

Change in Angle of Eyes with Primary Angle Closure Suspects One Year after Laser Peripheral Iridotomy : a randomised study

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Abstract

Background: To report the changes in anterior chamber angle and progression rate to PAC(primary angle closure) following laser peripheral iridotomy (LPI) in primary angle closure suspects(PACS).

Methods: Prospective, randomized controlled interventional clinical trial conducted at the Handan Eye Hospital, China. 134 bilateral PACS, defined as non-visibility of the posterior trabecular meshwork for ≥ 180 degrees on gonioscopy were randomly assigned to undergo LPI in one eye. Gonioscopy and Goldmann applanation tonometry were performed prior to, on day 7 and 12 months' post LPI.

Results: 80 of 134 patients (59.7%) could be followed up at one year. The mean IOP

in treated eyes was 15.9 ± 2.7 mmHg at baseline, 15.4 ± 3.0 mmHg on day 7; 16.5 ± 2.9 mmHg at one month and 15.5 ± 2.9 mmHg at 12 months; the IOP in untreated eyes was similar ($p=0.834$). One or more quadrants of the angle opened in 93.7% of the LPI treated eyes, but 67.0% (53/79) remained closed in two or more quadrants. The progression rate to PAC in untreated eyes was 3.75% and one developed acute angle closure glaucoma(AACG), the progression rate to PAC(primary angle closure) in treated eyes 2.5% in treated eyes, none had developed PAS or AACG.

Conclusion: LPI can open some of the occludable angle in the majority of eyes with PACS, but 67% continue to have non-visibility of the trabecular meshwork for over 180 degrees. IOP remained similar in treated and untreated eyes. Further research is needed to determine the full implications of residual closure as well as the need for follow up and treatment in PACS. The cumulative incidence for PAC/AACG in treated eyes were not significantly different from untreated eyes.

Trial registration: Chinese Clinical Trial Registry ChiCTR-TCH-10000820. Registered on 08 April 2010(retrospectively registered).

Background

The prevalence of PACG is highest in Asia, it has been estimated that 87% of those blinded by primary angle-closure glaucoma (PACG) live in Asia, by 2020, China will be home to half of the patients with PACG [1-5]. LPI is the current standard of care in PACG [6-8], prevents acute angle closure glaucoma (AACG) and decreases risk of such acute attacks in fellow eyes [9-13].

However, there are approximately 28.2 million PACS in China and the role of LPI in their management is less clear [14,15].

A knowledge of the natural history of PACS and the effect of LPI would help in public health strategy as well as individual management decisions [16]. In a 6 year community based follow up study in urban China, Ye et al. reported that 4.1% (20/485) PACS [defined as less anterior chamber depth (ACD ≤ 2.0 mm, or limbal ACD $\leq 1/4$ corneal thickness(CT); or Iris light band ratio $\leq 1/4$ with oblique flashlight test), developed PAC or PACG [17]. In a population-based Indian cohort that used gonioscopy for the definition,

22% of PACS progressed to PAC and 28% of PAC progressed to PACG over 5 years; none of the PACS developed PACG in the 5 years of follow up[18].

The results of LPI in PACS are variably reported. In a retrospective hospital based case series, LPI controlled IOP over 5 years in 16/18 (90%) Chinese eyes with PACS [19]. In a two-year hospital based follow up study none of 27 eyes with PACS undergoing LPI progressed to PAC or PACG [20]. However, a population-based clinical trial reported that 6.7% of PACS in Mongolia progressed to PAC after LPI in 6 years [21].

Considering the large number of PACS in China and the potential significance of angle closure as a public health problem, we conducted a randomized trial, the aim of the present study was to investigate the efficacy of LPI in PACS in one eye and chart the course of untreated fellow eyes. Herein we report the one year results of IOP and angle changes in this trial. Our study adheres to CONSORT guidelines.

Methods

Participant and study design

The study was approved by the ethics committee of the Tongren Eye Centre, Capital Medical University, and the ethics committee of Handan Eye Hospital and conducted in accordance with the tenets of the Declaration of Helsinki at the department of ophthalmology in Handan 3rd Hospital (a branch of the clinical research center of Beijing Tongren Eye Center), Hebei Province, China. The trial was registered at the Chinese clinical trial registry center (see: <http://www.chictr.org.cn/showproj.aspx?proj=8716> , ChiCTR-TCH-10000820). All participants provided an informed consent.

