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Complications Of Phacoemulsification Vs Phacotrabeculectomy In The Treatment Of Chronic Angle Closure Glaucoma With Concomitant Cataract

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Abstract:

Aim: To assess whether phacoemulsification or phacotrabeculectomy (with adjunctive Mitomycin C) is the surgery of choice in eyes with chronic angle closure glaucoma (CACG) with concomitant cataract.

Method: Patients with CACG and coexisting cataract were randomized into 2 groups, comparing phacoemulsification (Group A) versus combined phacotrabeculectomy with adjunctive Mitomycin C (Group B). Group A had 62 eyes of medically controlled CACG with Cataract and 56 eyes of medically uncontrolled CACG with cataract. Group B had 55 eyes of medically controlled CACG with Cataract and 59 eyes of medically uncontrolled CACG with cataract. The 2 groups had identical study designs. All patients were reviewed three-monthly for two years after surgery. The main outcome measure was the surgical complications of phacoemulsification versus phacotrabeculectomy in CACG eyes with cataract

*Result: In Group A, five(4.2%) of the 118 eyes reported four surgical complications while in Group B, eighteen(15.8%) of the 114 eyes had sixteen surgical complications. The difference in the proportion of eyes with one or more surgical complications between the two groups was statistically significant ($P=0.003$, 95% CI) *. In addition to this the risk of surgical complication with phacotrabeculectomy was significantly higher when compared to phacoemulsification [3.73 ($p=0.003$, 95%CI, 1.43-9.70)] *. There was no statistically significant difference in final visual acuity or glaucomatous progression during the 24 month follow-up, between two groups.*

Conclusion: Phacoemulsification resulted in significantly less surgical complications than phacotrabeculectomy in CACG eyes with coexisting cataract. There was no difference in visual acuity or disease progression between the 2 groups.

* Fisher's Exact Test

Key words: Phacoemulsification, Phacotrabeculectomy, Adjunctive Mitomycin C, Chronic angle closure glaucoma, Cataract, Surgical Complications.

1.Introduction

Cataract extraction alone for the treatment of chronic angle closure glaucoma with coexisting cataract is today a subject of arguable discussion. A few previous studies have reported the apparent IOP-lowering effect of cataract extraction alone by phacoemulsification in CACG eyes,^{1,2,3,4,5}

In recent years, evidence that cataract extraction alone results in significant lowering of intraocular pressure (IOP) in CACG eyes have accumulated.⁶⁻¹²

Two randomized controlled trials compared the efficacy in IOP control using phacoemulsification alone versus combined phacotrabeculectomy with adjunctive mitomycin C chemotherapy in eyes with medically controlled¹³ and medically uncontrolled⁷ CACG with coexisting cataract. Except for IOP control, the two studies had identical inclusion criteria and study designs. There was no overlap of patients between the two studies.

Our study aims to assess whether phacoemulsification or phacotrabeculectomy (with adjunctive Mitomycin C) is the surgery of choice in eyes with chronic angle closure glaucoma (CACG) with concomitant cataract. This study compares the surgical complications of the two surgical procedures in CACG eyes with cataract.

2.Methods

Institutional Ethics Committee approval was obtained for conducting this randomized control trial from June 2010 to June 2012. Group A (Phacoemulsification alone) had 62 eyes of medically controlled CACG with Cataract and 56 eyes of medically uncontrolled CACG with cataract whereas Group B (Phacotrabeculectomy with Mitomycin C) had 55 eyes of medically controlled CACG with Cataract and 59 eyes of medically uncontrolled CACG with cataract. The two groups were analysed and the surgical complications of the two procedures during a 24 month follow up period were reported.

The inclusion criteria are summarized in Table1.

