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Comparative study between Early Lens Extraction and peripheral iridotomy for the Treatment of Primary Angle Closure Glaucoma

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Abstract
This study aimed to assess the effect of early lens extraction in patients with primary angle closure glaucoma compared to the standard treatment of laser peripheral iridotomy and anti-glaucoma medications; it is a prospective randomized study. The participants were divided into two groups (45 patients in each group); Group (I) involved subjects underwent lens extraction and group (II) received standard care by YAG laser iridotomy with anti-glaucoma medications. All participants subjected to complete history taking, full ophthalmological examination and Scheimpflug corneal topography to measure AC depth and angle measurements. The study found that early lens extraction has the same effect on control of IOP as the standard care treatment for PACG with more stability of the disease, less need for further interventions and less need for more glaucoma medications. It can be considered as the first line of treatment for African patients with chronic angle closure glaucoma.

Keywords: *Glaucoma, Lens Extraction, primary angle closure glaucoma*

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I. Introduction

Glaucoma has been the main cause of permanent blindness since 2012, according to the World Health Organization.[1] The number of people with primary angle-closure glaucoma is projected to rise dramatically, from the current 20 million. By 2040, about 34 million individuals will be affected, with 5.3 million of them being blind.[2]

Laser peripheral iridotomy with or without additional antiglaucoma medications remains the traditional treatment of primary angle closure glaucoma with resultant opening drainage channels and reduction of intraocular pressure (IOP). If the target IOP was not achieved, surgery, most often trabeculectomy, is recommended, which carries the risk of several complications.[3]

Surgical lens extraction, as used in managing age-related cataract, was reported to be an alternative approach for the management of primary angle-closure glaucoma. Its mechanism is explained by elimination of the effect of age-related growth of the lens on the mechanisms of angle closure particularly in patients with coexisting cataract.[4]

During the last decades, great advances have occurred regarding development and safety of phacoemulsification techniques. Clear lens extraction has been considered efficient in the management of early glaucoma and preferred for primary angle closure glaucoma management in the first line.[5]

Glaucomatous patients of African origin have distinctive characteristics that increase the risk of blindness and associated with raised failure rate of different surgical interventions. These features include early onset of the disease with more aggressive course, inability to afford medications with poor compliance to antiglaucoma medication as well as lack of adherence to follow up schedules.[6]

As there is a paucity of reports about effect of clear lens extraction on primary angle closure glaucoma in patients of African descent, this study was done in patients from Aswan governorate of Upper Egypt. The study aimed to assess the effect of early lens extraction in patients with primary angle closure glaucoma compared to the standard treatment of laser peripheral iridotomy and anti-glaucoma medications; as regards to IOP control and stability of the disease.

II. Patients And Methods

This prospective randomized interventional study was conducted at department of Ophthalmology, Aswan University Hospital during the period from January 2019 to March 2021. Approvals had been obtained from the Institutional Review Board and all study procedures was carried out in accordance to Declaration of Helsinki.

The study included phakic subjects aged 45 years or more with primary angle closure glaucoma (appositional or synechial angle closure ≥ 180 degrees in addition to reproducible glaucomatous visual field (VF) defects, glaucomatous optic neuropathy or asymmetry of cup disc ratio of 0.2 or more and an intraocular pressure (IOP) > 21 mm Hg on one or more occasions).

After thorough explanation of the procedure and its expected outcomes; informed written consents were obtained from all participants. Ninety eyes of 60 subjects who completed the follow up period were included. They were randomly distributed into two groups (45 patients in each group); group (I) comprised subjects underwent lens extraction by phacoemulsification and group (II) received standard care by YAG laser iridotomy with anti-glaucoma medications.

Patients with advanced glaucoma, previous acute angle closure attack, preceding intraocular surgery or laser treatment (including previous trabeculoplasty, gonioplasty, or laser iridotomy) in the intended eye were excluded. The exclusion list was extended to include patients with secondary angle closure glaucoma, Fuch's endothelial dystrophy and those who were unfit for surgery or for completion of the follow up.

