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Impact of Phacoemulsification versus combined Phacoemulsificationgoniotomy on intraocular pressure in primary open-angle glaucoma patients

Mohamed Abdelzaher Awwad (

mohamed.awad@fmed.bu.edu.eg)

Benha University

Hend Gouda Helal

Benha University

Taisir Hamouda

Benha University

Soha Moussa Mohamed

Benha University

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Abstract

Purpose:

To assess the effect of phacoemulsification and combined phacoemulsification-goniotomy on intraocular pressure (IOP) in patients with primary open-angle glaucoma (POAG).

Setting: Benha University Hospital

Design: A retrospective, observational, cohort study

Patients and Methods:

Sixty patients with cataract and POAG were allocated into two groups; group (P) had phacoemulsification, while group (PG) had combined phacoemulsification-goniotomy. Patients were subdivided into subgroups moderate (Pm and PGm) and severe (Ps and PGs) glaucoma based on the American Glaucoma Society classification of glaucoma severity. All patients had their presenting IOP, medicated IOP, number of IOP lowering medications, and postoperative IOP recorded. Postoperative IOP and IOP lowering drops number were followed up for 24 months after surgery. All intraoperative and postoperative complications were recorded and managed accordingly.

Results:

Group (P) showed an IOP reduction from 33 ± 1.9 and 35 ± 0.54 to 28 ± 1.2 and 31 ± 0.83 mmHg in subgroups Pm and Ps, respectively on the first postoperative week. All patients in group P needed to reinstate the IOP lowering drops with a non-significant change in the number of IOP reducing drops by the end of the study. In group (PG), a highly significant reduction in postoperative IOP was noted in the first postoperative week from 31 ± 0.9 and 34 ± 0.29 to 14 ± 0.9 and 26 ± 1.2 mmHg in subgroups PGm and PGs respectively P-value <0.0001). Patients with moderate glaucoma had stopped all IOP lowering drops, while those with severe glaucoma needed fewer medications by the end of the study.

Conclusion:

Combined phacoemulsification-goniotomy is superior to phacoemulsification alone in cases of POAG in terms of IOP control, especially for moderate POAG.

Summary

Primary outcome:

We aimed to evaluate the impact of combined phacoemulsification-goniotomy on the IOP and the number of IOP lowering medications used by primary openangle glaucoma patients. We also compared those results to patients with primary open-angle glaucoma who underwent phacoemulsification alone.

Secondary outcome:

Combined phacoemulsification-goniotomy proved to be an effective and cost-reliable surgery to lower the IOP and the number of IOP lowering medications in patients with primary open-angle glaucoma. However, that effect is more evident in moderate glaucoma patients than in those with severe glaucoma.

Introduction

Reducing intraocular pressure (IOP) to prevent optic nerve damage and preserve visual function is the mainstay of glaucoma treatment. Medical therapy with eye drops to lower the IOP has been the standard of care for open-angle glaucoma. However, as many as 50% of people fail in glaucoma medical therapy.¹ Cataract surgery lowers the IOP.² Different mechanisms of action had been proposed for that IOP-lowering effect following cataract surgery (CS), including the mechanical influence of the lens removal,³ increased uveoscleral outflow, and increased trabecular outflow.⁴

Minimally invasive glaucoma surgery (MIGS) was established lately and is quickly gaining popularity for reducing intraocular pressure (IOP) in patients with glaucoma. ⁵⁻⁷ MIGS reduces IOP by an ab interno or externo technique that maximizes aqueous outflow while avoiding neighbouring tissue injury. It also offers an excellent safety profile and a speedy recovery. ⁸ MIGS is a procedure that utilizes specialized implants or devices and can be performed alone or in conjunction with cataract surgery through a tiny corneal incision that does not damage the conjunctiva. Numerous studies have shown that combining cataract surgery and MIGS results in a greater reduction in IOP and a decrease in the number of antiglaucoma drugs required than cataract surgery alone. ⁹⁻¹² Goniotomy is an ab interno operation that is performed with a knife or needle under gonioscopic observation. ¹³ In 1938, Barkan described the technique in detail and documented its efficacy in treating congenital glaucoma. ¹² In principle, incision of the TM and inner wall of Schlemm's canal might minimize aqueous outflow resistance and enable direct passage of the aqueous to Schlemm's canal, hence lowering the IOP.