Inclusion Criteria	Eyes With CACG And Coexisting Cataract As Defined Below
CACG	180° of angle closure. Synechial or appositional, segmented or continuous, in the presence of a patent peripheral iridotomy. IOP > 21 mm Hg without IOP-lowering medications or requiring IOP-lowering medications Definition of medically controlled ¹³ ≤ 21 mm Hg, with ≤ 3 topical drugs (combination drugs counted as 2 drugs) Definition of medically uncontrolled ⁷ IOP >21 mm Hg despite maximally tolerated medications, or requiring > 3 topical drugs for IOP control (combination drugs counted as 2 drugs) Visual field loss compatible with glaucoma and/or glaucomatous optic disc changes ^a
Cataract	Presence of nucleus sclerosis, cortical cataract, or subcapsular cataract. VA ≤ 20/50 and affecting day to day activities
Exclusion criteria	One eyed Previous intraocular surgery, with the exception of laser peripheral iridotomy and ALPI Patients refusing either cataract extraction or trabeculectomy

Table 1: Inclusion Criteria

(Abbreviations: ALPI, Argon Laser Peripheral Iridoplasty; CACG, Chronic Angle-Closure Glaucoma; IOP, Intraocular Pressure; VA, Visual Acuity)

^aMinimal criteria for glaucomatous visual field defect as per the published standard¹⁴ are the following: glaucoma hemifield test result outside normal limits, pattern standard deviation with $P < 0.05$, or a cluster of 3 or more points in the pattern deviation plot in a single hemifield (superior or inferior) with $P \leq 0.05$, one of which must have $P < 0.01$. Any one of the preceding criteria, if repeatable, was considered sufficient evidence of a glaucomatous visual field defect.)

The study designs for the two trials were identical except for the definitions of medically controlled and medically uncontrolled in the inclusion criteria (Table 1). The surgical techniques are described in Table 2.

Group A Phacoemulsification	Topical Pilocarpine hydrochloride was stopped for 1 wk prior to phacoemulsification (other eye medications were continued up to and beyond phacoemulsification) Corneal incision was used to preserve conjunctiva for future filtration surgery. Topical prednisolone acetate, 1%, and topical moxifloxacin were given postoperatively; frequency and duration were dictated by clinical needs. Postoperatively, any glaucoma eyedrops were tapered if the mean IOP at 2 consecutive visits was <21 mm Hg; the order of stopping drugs was the reverse of the order of resuming drugs, ie, adrenergic agonists first, followed by pilocarpine hydrochloride, carbonic anhydrase inhibitors, prostaglandin analogues, and finally β blockers.
Group B Phacotrabeculectomy with Mitomycin C	Topical pilocarpine hydrochloride was stopped for 1 wk prior to phacotrabeculectomy (other eye medications were continued up to the day of phacotrabeculectomy) Double site phacotrabeculectomy was performed. Adjunctive mitomycin C (0.4 mg/mL) was applied to the scleral surface before scleral incision; the standard application duration was 3 minutes. Topical prednisolone acetate, 1%, and topical Moxifloxacin were given postoperatively; Frequency and duration were dictated by clinical needs.

Table 2: Surgical Techniques

3. Outcome Measures

The primary outcome measure was surgical complication. The surgical complications are subdivided into intraoperative complications and postoperative complications for further analysis.

Secondary outcome measures included final IOP control, visual field progression and optic disc changes. Progression based on changes in glaucomatous optic nerve head morphology was confirmed if 1 or more of the following criteria were fulfilled: (1) appearance of new splinter hemorrhage; (2) increase in vertical cup disc ratio of 0.1 or more observed at 2 or more separate follow-up visits; (3) appearance of new or extension of old neuroretinal rim notching observed at 2 or more separate clinic visits; and (4) appearance of new or extension of old nerve fiber layer defects observed at 2 or more separate clinic visits. The vertical cup-disc ratio was taken to be the longest vertical cup diameter divided by the longest vertical disc diameter. Progression based on changes in Humphrey Automated Perimetry (Carl Zeiss, USA) was as per the published standard¹⁴: the defect was deepened or enlarged if 2 or more points within or adjacent to an existing scotoma had worsened by at least 10 dB; all progression required confirmation on at least 1 subsequent field and clinical correlation with no other explanation for deterioration. Progressions of glaucomatous optic nerve head morphology and glaucomatous visual field loss were not counted as surgical complications in this study.