Patients were consecutively recruited from the glaucoma clinic of the Handan Eye Hospital, between October, 2005 and January, 2008, all eligible subjects have one year follow up .All subjects underwent a routine ophthalmic examination including best corrected visual acuity using a Log Mar chart (Precision Vision, La Salle, IL, USA), refraction, slit-lamp examination, gonioscopy (FSJ), optic disc assessment with direct ophthalmoscope (FSJ) and visual field test using the 24-2- Swedish Interactive Testing Algorithm (SITA) fast program with Humphrey Visual Field Analyzer 750i (Carl Zeiss, Jena, Germany).

PACS was defined as non-visibility of the filtering trabecular meshwork for ≥ 180 degrees on an “over the hill” view on gonioscopy (one mirror Goldman lens in dim illumination), without PAS and no clinically evident glaucomatous optic damage or visual field change [22,23].

Inclusion criteria for this study included :(1) Age ≥ 40 years; (2) non-visibility of the trabecular meshwork for $\geq 180^\circ$ in both eyes; (3) No PAS; (4) IOP ≤ 21 mmHg without any IOP lowering medications; (5) normal optic disc appearance (cup:disc ratio <0.7 , rim:disc ratio >0.1 and (6) normal visual field (VF) determined by a normal glaucoma hemifield test.

Patients with any of the following conditions were excluded: (1) Severe systemic disease such as heart, renal failure; which could preclude eye examinations and follow up. (2) Any past ocular surgery. (3)

History or signs of acute angle closure attack. (4) Need for frequent pupil dilation due to diabetes or other retinal disease; (5) Plan to move out of Handan city within 5 years (6) Unwillingness to sign an informed consent (7) Those considered at high risk of acute angle-closure glaucoma (an arbitrary IOP increase of ≥ 15 mmHg following mydriasis or darkroom provocative testing).

An incident event of AACG or PAC was the primary outcome. AACG was characterized by a combination of acute symptoms of pain, headache, blurred vision and haloes around lights with signs of ischemic iris changes, corneal edema, glaucomflecken, and elevated IOP above 30 mmHg. PAC was defined as PACS with IOP >21 mmHg on two separate occasions and / or peripheral anterior synechia of 0.5 clock hours.

Goldmann applanation tonometry was performed by a certified clinical nurse prior to LPI and on day 7, one month and 12 months post LPI. At each visit, the mean of 3 readings was recorded.

Gonioscopy was carried out by one glaucoma specialist (FSJ) who was blinded after assignment to the treatment prior to LPI, day 7, one month and 12 months post LPI, using a Goldmann-type 1-mirror lens with low-ambient illumination that did not impinge on the pupil. This was followed by dynamic gonioscopy using the same lens to confirm the absence of peripheral anterior synechia (PAS). The inter-observer reproducibility for gonioscopy between FSJ and another glaucoma specialist for clock hours of PAS was perfect [Intraclass correlation (ICC) =0.972].

Randomization and Allocation Concealment.

The SPSS program generated a series of numbers to randomly select the right or left eye of the participants to be treated with LPI. Allocation concealment was achieved by involving a research nurse(ZXY) in the process: when a patient met the criteria for enrollment, the ophthalmologist(FSJ) involved in this study contacted the research nurse who communicated the allocation.

Interventions

This study followed routine clinical practice. LPI was performed with an Abraham contact lens in the superior (10:00 to 2:00 o'clock) region of the iris by FSJ or LYB using a Nd:YAG laser (YL-1600; NIDEK Co., LTD, Japan).

1% pilocarpine eye drops (Freda Company, Shandong, China) were instilled 4 times at an interval of 5 minutes prior to treatment. The laser power was initially set at 4-mJ and increased as necessary (up to 11 mJ) until a patent iridotomy of approximately 0.2 mm was achieved. Full-thickness perforation was confirmed by dispersion of pigment with flow of aqueous from the posterior to the anterior chamber and direct visualization of the posterior chamber.

If the IOP measured 1 hour after iridotomy was ≥ 30 mmHg oral acetazolamide (250mg) was given. Due to non-availability of plain steroid drops, the eye undergoing LPI eye was treated with Tobradex eye drops (Alcon Laboratories, Fort Worth, TX) four times daily for 3 days.

