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

**Word count:** 4155

**Abstract**

**Purpose:**

To compare the efficacy and safety of combined phacoemulsification-goniotomy to phacoemulsification alone on intraocular pressure (IOP) primary open-angle glaucoma (POAG) patients.

**Design:** A comparative retrospective research

**Patients and Methods**:

The study included 2 groups with POAG & cataracts. Group (Ph) included thirty patients who had phacoemulsification alone; while Group (PhG) included thirty patients who had combined phacoemulsification-goniotomy. They were further divided into severe (Phs and PhGs) and moderate (Phm and PhGm) glaucoma groups depending on the level of glaucoma. We recorded the medicated preoperative IOP, number of glaucoma drops, and postoperative IOP for all patients. We followed up patients for 24 months for IOP and the number of IOP lowering drops. All complications were recorded and managed.

**Results:**

On the first postoperative week, Group (Ph) recorded a reduction of IOP from 35±0.54 and 33±1.9 to 31±0.83 and 28±1.2 mmHg in groups Phs and Phm, respectively. Therefore, we needed to reintroduce the IOP lowering medications for all patients in group Ph with no significant drop in the number of IOP lowering medications by the 24-month follow-up. In group (PhG), we noted a significant fall in postoperative IOP in the first follow-up week from 34±0.29 and 31±0.9 to 26±1.2 and 14±0.9 mmHg in groups PhGs and PhGm, respectively (P-value <0.0001). Patients in Pm and PhGm groups stopped all IOP lowering medications, while those in Phs and PhGs groups needed less medications by the end of follow-up period.

**Conclusion:**

Combined Phaco-goniotomy shows higher efficacy with a good safety profile when compared to phacoemulsification in POAG patients regarding IOP control, particularly the moderate POAG.

**Keywords**: Goniotomy, Phacoemulsification , IOP, Glaucoma, Medications.

**Strengths and Limitations of this study:**

* In our research, we divided the patients into severe and moderate glaucoma groups to assess the effect of goniotomy on the IOP in the study groups. This is the first study to compare the effect of goniotomy on various glaucoma severities.
* A good strength point for this study is the long follow-up (24 months) period.
* Single center setting, and small sample size of our study are the main limitations.

**Summary**

**Primary outcome:**

We targeted to assess the effect of phaco-goniotomy compared to phacoemulsification on the IOP level and the number of IOP lowering drops in POAG patients.

**Secondary outcome:**

To evaluate the safety and cost-effectiveness of combined phacoemulsification-goniotomy in patients with primary open-angle glaucoma. We also compared the IOP lowering effect in moderate and severe glaucoma patients.

**Introduction:**

Lowering the intraocular pressure (IOP) is the primary treatment method for glaucoma. Medical treatment with IOP-lowering drops is the standard care in patients with Primary Open-Angle Glaucoma (POAG). However, 50% of POAG patients show poor compliance with medical therapy.1 Phacoemulsification proved to lower the IOP.2 That IOP-lowering effect can be explained in several ways, for instance the mechanical effect of the lens extraction, 3 improved both trabecular and uveoscleral outflow.4

Minimally invasive glaucoma surgery (MIGS) was introduced recently to the glaucoma care armamentarium and is rapidly proving promising results for patients with POAG. 5-7 MIGS can be done via ab interno or ab externo approaches. The main advantage of MIGS is to improve the aqueous outflow while minimizing neighboring tissue damage. It also harbors a rapid recovery with a good safety profile. 8 MIGS can be done as a solo procedure or combined with cataract surgery. Preserving conjunctiva for a potential future filtering surgery is a benefit of MIGS. Researchers have extensively studied the effect of combining MIGS with cataract surgery. They proved a more significant fall in IOP and decreased the number of IOP lowering medications required than phacoemulsification alone.9-12 Goniotomy is performed via an ab interno approach with a needle or knife guided by a surgical gonioprism. 13 Barkan described the surgical principles of goniotomy in congenital glaucoma and proved its efficacy.12 Goniotomy is also proving good results in treating patients with adult POAG.7-10

This study aimed to assess the efficacy and safety of phaco surgery versus combined phaco-goniotomy in primary open-angle glaucoma (POAG) patients.