Methods:

All participants were subjected to complete history taking, full ophthalmological examination. The *Shaffer system* was used for assessment of the angle between the trabecular meshwork and the iris. Scheimpflug topographer (TMS-5, Tomey, Maryland, USA) was used to measure anterior chamber (AC) depth and angle assessments. AC depth was measured from inner surface of the cornea to anterior surface of crystalline lens; while angle measurements was obtained by two readings (at 0˚ and 180˚) on the horizontal axis of the eye and lower value is documented.[7]

Lens extraction was done by phacoemulsification using (OS3/NovitreX®, Oertli instruments, Berneck, Switzerland) followed by implantation of monofocal single-piece foldable IOL (Acrysoft®, Alcon, Fort worth, TX, USA). Prednisolone acetate 1% (Optipred, Jamjoum Pharma, Jeddah, KSA) and moxifloxacin hydrochloride 0.5% drops (Vigamox, Alcon, Fort worth, TX, USA) were used postoperatively. Standard care was done with laser iridotomy using Nd-YAG laser 1064 nm by Q-LAS machine (A.R.C. Laser, Nuremberg, Germany) and regular antiglaucoma medications as appropriate.

Follow up for visual acuity, intraocular pressure was done one day, one week, one month and three months postoperatively. Scheimpflug topography was done at one month and three months post operatively.

Success rate was defined as complete success, qualified success or failure. ***Complete success*** was considered if the IOP was reduced to normal (10-20 mmHg) after intervention without need for anti-glaucoma medication or further surgical intervention. ***Qualified success*** was considered if the IOP was decreased to normal under support of anti-glaucoma medication. ***Failure*** was considered if the IOP cannot be reduced to normal, and the patient needed further medication and/or surgical intervention.

Study protocols were verified and approved by the Institutional Review Board of Faculty of Medicine Aswan University and all the procedures done were in adherence to Declaration of Helsinki. Informed consents were signed by patients before any intervention and after detailed discussion of the expected results and drawbacks of the procedures. Confidentiality of patients data were guaranteed through all steps of treatment and follow up.

Statistical analysis:

The Statistical package for Social Science (SPSS for IBM, Version 21.0, Armonk, NY) was used. The Mean and standard deviation (mean ± SD) were used to describe the parametric numerical data. The frequency and percentage were used to describe the non-numerical data. Inferential analysis was conducted using Student's t Test to compare pre- and post-intervention change. Stability was detected by comparing the immediate postoperative assessment to last follow up assessment. Moreover, ANOVA test for repeated measures was used to identify the change in trend of IOP through different follow-up assessment visits. The level of significance considered when p value below 0.05.

III. Results

In the current study a total of 90 eyes of 60 patients were recruited and randomly divided into two groups. Both groups were found to be well matched with no significant difference regarding age, sex distribution or laterality. Details about their demographic characteristics are listed in table (1).

Table 1: Demographic and clinical characteristics of lens extraction group (group I) and Standard treatment group (group II).

Variable	**Category**	**Group (I) N: 31**	**Group (II) N: 29**	***p* value**
		No. (%)	No. (%)	
Age	Mean ±SD Range	55.1 ±7.6 (44 – 70)	55.1 ±5.7 (45 – 67)	0.998
Sex	Male	6 (19.4)	8 (27.6)	0.384
	Female	25 (80.6)	21 (72.4)	
Laterality	Unilateral	17 (54.8)	13 (44.8)	0.606
	Bilateral	14 (45.2)	16 (55.2)	
Eye	OD	27 (60)	21 (46.7)	0.291
	OS	18 (40)	24 (53.3)	

P value < 0.05 = significant

In lens extraction group (group I), the mean intraocular pressure (IOP) revealed significant reduction from **29.3±5.1** mmHg preoperatively to **14.7±3.5**, **14.9±1.5** and **15.1±2.1** mmHg on the second day, three and six postoperative months respectively (p<**0.0001**). To investigate stability of the results, comparisons was done between second day postoperative mean IOP and the mean IOP at three and sixth postoperative months which revealed no changes (P=**0.689** and **0.417** respectively) (Table 2).