This study compared the impact of phacoemulsification versus combined phacoemulsification-goniotomy on IOP control in patients with primary open-angle glaucoma (POAG), cost-efficacy, and patient compliance.

Patients And Methods

This is a retrospective, observational, cohort study held at Benha University Hospital, ophthalmology department. Benha University Hospital ethics review board approved the study (Approval number: RC 5-12-2021), and it adheres to the tenets of the Declaration of Helsinki. All patients enrolled in this study were recruited from the glaucoma outpatient clinic at the ophthalmology department, Benha University. The study targeted adult patients diagnosed with cataract plus primary open-angle glaucoma based on standard slit-lamp examination, best-corrected visual acuity test using the Snellen chart, IOP measurement (Goldman applanation tonometer), fundus examination with the 90 diopters Volk lens, and gonioscopy (4-mirror Volk contact lens). In addition, all patients had a 24-2 Humphrey visual field test (Zeiss Medical Technology, United States) and an Optical Coherence Tomography (OCT) for the optic disc, Retinal Nerve Fiber Layer (RNFL), and Ganglion Cell Complex (GCC) (Topcon SD-OCT, Topcon Corporation, Japan) when fundus view was achievable. In addition, both maximum and presenting IOP and the number of IOP lowering medications were recorded for each patient. Preoperative medicated IOP was also recorded for all patients in the study. We excluded patients younger than 18 years old, those who had other ocular or systemic diseases or had a previous ocular surgery that might affect the IOP, and patients with other types of glaucoma like angle-closure, congenital, and secondary glaucoma. We also excluded those who failed to complete the 24-month postoperative follow-up period and those unwilling to have the surgery. A written informed consent including the aim of surgery, detailed steps, and potential complications was signed by each patient before surgery.

Patients were allocated into two groups; Group (P), in which patients had phacoemulsification alone, and Group (PG), in which patients had combined phacoemulsification-goniotomy. Each group was further subdivided into moderate and severe glaucoma subtypes based on the degree of glaucoma damage. We depended on the American Glaucoma Society classification of glaucoma severity ¹⁴ where optic nerve abnormalities consistent with glaucoma and glaucomatous visual field abnormalities in one hemifield and not within 5 degrees of fixation were considered as moderate glaucoma (Sub-groups Pm and PGm, respectively). On the other hand, optic nerve abnormalities consistent with glaucoma and glaucomatous visual field abnormalities in both hemifields and/or loss within 5 degrees of fixation in at least one hemifield were considered severe glaucoma (Sub-groups Ps and PGs, respectively)

Surgical technique:

All surgeries were performed by the same surgeon (MAM) under local peri-bulbar anesthesia (2% lidocaine, 0.5% bupivacaine, and hyaluronidase). All patients had a temporal 2.4 mm clear corneal incision, Sodium Hyaluronate (Healon, Johnson & Johnson Vision Care, USA) into the anterior chamber, capsulorhexis, hydrodissection, phacoemulsification, and a foldable in-the-beg Intraocular lens IOL (Sensar, Johnson & Johnson Vision Care, USA). In the PG group, goniotomy was performed using an MVR blade and the gonioprism (Katena, Parsippany, New Jersey, USA) through the temporal corneal incision. The patient's head was turned nearly 45° away from the surgeon and the surgical microscope was tilted 45° toward the surgeon. The MVR blade was advanced toward the nasal angle through the anterior chamber. The trabecular meshwork was circumferentially incised at the level of the pigmented band of the trabecular meshwork for approximately 120°. The MVR was then withdrawn, the patient's head and the surgical microscope were returned to the primary position, and the Healon was washed-out from the anterior chamber.