Sample size estimation

Based on an expected 22% incidence of PAC in control PACS and reduction to 5% with LPI²², a sample size of 116 patients was calculated to allow demonstration of superiority at the 5.0 % significance level with a power of 80%. Anticipating a loss to follow up of 10% per year, the sample size was increased to 177. Enrollment was slow and 134 eligible subjects were recruited between October 2005 and January 2008.

Statistical Analysis

All analyses were performed using SAS 9.0.3 statistical software (SAS Inc., Chicago, IL). Data from the 1-year visit were used for analysis.

A paired t-test was used to compare the change in VA (LogMAR), IOP, Spherical equivalent (SE), anterior chamber depth (ACD), lens thickness (LT) and axial length (AXL) in the treated eye to that in the untreated fellow eye. We used a general linear model to test the difference in IOP with repeated measurements. The means and standard deviations (SD) were calculated for continuous outcome variables with a normal distribution. Statistical significance was determined using the Student's t-test (normal distribution) or rank-sum test (non-normal distribution). To compare the incidence rate of PAC/AACG between treated eyes and untreated eyes, we used Fisher exact test (1-sided). $P < 0.05$ was considered to be statistically significant.

Results

Characteristics of the participants

191 subjects were eligible for the study. 12 patients who declined to participate and 45 who refused randomization were excluded. 134 patients were followed up for one year and one eye was treated with LPI at random. 10 subjects were lost to follow up on day 7, 23 subjects were lost to follow up at one month and 54 subjects (8 patients declined follow up, 25 could not be contacted, 2 patients moved and could not be contacted and 19 did not attend follow up despite repeated requests) were lost to follow up at 1 year (Figure 1). The mean age of the treated participants was 60.5 ± 8.0 years and 87% were female (117/134). 80 (58.9%) attended the one year follow up. 26 of the 134 patients who could not attend the follow up were contacted by telephone and none of them had experienced symptoms of AACG.

The baseline characteristics and the quadrants of non-visible trabecular meshwork in the treated eyes was not significantly different from the fellow eye (Table 1). Since the drop off rate was high, we compared the baseline characteristics between the those who attended follow up and those who did not attend follow up: there was no significant difference in age, gender, ocular parameters or quadrants of non-visible meshwork. The IOP in the participants who missed the 1-year follow-up was a little lower, and they had better VA than the participants who attended (Table 2).

IOP outcomes

The mean IOP in the treated eyes was 15.9 ± 2.7 mmHg at baseline, 15.4 ± 3.0 mmHg on day 7; 16.5 ± 2.9 mmHg at one month and 15.5 ± 2.9 mmHg at 12 months. The change in IOP between the baseline and follow up visits were very similar in the treated eyes and the untreated fellow eyes at all follow up visits (Figure 2). IOP in eyes with four, three and two quadrants of non-visible trabecular meshwork pre operatively decreased by 0.82 ± 3.3 mmHg, 0.14 ± 3.4 mmHg and 1.6 ± 3.5 mmHg respectively. There was no difference between treated and untreated eyes ($p=0.440\sim 0.612$).

Gonioscopy outcomes

79 patients underwent gonioscopy at the 12 month visit. Five of the untreated eyes (6%) showed one quadrant of increase in “closure” but none developed PAS (Table 3). 13 treated eyes (16.5%) had a completely open angle, 74 (93.7%) had opened by at least one quadrant and in 67.0% (53/79) the trabecular meshwork remained non-visible in two or more quadrants (Table 3).

Progression rate to PAC outcomes

Five of the 80 patients who attended the 1 year follow up had developed PAC or AACG. Those who progressed were females aged 49 to 69 years. Of the untreated eyes, one developed AACG while two eyes recorded an IOP >21 and were classified as PAC, the progression rate to PAC in untreated eyes was therefore 3.75% (95% CI, 0 -7.9%). Two of the treated eyes had an IOP above 21mmHg and were classified as PAC (2.5%; 95% CI, 0 -5.9%); none had developed PAS or AACG. The cumulative incidence for PAC/AACG in treated eyes were not significantly different from untreated eyes ($p=0.650$).