4. Statistical Analysis

SPSS-18 was used for statistical analysis and a p value of <0.05 was considered significant. Chi-square test was used for evaluating change in categorical variables and continuous variable like IOP, BCVA, progression in glaucomatous optic neuropathy and progression in glaucomatous visual field loss were analyzed using student t-test.

5. Results

Two hundred thirty two CACG eyes with cataract from 232 patients were included. 118 CACG eyes were randomized to receive phacoemulsification alone- Group A, and 114 eyes to combined phacotrabeculectomy with Mitomycin C - Group B. Group A (Phacoemulsification alone) had 62 eyes of medically controlled CACG with Cataract and 56 eyes of medically uncontrolled CACG with cataract whereas Group B (Phacotrabeculectomy with Mitomycin C) had 55 eyes of medically controlled CACG with Cataract and 59 eyes of medically uncontrolled CACG with cataract.

Demographic characteristics of the patients in the 2 groups are summarized in Table 3. There were no statistically significant differences between the 2 treatment groups in age, sex ratio, or laterality of recruited eyes (P>0.05).

Characteristic	Phacoemulsification Group A	Combined Phacotrabeculectomy with MMC Group B	p value
No of Eyes	118	114	
Age [range]	50-75	55- 80	P= 0.74
No of Male/female	70/48	65/49	P=0.62
No of Eyes medically controlled before surgery,	62	55	P=0.61
No of Eyes medically uncontrolled before surgery,	56	59	P=0.56
No of eyes Right / Left	61/ 57	54 / 60	P=0.51

Table 3: Groups A And B: Demographic Characteristics

The preoperative clinical status of the patients is summarized in Table 4. There were no statistically significant differences between the two groups in the preoperative Best Corrected Visual Acuity (BCVA) , preoperative IOP, number of preoperative topical IOP lowering drugs used, , preoperative vertical cup-disc ratio, pattern standard deviation in automated perimetry, and proportion of eyes with previous acute angle-closure attack .

All included patients were reviewed every 3 months for a period of 24 months. Outcome measures up to 24 months are reported.

Clinical status	Phacoemulsification Group A	Combined Phacotrabeculectomy with MMC Group B	p value
Preoperative IOP, mm Hg	13 - 35	12 - 37	p=0.296
Preoperative IOP-lowering drugs, No	1 - 4	1 - 4	p=0.873
Preoperative best-corrected visual acuity, logMAR	0.40 -0.30	0.40 – 0.20	p=0.149
Vertical cup-disc ratio	0.4 – 0.8	0.4 - 0.9	p=0.602
Automated perimetry, dB			
Pattern standard deviation	1.4 – 12.7	1.8 – 15.7	p=0.939
No of eyes (%) previous acute angle-closure attack,	14	15	p=0.766

Table 4: Preoperative Clinical Status Of Groups A And B

5.1.Primary Outcome Measures

In Group A, 5 (4.2%) of the 118 CACG eyes reported for 4 surgical complications; in contrast to this 18 (15.8%) of the 114 CACG eyes had a total of 16 surgical complications, in Group B. The difference in the proportion of eyes with 1 or more surgical complications between the two groups was statistically significant ($P=0.003$, 95% CI)*. In addition to this the risk of surgical complication with combined phacotrabeculectomy was significantly higher when compared to phacoemulsification alone [3.73 ($p=0.003$, 95% CI, 1.43-9.70)]*. There was no statistically significant difference in final visual acuity or glaucomatous progression during the 24 month follow-up, between two groups.

5.2.Intraoperative Complications

Table 5 presents the intraoperative complications in the 2 groups. 3 of the 118 eyes in the phacoemulsification group (2.5%) had a total of 4 intraoperative complications, while 6 of the 114 eyes in the combined phacotrabeculectomy group (5.2%) had a total of 4 intraoperative complications

Intra Operative Complication	Phacoemulsification Group A	Combined Phacotrabeculectomy with MMC Group B
Intraoperative complications, total No	3	6
Zonular dehiscence	1	3
Posterior capsular rupture	2	4
Eyes with >1 intraoperative complication	1	3

Table 5: Intra Operative Complications In Group A And B

Table 6 and Table 7 show the clinical outcomes in the eyes with intraoperative complications in Group A and Group B, respectively.