All patients had postoperative topical Moxifloxacin (5mg/ml), and Prednisolone acetate 1% eye drops four times daily for two weeks. All IOP lowering drops were discontinued after surgery. However, they were reinstated once IOP started to exceed its target for each patient.

Complications, either pre-or postoperative, were recorded and managed accordingly. All patients were followed up for 24 months after surgery. Postoperative visits were scheduled into one week, one month, three months, six months, 12 months, and 24 months. Patients had their IOP checked in all visits, the number of IOP lowering drops used, best-corrected visual acuity, and any postoperative complications. Success criteria were defined as final IOP ≤21 mmHg, a 20% decrease from the preoperative non-medicated IOP, and no need for further IOP lowering surgery.

Data were analyzed using Graph Pad Prism 5 (GraphPad Software, Inc., La Jolla, CA, USA). All results are presented as mean values ± standard error of the mean. One-way analysis of variance (ANOVA) was used with Tukey-Kramer *post-hoc-test*. Differences were considered statistically significant at a P-value <0.05.

Results

This study included patients with medically controlled POAG and a visually significant cataract. We excluded patients with uncontrolled POAG, angle-closure glaucoma, and those with secondary glaucoma. Forty-two eyes had phacoemulsification alone (group P), and thirty-seven eyes had combined phacoemulsification-goniotomy (group PG). We excluded twelve eyes from group P and seven from group PG because they could not complete the twenty-four-month follow-up period. By the end of the study, we had thirty eyes in each group. Each group was further subdivided into moderate and severe glaucoma. **Table (1)** shows the demographic criteria for the study groups. There were no statistically significant differences in age, sex, and laterality between all groups.

The preoperative non-medicated IOP was 33 ± 1.9 mmHg and 31 ± 0.9 in Pm and PGm groups, respectively, with no significant difference between both groups (P = 0.3496 **table 2**). Moreover, there were no statistically significant differences between preoperative medicated IOP (P = 0.3959 **table 2**) and preoperative number of IOP lowering drops (P = 0.1032).

Regarding the severe glaucoma groups, the preoperative non-medicated IOP was 35 ± 0.54 mmHg and 34 ± 0.29 mmHg in Ps and PGs groups, respectively (p = 0.114), with no statistically significant difference. The preoperative medicated IOP (P = 0.2505) and the number of IOP lowering drops (P = 0.0930) showed no statistically significant differences. **Table 3**

After surgery, we compared the change in IOP and the number of antiglaucoma medications in the four groups. In the Pm group, the IOP dropped from 33 ± 1.9 mmHg preoperatively to 28 ± 1.2 mmHg at the first week postoperative follow-up visit. Figure 1 However, that change was insufficient to reach the target IOP.

Therefore, we reinstated the IOP lowering drops for those patients. By the end of the 24-month follow-up period, all patients in the PM needed the same number of IOP lowering drops as before surgery.

In the Ps group, the IOP at the first-week follow-up visit was 31 ± 0.83 mmHg, which was then reduced by reinstating the IOP lowering drops to reach 14 ± 0.09 mmHg by the end of the study. There was no change in the number of antiglaucoma drugs that were used before the operation (**Fig. 2**)

On the other hand, in the PGm group, IOP plunged from 31 ± 0.9 mmHg preoperatively to 14 ± 0.9 mmHg at the first postoperative follow-up week (p < 0.0001). That effect was maintained throughout the 24-month follow-up without the need to introduce any IOP lowering drops **Fig. 3**. While in the PGs group, the IOP changed from 34 ± 0.29 mmHg preoperatively to 26 ± 1.2 mmHg at the first week postoperative visit (p < 0.0001). However, the IOP lowering drops were reinstated to achieve the target IOP. By the end of the study, the mean number of IOP lowering drops used by those patients was 2 in contrast to 3 before surgery. (Fig. 4)

By the end of the study, we compared the percentage of IOP reduction in the four study groups. The percentages were 15.15%, 11.43%, 54.8%, and 23.53% in Pm, PS, PGm, and PGs groups, respectively. (Fig. 5).