In standard treatment group (group II), the mean intraocular pressure (IOP) revealed significant reduction from **22.4±6.0** mmHg preoperatively to **15.7±4.1** and **15.9±2.6** mmHg on the second day and six postoperative months respectively (p<**0.0001**). Nevertheless, the mean IOP had non-significant reduction from **22.4±6.0** on the second postoperative day to **21.8±8.4** mmHg three months postoperatively (P value=**0.766**). To investigate stability of the results in group II, significant increase in the mean IOP was found between the second day postoperative and its value after three months postoperative (P<**0.0001**) while no changes was found when compared to the mean IOP after six months postoperatively (**p=0.793**) (Table 2).

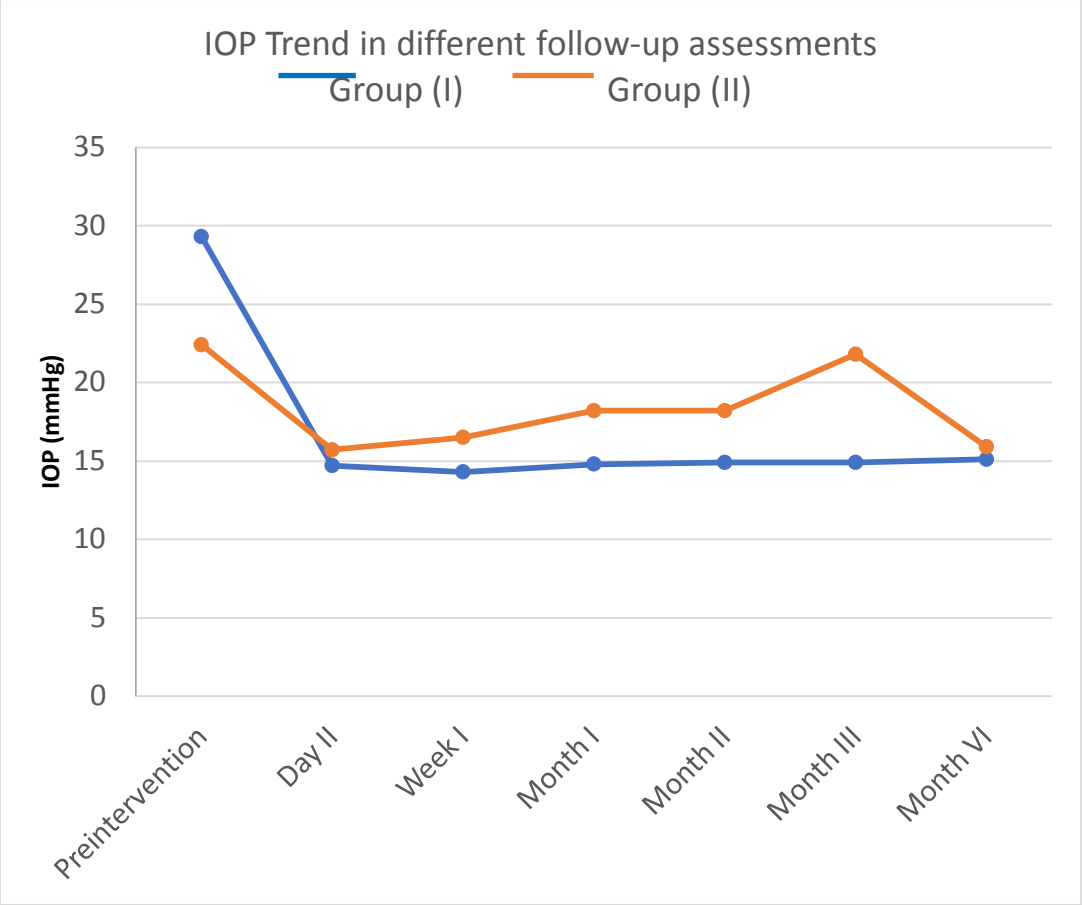
Table 2: Pre- and post-intervention changes in glaucoma specific indices in both study groups