Discussion

This randomized study found that at one year 3.75% of untreated PACS fellow eyes progressed to PAC / AACG; however, in this sample with a small number of events LPI did not significantly reduce the incidence of PAC. There was no significant reduction of IOP following LPI and 67.0% (53/79) of treated eyes continued to have non visibility of trabecular meshwork in two or more quadrants.

In our study, we found that the angle opened in at least one quadrants in 93.7% of the PACS eyes which is consistent with the reported role of pupillary block in angle closure disease among the Chinese population [24, 25]. However, following LPI about 2/3 of the PACS eyes did not open in 2 or more quadrants; and 17.8% did not open in 3 quadrants or more. This result is very similar to that of a population-based study from southern China in which about 19.4% still had 3 or more quadrants of non-visibility of meshwork following laser iridotomy [24]. Previous studies had reported that 37% to 60% of Chinese eyes undergoing LPI for early primary angle closure were still positive on the dark room prone provocative test [26, 27]. Non responsive cases may have some of the multiple mechanisms of angle-closure reported in Asian eyes [24, 25, 28-30].

Several studies have reported an association of IOP and angle width. Foster estimated a 0.2 mm Hg increase per 10° change in width in all four quadrants [31, 32]. He et al reported a 3.1mmHg reduction in mean IOP at 2 weeks' post LPI [25], while Hisao et al observed a reduction of 2.3mmHg in mean IOP after LPI [33]. We did not observe significant IOP reduction following LPI at any of the follow up visits, did not find an association of IOP with the number of non-visible quadrants, and the change in IOP was similar to the fellow untreated eyes. In the present study, we found that at 7 days, one month and one year after LPI, mean IOP rise and fall in the treated and fellow untreated eyes almost simultaneously (Figure 2). Such effect seems to occur after trabeculectomy[34], Diestelhorst[32] studied the effect of trabeculectomy on the aqueous humour flow of the unoperated fellow eye, he concluded that filtration surgery in one eye triggers a CNS mediated, reflective increase in aqueous flow to maintain physiological stability in the anterior chamber of the surgically treated eye,we supposed that LPI may have the same effect as trabeculectomy.

The incidence of PAC/AACG in the untreated eyes in our study was 3.75%, which was very similar to that reported in a population based Indian cohort 4.4% per year [22]. In Liwan study, approximately one in five people aged 50 years and older developed some form of angle closure over a 10-year period [36]. However, two of the LPI treated eyes also developed increased IOP without PAS in our study. All cases classified as progressing to PAC were based on recording an IOP > 21 mmHg. While a cut off is required for trial purposes, a single IOP recording could be erroneous and would not be considered clinically significant. While it is possible that indentation gonioscopy may have revealed differences in PAS between groups, it seems that any benefit of LPI at one year in preventing PAC is likely to be minimal, would not justify laser iridotomy for all and therefore cannot justify population based screening for PACS [16, 18, 21,26, 28, 37-39].

The major limitation of our study is the loss to follow up of 40% at one year, much higher than expected; 26 of those who did not attend follow up were contacted by phone and confirmed absence any symptoms of AAC. In addition, HEH is the only eye hospital in local area. As all subjects were informed and aware about the symptoms of angle-closure glaucoma and that free eye care would be available, it is unlikely that they had symptoms but did not attend. Also the baseline characteristics of patients who did or did not attend follow were similar for the treated eyes and the untreated eyes. Based on the PAC rate in this study, the power is low. The referred rate was 22% at 5 years. It may be due to different population. Accordingly, we believe pathology if any, in subjects lost to follow up was likely to be PAC, not AACG.

Another limitation is the subjective nature of gonioscopy for angle closure. Although the intraobserver agreement of gonioscopy for angle closure sounds good, in the untreated group one third of the cases had a wider angle comparing to the baseline, which probably represents variability in gonioscopy. The changes in the angle were however different in treated compared to untreated eyes.

Conclusions

The present registry study indicated that 3.75% of untreated PACS fellow eyes progressed to PAC / AACG, a rate of progression similar to that reported in the literature[22]. The progression rate to PAC in LPI treated eyes was lower than untreated eyes. IOP was not reduced significantly after LPI and about two thirds of PACS continued to have two quadrants of non-visible trabecular meshwork, possibly due to non-pupillary block mechanisms of angle closure. The further longitudinal studies may help better clarify the role of LPI and the implications of residual closure on the need for follow up and treatment.