We also compared the final number of IOP lowering drops used by patients in the study group by the 24-month follow-up. We found no change in the number of drops Pm and Ps groups. On the other hand, patients in PGm groups ended on no IOP lowering drops, while patients in PGs groups had that number reduced from 3 to 2 medications. (Fig. 6)

In figure (7) and table (4), we illustrate IOP change and IOP lowering drops number in the study groups during the scheduled follow-up visits.

There were no intraoperative complications encountered in the Pm and Ps groups. While in the PG group, hyphema occurred in 15 eyes while incising the trabecular meshwork **Figure (8)** (7 eyes and eight eyes in PGm and PGs groups, respectively). Blood was washed-out from the anterior chamber during irrigation-aspiration of the viscoelastic material. Those eyes were intentionally left pressurized around approximately high teens by the end of surgery. Minimal hyphema was noticed in 9 eyes of the PG group (5 eyes in the PGm groups and four eyes in the PGs group) during week one follow-up visit. (Table 5) That bleeding did not affect the IOP, and it disappeared spontaneously by the next 1-month follow-up visit. Mild corneal edema was recorded in 3 eyes in the Ps group, and posterior capsule opacification developed in 2 eyes in the PGm group. We did not record any vision-threatening complications in the four study groups.

Discussion

Trabeculectomy is the most frequently used surgery to lower the IOP in glaucoma patients. ^{4,15} However, that surgery is liable to risk complications like hypotony, shallow anterior chamber, bleb leak, choroidal detachment, and severe sight-threatening complications such as hypotony maculopathy, blebitis endophthalmitis, and wipeout by the IOP fluctuations that might happen intra- and post-operatively. ¹⁶

Micro-invasive Glaucoma Surgeries (MIGS) have been around for the last two decades. They aim to lower the IOP with a higher safety profile than the traditional trabeculectomy surgery. In addition, MIGS are not bleb-dependent, thus avoiding the significant complications of filtering surgeries. However, they produce limited IOP reduction when compared to trabeculectomy. 4,11,12,16

Goniotomy had proved to be an effective, minimally invasive method to reduce the IOP in patients with POAG. Goniotomy can be done via Kahook blade, 25-gauge needle with bent tip, or an MVR blade. Goniotomy provides an effective and cost-reliable way of management of open-angle glaucoma. It could be done as a standalone surgery or combined with cataract surgery. ¹⁷

In this study, we compared phacoemulsification alone versus combined phaco-goniotomy in patients with cataract and POAG in terms of IOP control, the number of antiglaucoma medications, and safety profile. We found a significant reduction of IOP in patients with moderate glaucoma who had combined phacogoniotomy. IOP dropped by 54.8% in the first postoperative week compared to the preoperative non-medicated level. That effect was maintained for 24 months without the need for antiglaucoma medications.

On the other hand, combined phacogoniotomy in cases of severe POAG resulted in a significant reduction of IOP of 23.5% from the preoperative non-medicated IOP. However, that effect was insufficient to reach the target IOP, so those patients needed to return to their IOP lowering drops. They ended with fewer antiglaucoma medications in contrast to the preoperative status.

Phacoemulsification alone did not result in a significant reduction of IOP. By the end of the study, all patients with glaucoma, either moderate or severe, returned to the same number of IOP lowering drops they were using before surgery.

The current results are consistent with previously published studies. A 6-month retrospective study of KDB goniotomy in Black and Afro-Latinx POAG patients revealed a 16.6% reduction in IOP when combined with phacoemulsification. The number of IOP lowering drops decreased by 48%. 18 Greenwood et al. 19 conducted a prospective interventional case series (n = 71) and detected a mean reduction of IOP of 4.6mmHg and a mean decrease in AGM of 0.7. In addition, Hirabayashi et al. 20 reported the mean reduction of IOP of 1.2 mmHg and the mean reduction of AGM of 2.1 in a retrospective study (n = 42). In our study, phacogoniotomy achieved a more significant IOP reduction than the previously mentioned studies. This discrepancy could be clarified because we subdivided the glaucoma patients into moderate and severe grades, and the more significant effect of the surgery was noticed in the moderate group. We also followed up with our patients for 24 months which is more extended than previously mentioned studies. Salins L et al. 21 conducted a multicentric study to assess the effect of goniotomy in severe and refractory glaucoma. They achieved > 20% IOP reduction in 57.7% of the study patients. However, it was a short-term study with a 6-month follow-up period only.