**Patients and Methods:**

This is a comparative, retrospective study. It was conducted at the ophthalmology department, Benha University Hospitals, from January 2018 to January 2022. Our local ethical committee at Benha Faculty of Medicine approved the study (Approval number: RC 5-12-2021). Our research adheres to the tenets of the Declaration of Helsinki. The study included adult patients with cataracts and primary open-angle glaucoma. We recruited all patients from the glaucoma outpatient clinic at Benha University Hospitals. They had a standard examination with slit-lamp, visual acuity with the Snellen chart, IOP check (Goldman applanation tonometer), fundus examination with the indirect ophthalmoscope, and gonioscopy using a 4-mirror Volk contact goniolens. We did a 24-2 Humphrey visual field test (Zeiss Medical Technology, United States) for all patients. In addition, an Optical Coherence Tomography (OCT) for the optic nerve head, peri-papillary Retinal Nerve Fiber Layer (RNFL), and the Ganglion Cell Complex (GCC) (Optovue SD-OCT, optovue avanti, France) was done whenever we could achieve a good fundus view. We recorded the maximum IOP, the presenting IOP, the preoperative medicated IOP, and the number of IOP lowering medications for each patient. We excluded patients aged 18 years or less. We also excluded patients with other systemic or ocular diseases or had a previous eye surgery that might influence the IOP, and patients with secondary open angle or closed angle glaucoma. In addition, we excluded patients who did not complete the 24-month follow-up period. All patients signed a written informed consent, involving the detailed surgical steps, aim and potential complications before undergoing surgery.

We further divided patients into two groups; Group (Ph), who had phaco, and Group (PhG), who had combined phaco-goniotomy. Based on glaucoma damage, patients were further divided into moderate and severe glaucoma groups. We used the American Glaucoma Society classification of glaucoma severity 14, where moderate glaucoma encompasses optic nerve changes consistent with glaucoma and glaucomatous visual field changes in one hemifield and not within 5 degrees of fixation (Sub-groups PhM and PhGM), while severe glaucoma includes optic nerve changes consistent with glaucoma and glaucomatous visual field defects in both hemifields and/or loss within 5 degrees of fixation in at least one hemifield (Sub-groups Phs and PhGs)

**Surgical technique:**

We performed all surgeries under local peri-bulbar anesthesia (0.5% bupivacaine, 2% lidocaine, and hyaluronidase). We used a temporal, clear corneal 2.4 mm incision, then we filled the anterior chamber with Sodium Hyaluronate (iOvisc, i-Medical, Germany), phacoemulsification completed, and a hydrophobic acrylic Intraocular lens (IOL) (Acrysof, Alcon, USA) was inserted. We performed goniotomy via an MVR and a surgical gonioprism (Alcon Vold Goniolens, Alcon laboratories, USA) in the PhG group through the temporal clear corneal incision. We turned the patient's head 40° away from the surgeon and the surgical microscope 40° toward the surgeon. Then, we advanced the MVR through the anterior chamber toward the nasal angle. Next, we circumferentially incised the pigmented part of the trabecular meshwork for approximately 135°. Then we withdraw the MVR, and the surgical microscope and patient’s head were returned to the primary position. Finally, we washed out the healon from the eye.

We prescribed postoperative Prednisolone acetate 1% and Moxifloxacin (5mg/ml) eye drops five times daily for four weeks for all study patients. We stopped all IOP lowering medications after surgery. However, they were reinstated if the IOP surpassed its target for each patient.

We recorded all the pre-or postoperative complications, and they were managed accordingly. We followed up all patients for 24 months. We scheduled postoperative visits for 1 week, 1 month, 3 months, 6 months, 12 months, and 24 months. We checked the IOP, the number of IOP lowering medications, the visual acuity, and any intra- or post-operative complications in all visits. We defined the success criteria at the end of the study as IOP ≤21 mmHg, a 20% reduction from the non-medicated preoperative IOP level, with no need to have further glaucoma procedures.