Declarations

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Authors' Contributions

P.Y and L.Y.B analyzed and interpreted the patient data. M.D.P, F.S.J., L.Y.B performed the patient examination, data collection and was a major contributor in writing the manuscript. All authors read and approved the final manuscript

Competing interests

The authors have no proprietary or commercial interest in any materials discussed in this article.

Ethics approval and consent to participate

The study was approved by the ethics committee of the Tongren Eye Centre, Capital Medical University, and the ethics committee of Handan Eye Hospital and conducted in accordance with the tenets of the Declaration of Helsinki at the department of ophthalmology in Handan 3rd Hospital (a branch of the clinical research center of Beijing Tongren Eye Center), Hebei Province, China. The trial was registered at the Chinese clinical trial registry center (<http://www.chictr.org.cn/showproj.aspx?proj=8716>.

ChiCTR-TCH-10000820). Informed consent obtained from all study participants was written.

Consent for publication

Not applicable.

Availability of data and materials

The data that support the findings of this study are available upon request from the corresponding author [Wang]. The data are not publicly available due to containing information that could compromise the privacy of research participants. Data are available from the authors upon reasonable request and with permission of the Beijing Tongren hospital, China.

Abbreviations

PACS: primary angle closure suspect; PAC: primary angle closure, AACG: acute angle closure glaucoma; BCVA: Best-corrected visual acuity; LPI: laser peripheral iridotomy; IOP: intraocular pressure; PACG: primary angle closure glaucoma; CT: corneal thickness; IOP, SE: Spherical equivalent, ACD: anterior chamber depth, LT: lens thickness; AXL: axial length; SD: standard deviations; PAS: peripheral anterior synechia; ICC: Intraclass correlation

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Tables

Table 1. Baseline Characteristics of Treated and Untreated Fellow Eye of Primary Angle Closure Suspects

Variable	Treated Eye (n=134)	Fellow Eye (n=134)	P value
IOP(mmHg)	15.9±2.6	15.9±2.8	.912*
Quadrants of occludable angle	3.5±0.7	3.6±0.6	.577*
BCVA	0.1±0.1	0.1±0.2	0.130**
SE	1.0±1.4	1.1±1.3	.210*
ACD(mm)	2.5±0.3	2.5±0.2	.260*
LT(mm)	4.7±0.3	4.7±0.4	.080*
AXL(mm)	22.2±0.8	22.1±1.1	.511*

IOP: intraocular pressure

BCVA: Best-corrected visual acuity (Logmar)

SE: Spherical equivalence

ACD: anterior chamber depth

LT: lens thickness

AXL: axial length

*paired-t test

** Wilcoxon Signed Ranks Test

Table 2. Baseline Characteristics in Subjects who Attended or Missed 1-year Follow-up

Parameters	Attended Follow-up	Missed Follow-up	p value
	n=80	n=54	
Female n(%)	67(84%)	50(93%)	.131
Age (years)	61.0±7.6	59.6±8.5	.344
	Treated eyes		
BCVA*	0.09±0.11	0.14±0.13	.039
SE (diopters)	0.9±1.5	1.0±1.3	.682
IOP(mmHg)	16.3±2.6	15.2±2.6	.014
ACD (mm)	2.5±0.2	2.5±0.3	.717
LT (mm)	4.7±0.3	4.7±0.3	.950
AXL(mm)	22.2±0.8	22.1±0.7	.605
Occludable angle(quadrants)	3.5±0.7	3.5±0.7	.981
	Untreated eyes		
BCVA*	0.11±0.17	0.13±0.24	.491
SE (diopters)	1.1±1.5	1.1±1.0	.981
IOP(mmHg)	16.3±2.8	15.2±2.7	.034
ACD (mm)	2.5±0.2	2.5±0.2	.761
LT (mm)	4.7±0.4	4.7±0.3	.994
AXL(mm)	22.1±1.3	22.2±0.7	.877
Occludable angle (quadrants)	3.6±0.6	3.5±0.6	.756

IOP: intraocular pressure

BCVA: Best-corrected visual acuity (Logmar)