It is noteworthy that Phacogniotomy was more effective in eyes with moderate glaucoma than those with severe glaucoma. This could be explained by the glaucoma-induced structural changes on the aqueous outflow pathway. Those changes include remodeling the extracellular matrix in the juxtacanalicular tissue region, increasing the fibrillar content, and disrupting the trabecular meshwork cytoskeleton. ²² Furthermore, Gottanka J et al. suggested that those trabecular meshwork changes positively correlate with glaucoma severity. ²³ More studies are needed to elucidate the effect of goniotomy on different glaucoma grades.

In conclusion, combined phacoemulsification-goniotomy is superior to phacoemulsification alone in POAG patients in terms of IOP control with a good safety profile. This effect is especially beneficial in moderate POAG grades.

Strengths and Limitations of this study:

- In this study, we classified the glaucoma patients into moderate and severe grades to assess the impact of goniotomy on the IOP in both groups. To our knowledge, no prior studies compared the effect of goniotomy on different glaucoma grades.
- The relatively long follow-up (24 months) is a good strength point for this study.
- The relatively small sample size and the single-center setting of the study are the main limitations.

Declarations

Ethics approval and consent to participate: This study was approved by ethical committee of Benha Faculty of Medicine, Benha University (Approval number: RC 5-12-2021). A written informed consent including the aim of surgery, detailed steps, and potential complications was signed by each patient before surgery.

Consent for publication: Consent for the publication of identifying patient/clinical data as well as identifying images was obtained from all relevant patients in writing.

Acknowledgments: not applicable

Conflict of Interest:

The authors declare no competing financial interests concerning this work.

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Author Contributions:

MAA: has a major role in conception and design of work, performing surgical tasks, data acquisition, interpretation and analysis, drafting and review of the manuscript. HGH: participated in data analysis, interpretation, drafting and final review of the manuscript. TH: participated in interpretation of data, drafting and revision of manuscript. SMM: participated in design of the work, statistical analysis, figures format, and manuscript revision. All authors have read and approved the manuscript in its current state.

Data Availability Statement:

The datasets of this study are available from the corresponding author on reasonable request.

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Tables

Table (1): Demographic criteria of the study groups

		Group Pm	Group PGm	Group Ps	Group PGs	P-value
Age (mean ± SE)		60.8±4.3	62.8±5.4	61.86±4.2	62.533±5.3	0.9887
Sex M		6/15 (40%)	8/15 (53.33%)	7/15 (46.67%)	8/15	-
					(53.33%)	
F		9/15	7/15	8/15	7/15	-
		(60%)	(46.67%)	(53.33%)	(46.67%)	
Laterality	RE	8/15	7/15	9/15	10/15	-
,	LE	7/15	8/15	6/15	5/15	-

SE: standard error, M: male, F: female, RE: right eye, LE: left eye

Table (2): Preoperative IOP (medicated and non-medicated) and number of IOP lowering drops in groups Pm and PGm

	Group Pm	Group PGm	P-value
Preoperative non medicated IOP (mean ± SE)	33±1.9	31±0.9	0.3496
Preoperative medicated IOP (mean ± SE)	14.66±1	13.5±0.9	0.3959
Preoperative Number of IOP lowering drops (mean ± SE)	3±0.09	3±0.07	0.1032

Table (3): Preoperative IOP (medicated and non-medicated) and number of IOP lowering drops in groups Ps and PGs