Variable	**Items**	**Groups**	
		Group (I) ***(lens extraction)***	**Group (II)** ***(standard treatment)***
		Mean (SD)	**Mean (SD)**
Intraocular pressure (IOP)	Preoperative [a] Day 2 postoperative [b]	29.3 (5.1) 14.7 (3.5)	22.4 (6.0) 15.7 (4.1)
	P value [a,b]	**<0.0001**	**<0.0001**
	Three Month postoperative [c]	14.9 (1.5)	21.8 (8.4)
	P value [a,c]	**<0.0001**	0.766
	Six Month postoperative [d]	15.1 (2.1)	15.9 (2.6)
	P value [a,d]	**<0.0001**	**<0.0001**
	Day 2 Postoperative [b] Three Month postoperative [c]	14.7 (3.5) 14.9 (1.5)	15.7 (4.1) 21.8 (8.4)
	P value [b,c]	*p*=0.689	**<0.0001**
	Six Month postoperative [d]	15.1 (2.1)	15.9 (2.6)
	P value [b,d]	0.417	0.793
Number of anti-glaucoma medications	Preoperative Postoperative	1.8 (0.9) 0.3 (0.7)	1.4 (1.3) 2.2 (1.2)
	P value	**<0.0001**	**<0.0001**

a= Preoperative IOP, b= Day 2 postoperative, c= Three Month postoperative, d= Six Month postoperative

Comparing the amount of IOP reduction between both study groups (preoperative and 6 months postoperative values) showed that, the average reduction in IOP in group (I) was 14.2±4.7 (48.5%), while it was 6.5±6.1 (29%) in group (II). This difference was clinically significant (p<0.0001). The trend for IOP changes in both study groups throughout the follow up period is demonstrated in Figure (1).

Figure (1): Trend of IOP change through different follow up assessments



Complete and qualified success was achieved in 75.6% and 15.6 % in patients of group (I) compared to 11.1% and 75.6% in group (II) respectively. This difference was clinically significant ($p<0.0001$). On the other hand, the failure rate was less in group (1) compared to group (II) (8.9% and 13.3 % respectively) however this difference was not significant.

Moreover, the number of anti-glaucoma medications needed to reach the target IOP was found to be significantly reduced in group (I) from preoperative value of 1.8±0.9 to 0.3±0.7 in the post-operative assessment ($p<0.0001$). Alternatively, in group (II), there was significant increase in the average number of medications from 1.4±1.3 to 2.2±1.2 ($p<0.0001$) (table 2).

In group (I) patients, the angle value was significantly changed from mean preoperative value of 24.6 $\pm 3.6^{O}$ to a postoperative value of 41.2 $\pm 3.9^{O}$, while in group (II) the changes in the mean angle values from 24.4 $\pm 2.9^{O}$ to 27.9 $\pm 3.1^{O}$ failed to reach significant level.

Likewise, the mean AC depth was increased among group (I) from a preoperative value of 2.2 ±0.4 to 3.3 ±0.4 mm postoperatively ($p<0.0001$) but there was no difference between pre- and post-intervention (2.1 ±0.3 and 2.1 ±0.2 mm, respectively) among group (II) ($p=0.998$).

Best corrected visual acuity (BCVA), as measured by decimal value, was significantly improved in group (I) from 0.22 to 0.48 but otherwise decreased among group (II) patients from 0.40 to 0.35 ($p<0.0001$ and 0.024 respectively).

Meanwhile, subscleral trabeculectomy (SST) was needed in two patients (4.4%) of the group (I) while it was needed for eight patients (17.8%) among group (II) but this difference failed to reach significant value ($p=0.089$).

In terms of complications, in group (I), six eyes (13.3%) suffered from mild to moderate corneal edema, while three eyes (6.7%) of the group (II) had mild hyphema. Comparing the overall rate of complications between both groups revealed no significant differences *($p=0.485$).*

More detailed comparisons of changes between pre and post intervention differences were given in table (3).