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

**Results:**

Our study targeted medically controlled POAG patients with cataract. Forty-four eyes had phaco surgery alone (group Ph), and thirty-nine eyes had combined phaco-goniotomy (group PhG). Fourteen eyes from group Ph and nine from group PhG were excluded as they failed to complete the designated 24-month follow-up. Our study ended up with thirty eyes in group Ph and thirty in group PhG. We further divided both groups into severe and moderate types. **Table (1)** illustrates the age, sex, and laterality of the study groups with no statistically significant differences. The mean age of patients in the study groups ± SD were 60.8±4.3, 62.8±5.4, 61.86±4.2, and 62.533±5.3 years in groups PhM, PhGM, PhS, and PhGS, respectively.

We recorded a non-medicated preoperative IOP of 33±1.9 and 31±0.9 mmHg in PhM and PhGM groups, respectively, that showed no significant difference (P=0.3496 **table 2**). In addition, the preoperative medicated IOP showed no statistically significant differences (P=0.3959 **table 2**) as well as the number of preoperative IOP lowering medications (P=0.1032).

Observing groups PhGs and PhS, we recorded a preoperative non-medicated IOP of and 34±0.29 and 35±0.54 mmHg, respectively (p=0.114), which was statistically insignificant. There were no statistically significant differences in the number of IOP lowering drops and preoperative medicated IOP (P=0.2505) (P=0.0930). **Table 3**

In each follow-up, we assessed the difference in the IOP level and the number of IOP lowering drops in the study groups. In the PhM group, the IOP declined from a preoperative level of 33±1.9 mmHg to 28±1.2 mmHg in the first postoperative week. **Fig 1** That fall was not enough to meet the desired IOP. For that reason, we reinstated the IOP lowering medications for PhM group patients. By the end of the study, all PhM group patients used the same number of glaucoma medications as before undergoing surgery.

In the PhS group, one week after surgery, the IOP was 31±0.83 mmHg, which then reached 14±0.09 mmHg via reinstating the IOP lowering drops by the end of the 24-month follow-up. There was no change in the number of IOP-lowering medications that were using before undergoing surgery (**fig 2)**

Regarding the PhGM group, IOP dropped from 31±0.9 mmHg before surgery to 14±0.9 mmHg one week after surgery (p<0.0001). That change was nearly constant throughout the 24-month follow-up period with no need to reinstate any IOP lowering medications **fig 3**. While in the PhGS group, the IOP altered from 34±0.29 mmHg before surgery to 26±1.2 mmHg one week after surgery (p<0.0001). However, the IOP lowering medications were reintroduced to reach the target IOP. By the end of the 24-month follow-up, the mean number of IOP lowering medications dropped from 3 to 2. (Figure **4)**

The percentage of IOP reduction in the study groups was compared by the end of the 24-month follow-up period. Those percentages were 11.43%, 15.15%, 23.53%, and 54.8% in PhS, PhM, and PhGS, and PhGM groups, respectively. (**Fig 5)**.

Moreover, the number of IOP lowering medications used by patients during the 24-month follow-up period was compared as well. We did not record a change in the number of medications in PhM and PhS groups. In contrary, patients in PhGM groups needed no IOP lowering drops by the end of the study, while patients in PhGS groups ended with fewer of IOP lowering drops. (**Fig 6)**

Figure (7) and table (4) show the change in IOP and the IOP lowering medications in the study groups during the 24-month follow-up period.

We did not record any complications during surgery in groups PhM and PhsS. In group PhG, we encountered hyphema in eight eyes during trabecular meshwork incision **Figure (8)** (six eyes and two eyes in PhGS and PhGM groups, respectively). We washed-out the blood from the anterior chamber while irrigating-aspirating the healon. During the first week after surgery, we noticed hyphema in 5 eyes of the PhG group (two eyes in the PhGM groups and three eyes in the PhGS group). (Table 5) That hyphema was minimal and did not raise the IOP, and it spontaneously resolved by the next 3-4 weeks. Mild to moderate corneal edema was noticed in 5 eyes in the PhS group, and opacification in the posterior capsule seen in 2 eyes in the PhGM group. We did not encounter any sight-threatening complication in all patients.