	Group Ps	Group PGs	P-value
Preoperative non medicated IOP (mean ± SE)	35±0.54	34±0.29	0.114
Preoperative medicated IOP (mean ± SE)	13.5±0.9	15.26±1.2	0.2505
Preoperative Number of IOP lowering drops (mean ± SE)	3±0.09	3±.01	0.0930

Table (4): Change in IOP from preoperative non medicated value and its relation to change in the number of antiglaucoma medications over 24 months follow up at one week, one month, 6months, 12months, and 24 months

	Before Surgery		After Surgery								
			One week		One month		Six months		12 months		24
Groups	IOP mean±SE (non- medicated)	No. of medication	IOP mean±SE	No. of medications	IOP mean±SE	No. of medications	IOP mean±SE	No. of medications	IOP	No. of medications	IOF
Pm	33±1.9	3	28±1.2	0	11±0.8	3	10±0.81	3	11±0.9	3	12:
Ps	35±0.54	3	31±0.83	0	18±1.2	3	17±1.1	3	15±1.4	3	14:
PGm											
	31±0.9	3	14±0.9	0	13±0.9	0	12±1.1	0	13±1.2	0	11:
PGs	34±0.29	3	26±1.2	0	14±0.6	1	13±0.95	1	16±1.3	2	13:

Table (5) the postoperative complications in the study groups.

	Group Pm	Group PGm	Group Ps	Group PGs
Hyphema	0	5/15 (30%)	0	4/15 (26.67%)
Corneal edema	0	0	3/15 (20%)	0
Posterior-capsule opacification	0	2/15 (13.33%)	0	0

Figures

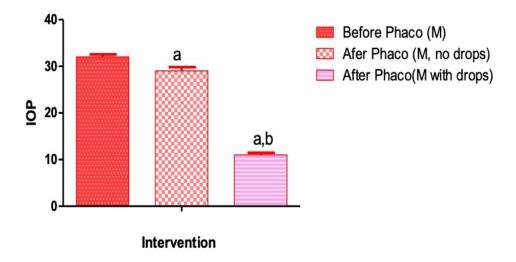


Figure 1

Effect of phacoemulsification on IOP in cases of moderate POAG

M: moderate POAG

a: difference (reduction) of IOP from before phaco with no drop.

b: difference from after phaco (no drops).

Data are presented as mean ± SE

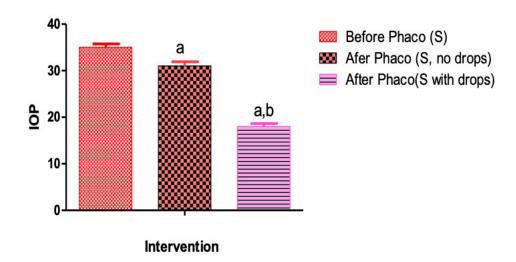


Figure 2 $\label{eq:continuous}$ Effect of phacoemulsification on IOP in cases of severe POAG Data are presented as mean \pm SE

S: Severe POAG

a: difference (reduction) of IOP from before phaco with no drop.

b: difference from after phaco (no drops).

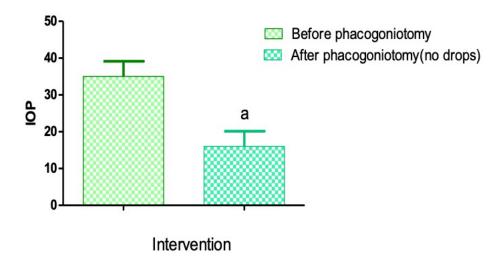


Figure 3

Effect of combined phacogoniotomy in moderate POAG

Data are presented as mean ± SE

a: difference of IOP after phacogoniotomy without the use of any drops from before phacogoniotomy