Table 3: Comparisons of changes between pre and postoperative indices between both study groups

Variable	Comparison items	Groups	
		Group (I) ***(lens extraction)***	**Group (II)** ***(standard treatment)***
		Mean (SD)	**Mean (SD)**
Visual Acuity (decimal value)	- Preoperative - Postoperative	0.22 (0.18) 0.48 (0.18)	0.40 (0.25) 0.35 (0.22)
	p value*	**<0.0001**	**0.024**
Subscleral trabeculectomy (SST)	- Yes; No. (%) - No; No. (%)	2 (4.4) 43 (95.6)	8 (17.8) 37 (82.2)
	p value	0.089	
AC Depth (mm)	- Pre-intervention - Post-intervention	2.2 (0.4) 3.3 (0.4)	2.1 (0.3) 2.1 (0.2)
	p value	**<0.0001**	0.998
Angle Measurement (degree)	- Pre-intervention - Post-intervention	24.6 (3.6) 41.2 (3.9)	24.4 (2.9) 27.9 (3.1
	p value	**<0.0001**	0.07
Complications	- Mild to moderate corneal oedema - Mild hyphema	6 (13.3%) 0 (0.0%)	0 (0.0%) 3 (6.7%)
	p value (Overall Complications)	0.485	

*Student's t-test

IV. Discussion

The standard of care for primary angle-closure glaucoma (PACG) is laser peripheral iridotomy aiming to open the drainage pathways and antiglaucoma medications to reduce intraocular pressure.[8]

In the recent years, clear lens extraction is claimed to be more effective for the treatment of early glaucoma and is recommended to be one of the first-line options for management of primary angle closure glaucoma.[9]

This study compared the effect of early lens extraction as a treatment for primary angle closure glaucoma with the standard care treatment (laser peripheral iridotomy with or without medical treatment).

This study was done in patients from Aswan governorate of Upper Egypt; all of them are of African descent and have darkly pigmented uveal tissue. Failure rate of different glaucoma surgeries and even laser procedures were reported to be higher among those patients.[6]

It is one of the leading studies, to the best of researchers knowledge, comparing these two procedures (early lens extraction and laser peripheral iridotomy) applied on African patients.

Concerning reduction of the intra-ocular pressure (IOP), the present study stated that **by the end of follow up period,** both approaches significantly reduced IOP from preoperative level of 29.3 ±5.1 and 22.4 ±6.0 mmHg to postoperative level of 15.1 ±2.1 and 15.9 ±2.6 mm Hg in group (I) and group (II) respectively with higher percentage of reduction in group treated with lens extraction.

Lai et al. also found significant decrease in IOP (from 19.7 ±6.1 mmHg to 15.5 ±3.9 mmHg) after phacoemulsification in patients with PACG and co-existing cataract (P = 0.022).[10]

Moreover, Tham et al. found 34% mean reduction IOP after clear lens extraction. This result was comparable to the 36% mean reduction of IOP obtained with trabeculectomy with mitomycin C for treatment of iridotomized eyes with PACG that was not controlled by medical treatment (P=0.76).[11] Similar results were also obtained by other investigators.[12]

In EAGLE study (Effectiveness of early lens extraction for the treatment of primary angle-closure glaucoma); initial clear lens extraction was found to be superior to laser peripheral iridotomy plus topical medications for treatment of patients with primary angle-closure glaucoma. Also visual impairment and disability as well as glaucoma-specific disability were all improved even if the patients did not have cataracts. [5]

The present study found that the number of anti-glaucoma medication has significantly reduced post operatively in the group (I). Unlikely, in group (II), there was a significant increase in the average number of medications.

