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Research Article

The Correlation Between Intraocular Pressure Reduction and Changes in Optic Nerve Head, Retinal Nerve Fibre Layer and Visual Fields in Open Angle Glaucoma Following Filtration Surgery

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Abstract

Aim: To study the correlation between intraocular pressure reduction and changes in structural (optic nerve head and nerve fibre layer) and functional (visual fields) parameters in open angle glaucoma patients following trabeculectomy.

Materials and Methods: A prospective, interventional study (n = 40) was done. Patients with COAG between 50 - 80 years with well documented glaucoma progression were included in the study. Patients with unreliable visual fields (fixation loss > 20%, false positive > 15%, and false negative > 33%), OCT images with less than 90% satisfactory A-scan or a signal-to-noise ratio of < 25 dB were excluded. Significant differences in mean test values over 12-months after intervention were evaluated with repeated measure ANOVA (analysis of variance). Logistic regression analysis was performed to study the effect of independent variables (age, gender, IOP reduction, duration of IOP control, change in rim area and rim volume) on dependent variables (RNFL thickness, mean sensitivity and mean deviation, respectively).

Results: Repeated measure ANOVA revealed a significant increase (P < 0.01) in rim area at all time points. There was a significant reduction in IOP at 1-month postoperative followed by slight paradoxical rise at 3 months. Significant changes in RNFL thickness were observed at 3, 6 and 12 months, respectively. On regression analysis, there was structural and functional correlation (IOP and RNFL thickness and rim area and mean deviation). There was 0.4microns change in RNFL thickness for 1mm of IOP reduction. Age (OR = 1.2, 95%CI, 0.89 - 1.34), gender (OR = 3.4, 95%CI, 507- 42.4), change in IOP (OR = 1.9, 95% CI, 1.2 - 32.8) and change in rim area (OR = 2.5, 95%CI, 0.25 - 29) significantly influenced change in RNFL thickness. Change in rim area exhibited higher odds (OR = 2.8) in causing change in mean deviation.

Conclusion: Despite a significant correlation between IOP reduction and RNFL thickness and change in mean deviation and rim area, lowering of IOP by surgical intervention may variably influence structural and functional parameters in glaucoma; these changes may depend on several factors like age, gender, the height and the amount of IOP reduction, the stage of glaucoma and follow up duration.

Keywords: Intraocular Pressure; Optic Nerve Head; Retinal Nerve Fibre Layer Thickness; Regression Analysis Trabeculectomy

Introduction

Chronic open-angle glaucoma (COAG) is a chronic disease which if left untreated, leads to progressive ganglion cell degeneration, retinal nerve fibre layer (RNFL) loss, thinning of the neuroretinal rim and corresponding visual field changes. These changes eventually, culminates in blindness. Therefore, diligent analysis of these parameters is vital for establishing clinical diagnosis, monitoring disease progression and functional evaluation in patients with glaucoma.

Intraocular pressure (IOP) has been identified as one of the most important modifiable risk factors responsible for glaucomatous damage and most treatment modalities revolve around IOP reduction including medications, lasers and glaucoma filtration surgery. The lamina cribrosa appears to be the main site of glaucomatous damage; due to mechanical effects of raised IOP, backward bowing occurs damaging nerve fibres passing through it.

Reversal/partial reversal of structural and functional parameters in glaucomatous eyes may depend upon several factors including ethnicity [1], age, magnitude of IOP reduction, time of assessment of parameters and the stage of glaucoma. Consequently, reversal of changes in optic disc, RNFL and visual field following IOP reduction following glaucoma filtering surgery may show variable outcomes.

A study by Wu., *et al*. found reversal of optic disc cupping after IOP reduction following trabeculectomy in young patients [2]. Chang., et al. did not observe any significant change in RNFL thickness after medical or surgical reduction in IOP when measurements were performed at a mean period 46.8 ± 11.2 days whereas Figus., et al. found a significant increase in retinal nerve fibre layer thickness after trabeculectomy at 6 months [3-4]. Tsai., *et al*. demonstrated reversal of cupping topographically after IOP reduction in adult patients with COAG over 38.4 ± 24.8 weeks follow-up [5].

Kotecha., et al. assessed optic nerve head structure and visual field changes in a cohort of 250 patients with glaucoma after trabeculectomy. The median follow-up IOP was significantly higher in those with documented glaucoma progression as compared to those without. Their study suggested that the progression of glaucoma after surgery was related to the magnitude of IOP reduction [6].

Due to variations in results of structural and functional assessment in patients with glaucoma, we conducted a prospective study at a referral and teaching hospital in the northern part of the Indian sub-continent. We evaluated changes in optic nerve head, RNFL thickness and visual fields after glaucoma filtering surgery in adult patients with COAG. We also analysed the correlation between the duration and magnitude IOP reduction and these parameters.