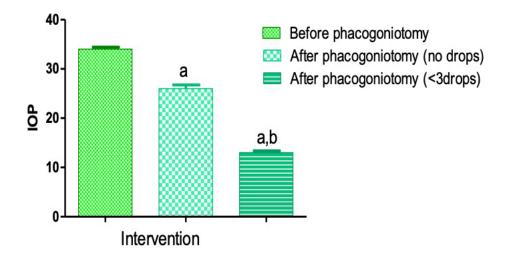


Figure 4

Effect of phacogoniotomy on IOP in severe POAG

Data are presented as mean \pm SE

a: difference from before phacogoniotomy

b: difference from after phacogoniotomy (no drops)

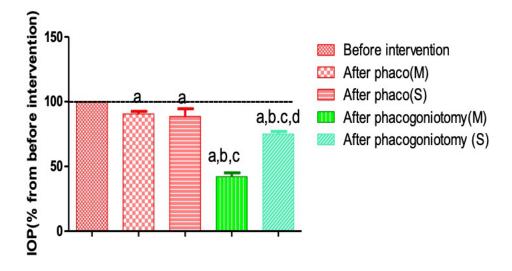


Figure 5 comparison between percentage postoperative IOP from preoperative non-medicated IOP in the study groups Data are presented as mean \pm SE

M: Moderate POAG

S: Severe POAG

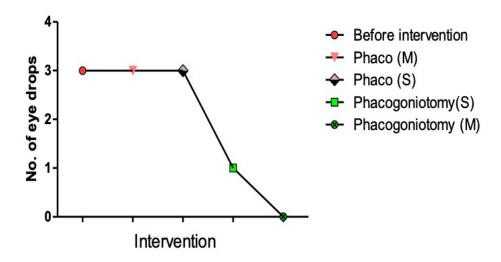


Figure 6

Comparison between the number of IOP lowering drops before and after phaco in Pm, Ps, PGs, and PGm groups

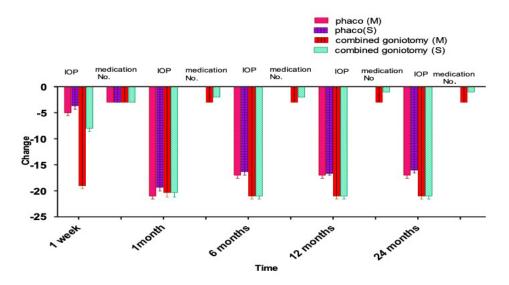


Figure 7

Change in IOP from preoperative non medicated value and its relation to change in the number of antiglaucoma medications over 24 months follow up at one week, one month, six months, 12 months, and 24 months

M: Moderate POAG

S: Severe POAG

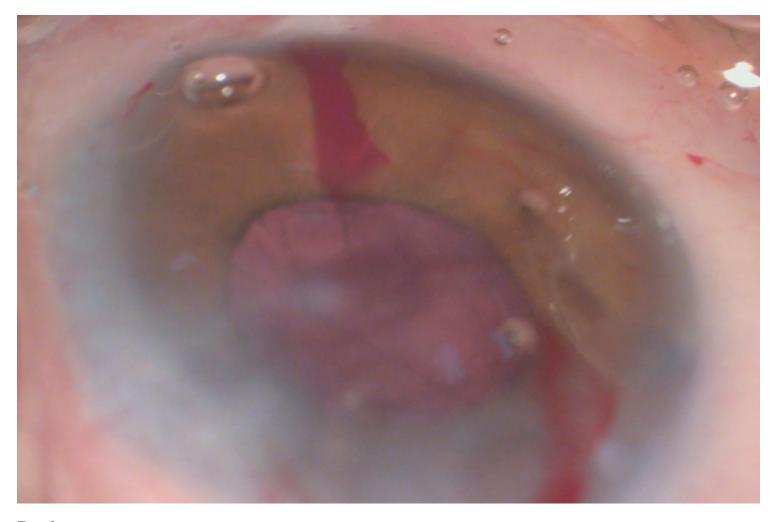


Figure 8

Hyphema after incising the trabecular meshwork

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Mastersheetphacogoniotomy.docx
- Mastersheetphacomoderate.docx
- Mastersheetphacosevere1.docx