>st</sup> month	17.2 (6.79)	0.0005
6 <sup>th</sup> month	19.15 (7.36)	0.0005
12 <sup>th</sup> month	20.95 (9.06)	0.0005
3 <sup>rd</sup> year	21.6(9.73)	0.0005
5 <sup>th</sup> year	21.45 (9.33)	0.0005

**Table 3: Intra and postoperative complications in two-site phacotrabeculectomy.**

Capsular rupture-PC IOL	1 (3.3%)
Day 1 IOP spike	2 (6.6%)
Conjunctival bleb leaks Early (<7 days)	1 (3.3%)
Hyphema <sup>^</sup>	2 (6.6%)
Iridocyclitis	2 (6.6%)
Early Hypotony	2(6.6%)
Nd-YAG capsulotomy	1 (3.3%)

**Table 4: Cumulative success rate at 6 months and 1 year based on no. of antiglaucoma medications.**

Category	%
0 glaucoma medication	
1 yr. post-op.	64.3
5 yr. post-op.	62.9
=/< 2 glaucoma medications	
1 yr. post.op	35.7
5 yr. post-op.	37.03

**Table 5: Mean number of glaucoma medications.**

Time	Medication
Pre-op.	2.7 (n= 30)
1 <sup>st</sup> month	0.6 (n= 30)
3 <sup>rd</sup> month	0.7 (n=24)
6 <sup>th</sup> month	0.5(n=28)
1 year	0.5 (n=28)
5 year	0.66(n=27)

## DISCUSSION

This two site phacotrabeculectomy was effective in reducing IOP and the mean IOP levels remained stable during the five year of follow-up. Procedure was also able to eliminate the need for antiglaucoma medications in many eyes over the entire study period. These results suggest that bleb function was maintained in a high proportion of all operated eyes.

The good results obtained with combined procedure in treated glaucoma patients, imply that this technique may be used to handle the problem of concurrent cataract and glaucoma in many patients. Factors that may favour a one-site approach are faster surgical time and reduced number of corneal incisions. However, there are situations in which a two-site approach may be indicated such as surgeon familiarity with temporal phacoemulsification, orbital anatomy and limited superior access or cases of conjunctival scarring limiting the location of the trabeculectomy to a site that would make phacoemulsification through the same incision difficult. At the same time surgeon did not find the procedure time consuming as stated in previous studies.

Previous study by J.Lochhead,(BJO2003;87:850-852), concluded that single site phacotrabeculectomy without use of MMC was not that effective in lowering the IOP.<sup>[26]</sup>

Studies conducted to date comparing the two procedures (phacotrabeculectomy and trabeculectomy) have reported various results. Derick et al compared 42 consecutive eyes that underwent phacotrab MMC with an age-matched control group of 42 eyes that underwent trabMMC and found no significant difference in mean postoperative IOP or mean IOP-lowering from baseline (both groups had similar preoperative IOPs) at a final follow-up time of  $21.8 \pm 6.0$  months.<sup>[24]</sup> Conversely, Kleinmann et al reported a lower mean postoperative IOP and a greater mean IOP drop from baseline in 33 eyes that underwent trabMMC as compared with 102 eyes that underwent phacotrabMMC; however, the mean follow-up time was significantly different between the two groups ( $22.6 \pm 13.3$  months in the trabMMC group versus  $14.2 \pm 8.0$  months in the phacotrabMMC group).<sup>[25]</sup> Of the studies that compare phacotrabeculectomy with trabeculectomy without the use of intraoperative MMC, some report no difference in

mean postoperative IOP or mean IOP-lowering from baseline,<sup>[27,31]</sup> while others report better IOP-lowering with trabeculectomy alone.<sup>[26,28,29]</sup> Of note, all these studies observed a significant decrease in IOP from baseline in both procedures and most also reported an overall low rate of complications, with the highest rates generally seen for hyphaema and early IOP spikes.

Study by. Murthy et al was retrospective in nature lends itself to a number of unavoidable random and systematic errors in data.

Interpretation.<sup>[34]</sup> One manifestation of this was the significant lost to follow-up encountered in the study which was resulted into low cumulative success rate in both trabeculectomy and phacotrabeculectomy.

Our study showed relatively higher cumulative success rate as lost to follow up was very less (10%). one year. The decrease in mean IOP level was 21.05 (3.5) mm of Hg at the end of one year was significantly higher than previous studies, which might be due to very high preoperative IOP levels in few patients. At the end of the year need for antiglaucoma medication was increased as compared to six month follow up. Still there was significant decrease in IOP levels in the patients.<sup>[17,20]</sup>

A study conducted by Eleni Bagli, Christos Gartzios after three years of follow-up, showed the mean IOP was  $15.04 \pm 1.57$  mmHg in the one-site,  $15.04 \pm 1.99$  mmHg in the two-site group with POAG,  $15 \pm 1.8$  mmHg in the one-site,  $15.32 \pm 1.31$  mmHg in the two-site group with PEXG. Without use of MMC.<sup>[33]</sup>

Fewer complications were occurred which were treated at their best and long term follow up are the strengths of our study. Only drawback of our study was lost to follow up (10%) and relatively less sample size (n=30) and also inclusion of only POAG case which might be the reason for higher cumulative success rate of the study. So, study needs further evaluation for other types of glaucomas (i; e. chronic congestive glaucoma, pseudoexfoliation glaucoma, pigmentary glaucoma, neovascular glaucoma, aphakic glaucoma etc.) But this procedure was found effective for POAG and CACG.

## CONCLUSION

This approach of two sites can be performed in patients with POAG and CACG with the expectation of decreased IOP levels, decreased need for AM and increased VA and fewer complications.

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