Material and Methods

In this prospective study, 40 adult patients with COAG who underwent trabeculectomy from January 2016 to August 2017 were enrolled. The institutional review board and the Ethics committee approve the trial. An informed consent was obtained from all participants and the study design adhered to the tenets of the Declaration of Helsinki.

Inclusion and exclusion criteria

Patients with COAG between 40 - 80 years of age with documented glaucoma progression despite maximum tolerated medical therapy were included.

Patients were excluded if they had advanced glaucomatous damage, normal tension glaucoma, unreliable visual fields (fixation loss > 20%, false positive > 15%, and false negative > 33%), OCT images with less than 90% satisfactory A-scan or a signal-to-noise ratio of less than 25 dB, and any ocular disease affecting visual function and fields.

Complete ophthalmic examination was done which included measurement of corrected distance visual acuity (CDVA), slit-lamp bio-microscopy with + 90D lens, Goldman's applanation tonometry, gonioscopy with Susman's 4-mirror lens, OCT, automated perimetry, and cup/disc ratio estimation. A detailed medical history included age, gender, history of anti-glaucoma medications, hypertension, and previous ocular surgery.

IOP measurements

Three readings were taken at the same time of the day (9.am) and averaged. There was an interval of 30 minutes between each reading. The central corneal thickness (CCT) was measured using the specular microscope EM-3000® (Tomey Corp., Nagoya, Japan).

Visual field testing

Visual field analysis was done using octopus 900 automated perimetry machine. The pre-operative, 3-months, 6-monthsand 12-months post-operative mean sensitivity (MS), mean deviation (MD), and loss of variance were compared.

Optical coherence tonography

Optic nerve head parameters and RNFL thickness were assessed using Topcon 3D OCT-1Maestro. All OCT scans were obtained by an independent investigator. OCT scans were obtained after pupillary dilatation using 5% phenylephrine and 1% tropicamide eye drops. Good scans were defined as focused images from the ocular fundus, with an adequate signal-to-noise ratio and a cantered, circular ring around the optic disc. The average of the three valid circular scans was used to calculate the mean and quadratic RNFL thickness.

Surgical procedure

Peribulbar anaesthesia was achieved. A fornix based conjunctival flap was made, the sclera was exposed. A partial thickness (one-third) scleral flap (5.0 mm × 5.0 mm) was dissected superiorly into 1 mm of clear cornea. A deep sclerectomy was done and Schlemm's canal was deroofed. A window was created between trabecular meshwork (TM) and Descemet's membrane and the juxta-canalicular TM and Schlemm's endothelium were removed using small blunt forceps. The superficial scleral flap was sutured with 2 to 4 interrupted nylon 10-0 sutures.

Outcome measures

Change in RNFL thickness was the primary outcome measure. Changes in ONH parameters (rim area and volume) and visual fields (mean sensitivity and mean deviation) were secondary outcome measures.

Sample size calculation

To calculate the sample size, a pilot study was first done on 10 subjects. It was based on the principal of 'Inference for mean; comparing a mean (primary outcome) to a known value.' The change in RNFL thickness between pre and postoperative period was compared. The alpha was set at 0.05 and power 80%. The estimated sample size was calculated to be 40. (https://www.stat.ubc.ca/~rollin/stats/ssize/n1.html).

Statistics

Statistical analysis was performed on an intent-to-treat basis using IBM, SPSS Statistics version 25 (IBM Inc.). A one-way repeated-measures analysis of variance (ANOVA) was conducted to determine whether there were significant differences in mean test values over the course of 12-months follow up. There were no outliers, and data were normally distributed, as assessed by a box plot and Shapiro–Wilk test (P.0.05), respectively. The assumption of sphericity was violated, as assessed by the Mauchly test of sphericity (P<0.05). Therefore, a Greenhouse–Geisser correction was applied. A post hoc (Tukey) test was performed using the Bonferroni correction, to determine where differences occurred; the F-statistic was reported as F (df time, df error) =F value, P value. A P value less than 0.05 was considered statistically significant. A regression analysis was performed to study the effect of independent variables (IOP, rim area and rim volume) on dependent variables (RNFL thickness, mean sensitivity and mean deviation, respectively).