NO of Eyes	Complication	Management of Complication	BCVA LogMar		IOP Mm of Hg		No of Topical IOP lowering drugs		Progression GON	HVF loss
			Pre	Post	Pre	Post	Pre	Post		
	Zonular dehiscence	No Capsular tension ring used.IOL implanted	1.20	1.0	28	17	4	2	No	No
	Posterior capsular rupture	Sulcus implantation of intraocular lens with Anterior vitrectomy	1.0	0.80	32	18	3	0	No	No
	Posterior capsular rupture	Anterior chamber implantation of intraocular lens with Anterior vitrectomy	1.0	0.50	24	20	3	2	No	Yes
	Phacoemulsification in all 118 eyes mean		0.70	0.40	20.6	15.2	2.8	1.2		

Table 6: Clinical Outcomes Following Intra Operative Complications In Group A

No Of Eyes	Complication	Management Of Complication	BCVA logMar Pre Op	Post op	IOP mm of Hg Pre op	Post op	Topical IOP Lowering Drugs Pre op	Post op	Progression GON	HVF loss
	Zonular dehiscence	No Capsular tension ring used. IOL implanted	0.50	0.40	22	14	4	0	No	No
	Posterior capsular rupture	Sulcus implantation of intraocular lens with Anterior vitrectomy	1.70	1.0	24	16	3	0	No	Yes
	Posterior capsular rupture	anterior chamber implantation of intraocular lens with Anterior vitrectomy	0.70	0.40	22	18	3	0	Yes	No
	Phacotrabeulectomy in all 114 eyes mean		0.82	0.57	22.67	12.0	2.68			

Table 7: Clinical Outcomes Following Intra Operative Complications In Group B

Table 8 compares the eyes with and without intraoperative complications in the phacoemulsification group. There were no statistically significant differences in preoperative ($p = 0.941$) and postoperative ($p = 0.983$) BCVA between eyes with and eyes without intraoperative complications. Intraoperative complications were not associated with progression in glaucomatous optic neuropathy ($p = 0.631$) or with progression in glaucomatous visual field loss ($p = 0.809$).

Characteristic	Eyes with Intra Operative Complications n=5	Eyes without Intra Operative Complications n=113	P value
BCVA mean, range LogMar pre op	1.22±0.54 (between 0.50 - 1.70)	1.24± 0.61 (between 0.40 – 3.00)	p=0.941
BCVA mean, range LogMar postop(24m)	0.76 ±0.23 (between 0.40–1.0)	0.77±0.65 (between 0.00 – 3.00)	p=0.983
, No. (%)Progression in glaucomatous optic neuropathy	0 (0%)	5 (4.4%)	p=0.631
No. (%)Progression in Glaucomatous visual field loss	1 (20%)	18 (15.9%)	p=0.809

Table 8 Group A : Comparison Of Eyes With And Without Intraoperative Complications

Table 9 compares the eyes with and without intraoperative complications in the combined phacotrabeulectomy group. There were no statistically significant differences in preoperative ($p=0.957$) and postoperative ($p=0.813$) BCVA between eyes with and eyes without intraoperative complications. Intraoperative complications were not associated with progression in glaucomatous optic neuropathy ($p=0.599$) or with progression in glaucomatous visual field loss ($p=0.225$)

Characteristic	Eyes with Intra Operative Complications n=18	Eyes without Intra Operative Complications n=96	P value
BCVA mean, range LogMar pre op	.13 ± 0.38 (between 0.50 - 1.70)	1.14 ± 0.47 (between 0.40 – 3.00)	p=0.957
BCVA mean, range LogMar postop(24m)	0.79 ± 0.19 (between 0.40–1.0)	0.81 ± 0.70 (between 0.00 – 3.00)	p=0.813
No. (%)Progression in glaucomatous optic neuropathy	1 (5.6%)	9 (9.4%)	p=0.599
No. (%)Progression in Glaucomatous visual field loss	1 (5.6%)	16 (16.7%)	p=0.225