SE: Spherical equivalence

ACD: anterior chamber depth, LT: lens thickness, AXL: axial length

* t-test for continuous variables, Chi-square test for categorical variables, non-parametric t-test for BCVA

Figures

Table 3. The Number of Closed Quadrants (by static gonioscopy) at 1-Year and Baseline in Treated and Untreated Eyes

Closed Angle Before LPI	Treated Eyes					
	Closed Angle 1year After LPI (%)					
	None	One quadrants	Two quadrants	Three quadrants	Four quadrants	Total (%)
Two Quadrants	4 (57.1)	1 (14.3)	1 (14.3)	1 (14.3)	0 (0.0)	7 (100.0)
Three Quadrants	6 (27.3)	6 (27.3)	8 (36.4)	2 (9.1)	0 (0.0)	22 (100.0)
Four Quadrants	3 (6.0)	6 (12.0)	30 (60.0)	10 (20.0)	1 (2.0)	50 (100.0)
Total	13 (16.5)	13 (16.5)	39 (49.4)	13 (16.5)	1 (1.3)	79 (100.0)
Untreated Eyes						
Closed Angle at Baseline	Closed Angle at 12 th month visit n (%)					
Two Quadrants	0 (0)	1 (16.7)	4 (66.7)	1 (16.7)	0 (0)	6 (100.0)
Three Quadrants	1 (4.8)	1 (4.8)	5 (23.8)	10 (47.6)	4 (19.0)	21 (100.0)
Four Quadrants	2 (3.8)	0 (0)	6 (11.5)	13 (25.0)	31 (59.6)	52 (100.0)
Total	3 (3.8)	2 (2.5)	15 (19.0)	24 (30.4)	35 (44.3)	79 (100.0)