Results

A total of 49 patients were enrolled in the study. However, 6 patients with unreliable visual fields and three patients with suboptimal OCT scans were excluded from the study. Therefore, 40 patients were included for statistical analysis. Data are mean ± standard deviation, unless otherwise stated. The mean age of patients was 56.7 ± 8.97 (range, 42 - 76 years). There were 28 (70%) males and 12 (30%) females, respectively. One eye was selected at random in case of bilateral involvement. The right eye was operated in 28 (70%) cases and the left eye in 12(30%) cases, respectively. The pre-intervention indices of patients are depicted in table 1 [Plus-minus values are means ± SD. Baseline values were the means of the values obtained during screening and eligibility confirmation visits. Snellen vision was converted to Log MAR units for comparison. Rim area was measure in millimetres and Mean deviation in decibels. Retinal nerve fibre layer (RNFL) was measured in microns].

There was a decrease in IOP from 27.4 ± 2.7 mm of Hg pre-intervention to 12.6 ± 2.7 mm of Hg, 12 months into the surgical intervention, a statistically significant decrease of 14.7 ± 0.64 mg/L [mean ± standard error], p < .0001. Post hoc analysis with a Bonferroni adjustment revealed that IOP statistically significantly decreased from pre-intervention to 1 month, 3months, 6 months and

Parameter	Minimum	Maximum	Mean ± SD
Age (years)	42	76	56.7 ± 8.97
CDVA (Log MAR)	0.1	0.5	0.23 ± 0.1
IOP (mm Hg)	22	32	27.4 ± 2.74
Rim Area (mm^2)	0.08	0.97	0.51 ± 0.26
RNFL thickness (microns)	23	82	60.6 ± 6.90
Mean Deviation (dB)	11.6	26.1	19.4 ± 4.5

Table 1: Baseline Parameters.

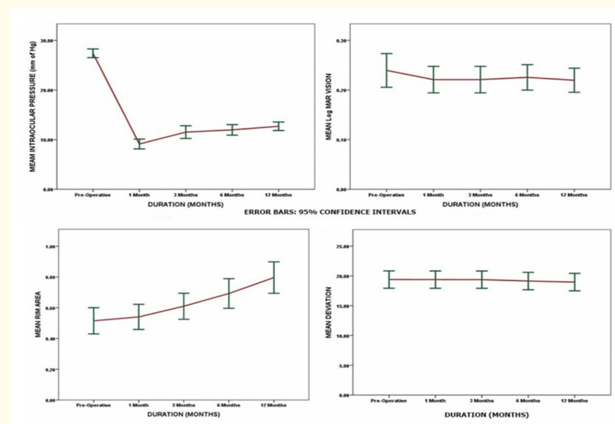

Figure 1: Mean change from baseline in IOP, best corrected vision, rim area and mean deviation to post-intervention, respectively.

12 months. However, the decrease from 3 months to 6 months was not significant (0.45 (95% CI, -.6-0.744, P = 0.451). Figure 1 shows mean change from baseline in IOP, BCVA, rim area and mean deviation to post-intervention, respectively.

The surgical intervention elicited statistically significant changes in vision over time, F (1.361, 52.973) = 4.250, p < .05, partial η^2 = 0.882. There was an improvement in vision from 0.24 ± 0.1 Log MAR units' pre-intervention to 0.2 ± 0.07 Log MAR units, 12 months into the surgical intervention, a statistically significant decrease of 0.02 ±.009 Log MAR units [mean ± standard error], p < .0001.

Rim area increased from 0.51 ± 0.27 mm^2 pre-intervention to 0.61 ± 0.26 mm^2 three months into the intervention to 0.79 ± 0.31 mm2, 12 months post-intervention. Epsilon (ε) was 0.648, as calculated according to Greenhouse and Geisser (1959), was used to correct the one-way repeated measures ANOVA (sphericity violated). The surgical intervention elicited statistically significant changes in rim area over time, F (1.455, 57.064) = 44.973, p < .0005, partial η^2 = .280. Post hoc analysis with a Bonferroni adjustment revealed that rim area was statistically significantly increased at all time points (pre-intervention to 3 months, 6 months and 12 months post-intervention, respectively).

Mean deviation decreased from 19.4 ± 4.5 dB pre-intervention to 19.1 ± 4.6 dB 6 months into intervention to 18.9 ± 4.6 dB, 12 months post intervention. The surgical intervention elicited statistically significant changes in mean deviation over time, F (1.479, 57.69) = 82.987, $p < .0005$, partial $\eta^2 = .680$. Repeated measure ANOVA revealed that change in mean deviation occurred at 5.38 ± 1.8 months, post-intervention. Post hoc analysis with a Bonferroni adjustment revealed that mean deviation did not statistically decrease from pre-intervention to 1 month (P = 0.989) and pre-intervention to 3 months (P = 0.330), post-intervention, respectively. However, there was a significant decrease at six (0.253 (95% CI, 0.175 - 0.330, P < 0.005) and 12 months (0.428 (95% CI, 0.302-0.553), respectively.