Table 9 Group B: Comparison Of Eyes With And Without Intraoperative Complications

5.3. Post Operative Complications

Table 10 shows the postoperative complications in the two groups. None of the 118 eyes in the phacoemulsification group had any postoperative complication, while eighteen of the 114 eyes in the combined phaco trabeculectomy group (15.7%) had a total of sixteen postoperative complications ($p=0.003$)

Postoperative complications were not associated with progression in glaucomatous optic neuropathy ($p=0.599$) or with progression in glaucomatous visual field loss ($p=0.225$) in the combined phacotrabeulectomy group.

Postoperative Complication	Group A n= 118	Group B n= 114
Conjunctival wound leak healed with conservative measures	0	4
Conjunctival wound leak requiring suturing	0	5
Anterior chamber shallowing requiring reformation	0	1
Overdrainage with choroidal detachment	0	2
Posterior capsular opacity requiring YAG capsulotomy	0	3
Hyphema	0	3
total No Postoperative complications,	0	18
Eyes with ≥1 postoperative complication	0	18

Table 10: Postoperative Complications In Group A Vs Group B

5.4. Secondary Outcome Measures

At 24 months, the phacoemulsification group had a mean BCVA of 0.76 ± 0.23 (between 0.40–1.0) while the combined phacotrabeculectomy group had mean BCVA of 0.79 ± 0.19 (between 0.40–1.0) ($p=0.898$) Based on our definition of progression of glaucomatous visual field loss, 1 (20%) in the phacoemulsification group had progression of glaucomatous visual field loss at 24 months as compared with 1 (5.6%) in the combined phacotrabeculectomy group ($p=0.517$)

6. Discussions And Conclusion

Our study confirmed that combined phacotrabeculectomy resulted in significantly more surgical complications, particularly postoperative complications, than phacoemulsification alone in CACG eyes with coexisting cataract.

Our study also demonstrated that phacoemulsification in CACG eyes was associated with a higher rate of surgical complications (4.0 %) than we would normally expect for phacoemulsification in eyes with cataract alone. Furthermore, approximately 1 in 8 CACG eyes (15.7%) receiving combined phacotrabeculectomy may have 1 or more surgical complications.

Surgical complications are no doubt associated with more clinic visits, more operative time, inconveniences, financial costs to patients and society, and negative emotions for patients and health care professionals. All these should be taken into consideration in addition to the IOP lowering effects of the 2 procedures when deciding whether to perform combined phacotrabeculectomy or phacoemulsification alone for any patient with CACG. Eyes with CACG pose unique technical challenges to the cataract surgeon. These eyes have characteristically shallow anterior chambers,¹⁵⁻¹⁷ which may render anterior chamber surgical maneuvers more difficult and risky. Eyes with CACG, especially those with previous episodes of acute angle closure,¹⁸ often have lower corneal endothelial cell density and are therefore more prone to intraoperative and postoperative corneal edema. Previous acute angle closure and long-term use of topical pilocarpine hydrochloride may also have resulted in atrophic iris, smaller pupils, and posterior synechiae. All these characteristics of CACG eyes render cataract extraction technically more challenging and may increase the risk of surgical complications

Our study stands apart in standardization from other similar studies in that all phacotrabeculectomy procedures were of double site and augmented with Mitomycin C only.

The ultimate goal for any glaucoma intervention is to halt progression of the disease. Glaucomatous progression was not counted as a surgical complication in this study.¹⁹ But there was no statistically significant difference in the proportion of eyes with progression in glaucomatous optic neuropathy ($p=0.599$) or visual field loss ($p=0.225$) between the 2 groups despite the difference in IOP control.

Therefore we conclude that Phacoemulsification alone is associated with significantly fewer surgical complications, especially postoperative complications, than combined phacotrabeculectomy with adjunctive mitomycin C in CACG eyes with coexisting cataract.

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