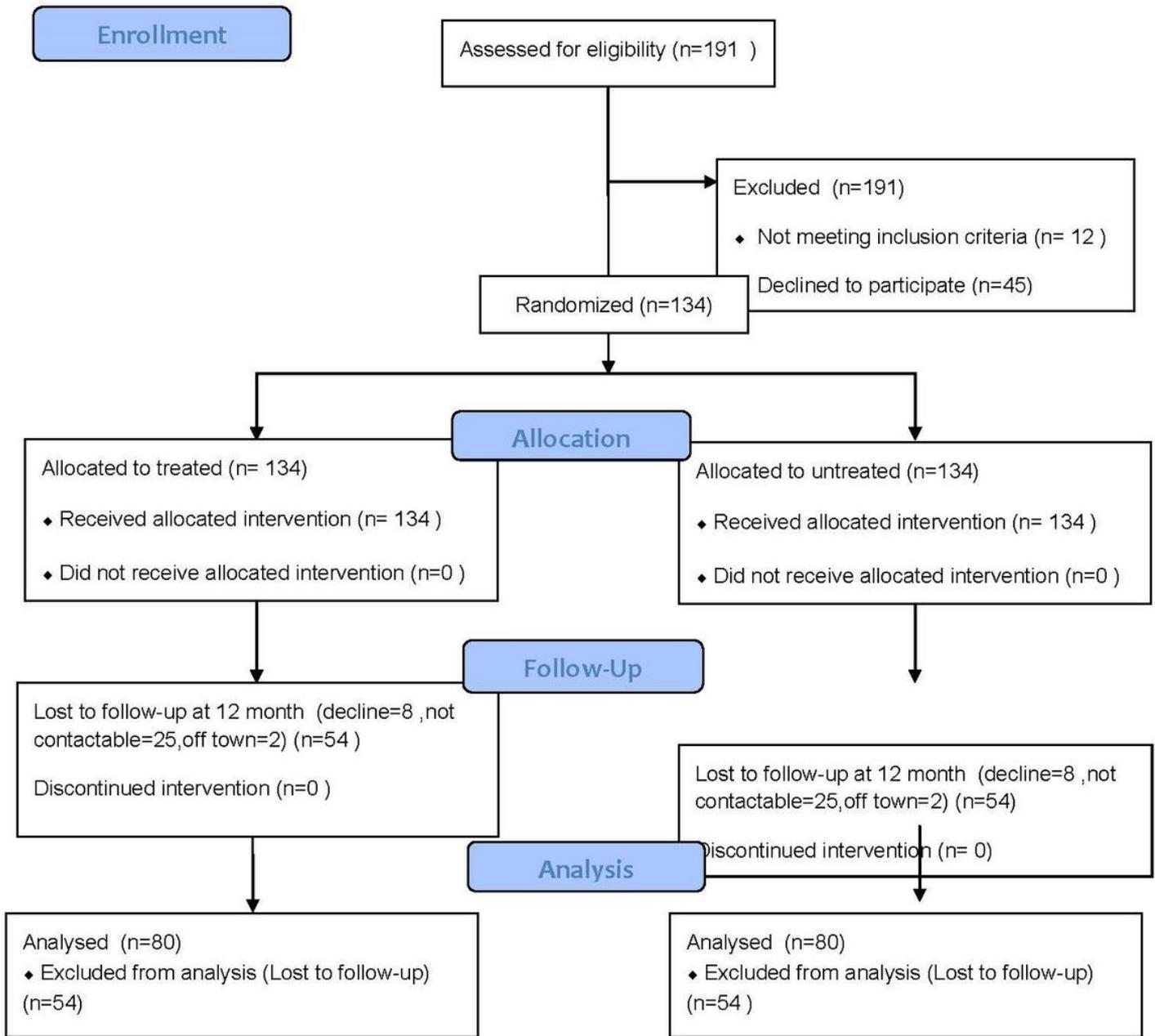


Figure 1

Flow chart of participants in the trail

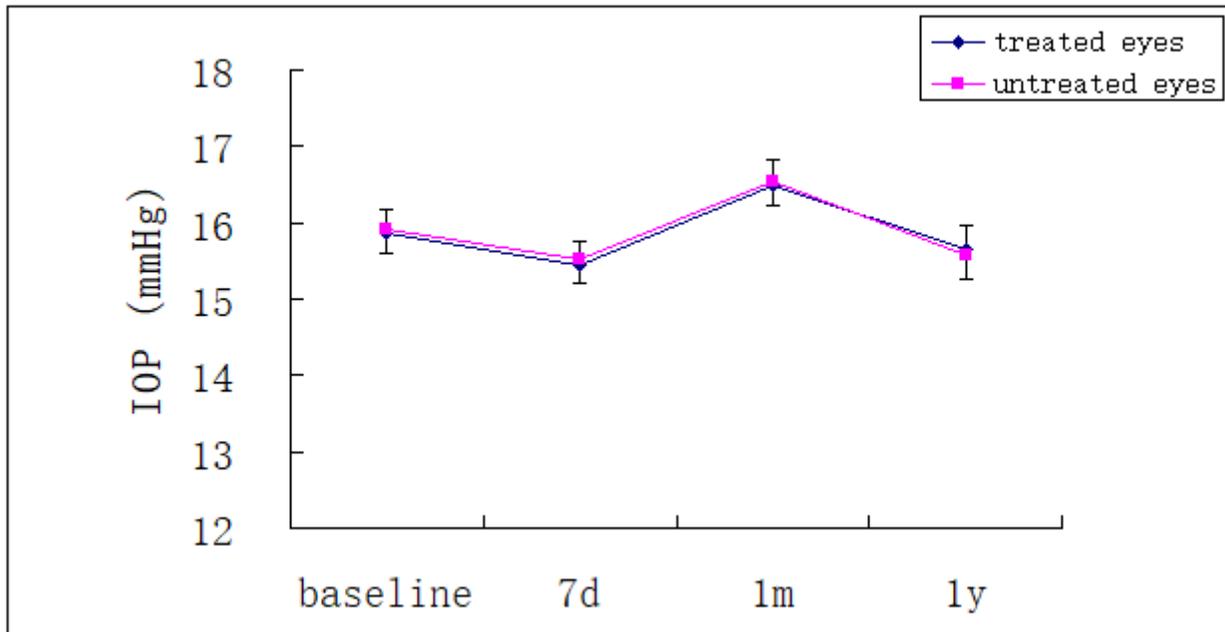


Figure 2

Intraocular Pressure (IOP) Changes Before and After Laser Peripheral Iridotomy in the Treated And Fellow Untreated Eye

Supplementary Files

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

- [CONSORT2010Checklistmdp.doc](#)