**Discussion:**

Trabeculectomy is the mainstay surgical management for uncontrolled glaucoma patients. 4,15 However, it carries the risk of potential complications for instance, shallow or lost anterior chamber, hypotony, bleb leak or failure, elevated IOP, choroidal detachment, and sight-threatening complications like blebitis or endophthalmitis, and wipe‑out syndrome caused by intra- or post-operative turbulence in the IOP. 16

MIGS shows a good safety profile when compared to traditional trabeculectomy surgery. They bleb-independent, therfore avoiding the potential hazardous complications of trabeculectomy. However, trabeculectomy is still the gold standard surgical choice when the target IOP of glaucoma patients is very low. 4,11,12,16

Goniotomy is a minimally invasive and effective surgery to lower the IOP in POAG patients with minimal collateral damage. It can be done using Kahook dual blade, a bent-tip 25-gauge needle, or an MVR knife. Goniotomy proved to be a cost-reliable and effective surgery of open-angle glaucoma. It could be performed as a solo procedure or combined with phacoemulsification. 17

Our research compared the effect of combined phacoemulsification-goniotomy vs phacoemulsification in patients with POAG and cataract regarding the IOP change, the number of IOP-lowering medications, as well as the safety profile. We noticed a significant drop in the IOP in moderate POAG patients who underwent Phacoemulsification-goniotomy. IOP plunged by 54.8% in the first follow-up week. In addition, that effect was nearly constant during the study period with no need to reinstate the IOP lowering drops.

In contrast, combined Phacoemulsification-goniotomy achieved a significant 23.5% IOP reduction in patients with severe POAG compared to the non-medicated preoperative IOP. However, that effect was not enough to reach their target IOP, therefore we needed to reinstate the IOP lowering medications for those patients. By the end of the study, they needed a fewer number of IOP lowering medications than they used before undergoing surgery.

Patients who had Phacoemulsification alone did not achieve a significant change in their IOP. By the end of the study, all moderate and severe glaucoma pattients ended with the same number of IOP lowering medications as they were using before undergoing surgery.

Our results are in line with the published literature. In retrospective study with 6-month follow-up using Kahook Dual Blade goniotomy in the ethnic group of Afro-Latinx and Black POAG patients, researchers stated a reduction of 16.6% in the IOP when done with phaco surgery. The IOP lowering medications plunged by 48%. 18 In their interventional prospective case series (n=71), Greenwood et al 19 claimed a 4.6 mmHg mean reduction in the IOP and an 0.7 mean decrease in IOP-lowering drops. Furthermore, Hirabayashi et al. 20, conducted a retrospective study, and reported 1.2 mmHg IOP reduction and 2.1 reduction in the IOP-lowering medications (n=42). In the current study, combined phacoemulsification-goniotomy succeded to achieve more significant IOP drop than the previously mentioned research. That difference could be clarified as we divided patients into moderate and severe glaucoma groups, and we noticed the more significant IOP drop in the moderate ones. In addition, we followed up with our patients for a longer period than the forementioned research. Salins L et al. 21 launched multicentric research to evaluate the influence of goniotomy in refractory and severe glaucoma. They stated > 20% IOP reduction in 57.7% of their study patients. However, they had a short six-month follow-up period.

It is noticeable that combined Phacoemulsification-goniotomy achieved lower IOP level in patients with moderate than those with severe glaucoma. That could be understood by the structural changes provoked by glaucoma in the aqueous outflow passages. Remodeling of the extracellular matrix in the juxtacanalicular tissue, with subsequent fibrillar content accumulation and disruption of the trabecular meshwork skeleton is one of those changes. Those changes are more evident in patients with severe glaucoma, as suggested by Gottanka J et al. 22,23 More research is required to clarify the impact of goniotomy on various glaucoma levels.