Similarly in EAGLE study; the number of antiglaucoma medications was decreased significantly in clear lens extraction group from 1.0 ±1.0 to 0.4 ±.8; and increased in laser peripheral iridotomy group from 1.0 ±1.0 to 1.3 ±1.0.[5]

Moreover, Lai et al. showed that the number of glaucoma medication was decreased significantly from a preoperative value of 1.91 ±0.77 to 0.52 ±0.87 at final follow-up after phacoemulsification in PACG with co-

existing cataract.[10] Also, Tham *et al.* showed that cataract extraction reduce the mean number of antiglaucoma medications from 3.46 drugs pre-operatively to 0.40 drugs post-operatively.[11]

The present study showed that mean BCVA has significantly improved in clear lens extraction group and reduced in peripheral iridotomy group. This agreed with results of EAGLE study; where the mean visual acuity was improved in clear lens extraction group from 0.7 to 0.8 and became worsened from 0.67 and 0.66 in laser peripheral iridotomy group.[5] Other investigators reported improvement of visual acuity in only 47.6% of eyes underwent lens extraction, with 42.9% of eyes had stable vision while visual acuity was found to be deteriorated in 9.5% of eyes.[10]

Subscleral trabeculectomy (SST) was needed in two eyes (4.4%) in the clear lens extraction group while it was needed for eight eyes (17.8%) among standard treatment group. Comparable results were obtained in EAGLE study; where glaucoma surgery was needed in one (0.5%) eye in clear lens extraction group and in 24 (11.4%) eyes in laser peripheral iridotomy group.[5]

While cataract extraction surgery was needed in 12 (6%) patients in laser peripheral iridotomy group in EAGLE study, no patients of group (II) developed cataract in the recent one; this may be due to short follow up period compared to that in EAGLE study (6 months versus 36 months).[5]

Transient complications were reported in both study groups. In group (I) six eyes (13.3%) suffered from mild to moderate corneal edema, while three eyes (6.7%) in group (II) had mild hyphema with no serious complications reported. In EAGLE study; complications has occurred in 32 eyes (15%) of clear lens extraction group and in 59 eyes (28%) in laser peripheral iridotomy group, and ranged from mild complications as corneal edema to more serious complications as posterior capsule rupture and malignant glaucoma.[5]

In the present study Scheimpflug topographer, which has most of Pentacam capabilities, was used to measure AC depth and AC angle. It was found to be easy, accurate and reproducible technique in evaluation of anterior chamber pre and post intervention in both study groups.

Instruments using Scheimpflug technique were reported to be exceptional option in evaluation of different AC parameters such as AC depth, AC angle values, AC volume, pupil diameter as well as corneal thickness.[13,14]

It is noninvasive, non-contact, reproducible and fast tool that can be helpful in studying different AC parameters in health and disease. It is also able to compare AC changes after different lines of management of primary closed angle glaucoma.[15-17]

In the present study, the mean anterior chamber depth (ACD) had significantly increased following clear lens extraction. Man et al. also found that the mean ACD measured by UBM was significantly increased from 1,983.8±176.8 to 3,335.0±174.2 microns after clear lens extraction.[12]

Among group (II) of the present study there was no significant change in the AC depth between pre- and post-intervention (2.1±0.3 and 2.1±0.2, respectively). Similar results were revealed by Talajic et al where AC changed from 2.13 ±0.05 mm to 2.15 ±0.05 mm after peripheral iridotomy (P=0.109). [16] Vryonis *et al.* also found insignificant change in AC depth after Laser PI; from 1.88 ±0.36 to 1.93 ±0.32 mm.[18]

In lens extraction group the angle value has significantly increased from an average preoperative value of 24.6 $\pm 3.6^{O}$ to a postoperative value of 41.2 $\pm 3.9^{O}$ while in standard treatment group the angle measurement changed from 24.4 $\pm 2.9^{O}$ to 27.9 $\pm 3.1^{O}$.

Şimşek et al reported widening of AC angle after phacemulsification from preoperative value of 42.09 ±7.49 to 51.46 ±5.63 postoperatively as measured by Sirius 3D Rotating Scheimpflug camera topography system.[19] Comparable results was obtained by other investigators.[12-14]

Another study by Baig *et al*, showed that; cataract extraction or clear lens extraction can significantly deepen the anterior chamber, open up the drainage angle, and thereby reverse the anatomical predisposition to angle closure.[20]

V. Conclusion

Early lens extraction has the same effect on control of IOP as the standard care treatment for PACG with more stability of the disease, less need for further interventions and less need for more glaucoma medications. It can be considered as the first line of treatment for African patients with chronic angle closure glaucoma.

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