We conclude that combined phaco-goniotomy shows higher efficacy with a good safety profile when compared to phaco surgery alone in POAG patients regarding the control of IOP, especially in moderate POAG.

**Figure Legends:**

**Figure (1):** Effect of phacoemulsification on IOP in cases of moderate POAG

Data are presented as mean ± SE

M: moderate POAG

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

b: difference from after phaco (no drops).

**Figure (2):** Effect of phacoemulsification on IOP in cases of severe POAG

Data are presented as mean ± 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 ± 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 ± 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)** IOP change from non-medicated preoperative level and its relation to change in the number of IOP lowering drops over the study period 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

**Tables**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Group PhM** | **Group PhGM** | **Group PhS** | **Group PhGS** | **P-value** |
| **Age (**mean ± SE) | 60.8±4.3 | 62.8±5.4 | 61.86±4.2 | 62.533±5.3 | 0.9887 |
| **Gender** | **Male** | 6/15 (40%) | 8/15 (53.33%) | 7/15 (46.67%) | 8/15(53.33%) | - |
| **Female** | 9/15(60%) | 7/15(46.67%) | 8/15(53.33%) | 7/15(46.67%) | - |
| **Eye** | **R** | 8/15 | 7/15 | 9/15 | 10/15 | - |
| **L** | 7/15 | 8/15 | 6/15 | 5/15 | - |

**Table (1):** Demographic criteria of the four groups

**SE**: standard error, **R**: right eye, **L**: left eye

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Group PhM** | **Group PhGM** | **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 medications (mean ± SE)** | 3±0.09 | 3±0.07 | 0.1032 |

**Table (2):** Preoperative medicated and non-medicated IOP and number of IOP lowering medications in PhM and PhGM groups

|  |  |  |  |
| --- | --- | --- | --- |
|  | **PhS group** | **PhGS group** | **P-value** |
| **non medicated Preoperative IOP (mean ± SE)** | 35±0.54 | 34±0.29 | 0.114 |
| **medicated Preoperative IOP (mean ± SE)** | 13.5±0.9 | 15.26±1.2 | 0.2505 |
| **Preoperative Number of IOP lowering medications (mean ± SE)** | 3±0.09 | 3±.01 | 0.0930 |

**Table (3):** medicated and non-medicated preoperative IOP and number of IOP lowering drops in PhS and PhGS groups

|  |  |  |
| --- | --- | --- |
| Groups | Preoperative | Postoperative |
| One week | One month | Six months | 12 months | 24 months |
| IOPmean±SE (non-medicated) | Number of medication | IOP mean±SE | Number of medications | IOP mean±SE | Number of medications | IOPmean±SE | Number of medications | IOP | Number of medications | IOP | Number of medications |
| PhM | 33±1.9 | 3 | 28±1.2 | 0 | 11±0.8 | 3 | 10±0.81 | 3 | 11±0.9 | 3 | 12±0.81 | 3 |
| PhS | 35±0.54 | 3 | 31±0.83 | 0 | 18±1.2 | 3 | 17±1.1 | 3 | 15±1.4 | 3 | 14±0.9 | 3 |
| PhGM | 31±0.9 | 3 | 14±0.9 | 0 | 13±0.9 | 0 | 12±1.1 | 0 | 13±1.2 | 0 | 11±0.9 | 0 |
| PhGS | 34±0.29 | 3 | 26±1.2 | 0 | 14±0.6 | 1 | 13±0.95 | 1 | 16±1.3 | 2 | 13±0.11 | 2 |

**Table (4):** IOP change from non-medicated preoperative level correlated to change in the number of IOP lowering drops over study period

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Group PhM** | **Group PhGM** | **Group PhS** | **Group PhGS** |
| **Hyphema** | 0 | 2/15 (13.3%) | 0 | 6/15 (40%) |
| **Corneal edema** | 0 | 0 | 5/15 (30%) | 0 |
| **PCO** | 0 | 2/15 (13.3%) | 0 | 0 |

**Table (5)** postoperative complications in the four groups.

**PCO** (Posterior Capsule Opacification)

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