The retinal nerve fibre layer (RNFL) thickness increased from 60.6 ± 6.9 microns pre-intervention to 63.4 ± 6.56 microns 6 months into intervention to 64.78 ± 6.8 microns, 12 months post intervention. The surgical intervention elicited statistically significant changes in RNFL thickness over time, F (1.518, 59.20) = 122.03, $p < .0005$, partial $\eta^2 = .758$. Post hoc analysis with a Bonferroni adjustment revealed that mean deviation did not statistically decrease from pre-intervention to 1 month (-0.425 (95% CI, -1.027 - 0.177, P = 0.421). However, there was a significant increase at all other time points. Figure 2 shows the mean change from baseline in RNFL thickness to post-intervention in inferior, superior, nasal and temporal quadrants, respectively.

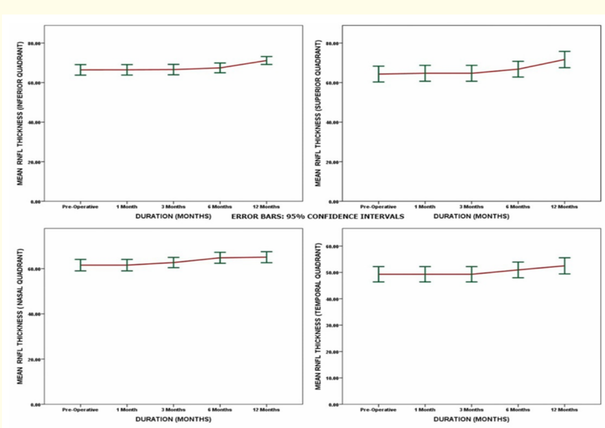

Figure 2: Mean change from baseline in RNFL thickness to post-intervention in inferior, superior, nasal and temporal quadrants, respectively.

On regression analysis, the mean change in RNFL thickness was significantly (P < 0.05) associated with change in IOP post intervention. The change in mean deviation was significantly (P < 0.05) associated with change in rim area. Figure 3 and figure 4 shows regression plots at baseline and at 12 months post-intervention between these parameters. There was 0.4microns change in RNFL thickness for 1mm of IOP reduction. Logistic regression revealed that age (OR = 1.2, 95%CI, 0.89 - 1.34), gender (OR = 3.4, 95%CI, 507 - 42.4), change in IOP (OR = 1.9, 95% CI, 1.2 - 32.8) and change in rim area (OR = 2.5, 95%CI, 0.25 - 29) significantly influenced change in RNFL thickness (Table 2). Change in rim area exhibited higher odds (OR = 2.8) in causing change in mean deviation.

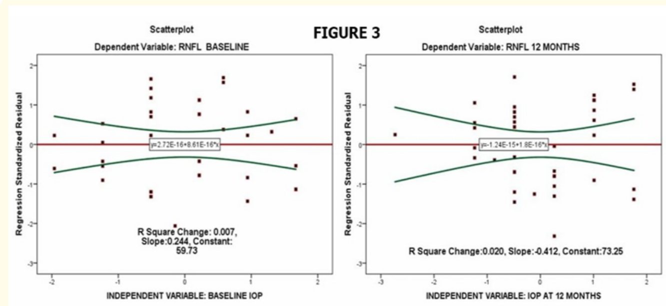

Figure 3: Regression plots at baseline and at 12 months post-intervention between IOP and retinal nerve fibre layer thickness.

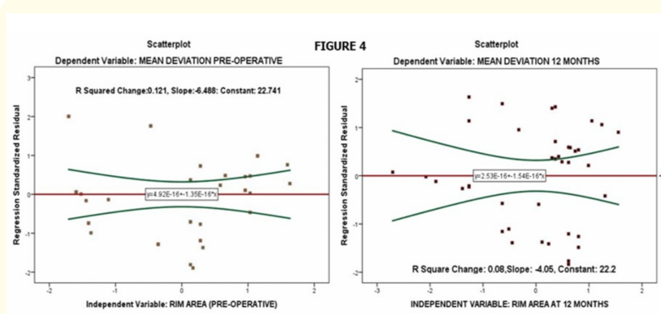

Figure 4: Regression plots at baseline and at 12 months post-intervention between Rim area and mean deviation.

Variable	B	S.E.	df	Sig.	Odds R	95% C.I. for OR	
Age	.007	.063	1	.06	1.2	0.89	1.34
Gender	2.24	1.32	1	.05	3.4	.507	42.4
Change in IOP	-.007	1.43	1	.009	1.9	1.2	32.8
Change in Rim Area	1	1.20	1	.406	2.5	0.25	29
Constant	-6.2	4.35	1	0.042			

Table 2: Logistic Regression predicting likelihood of change in RNLF Thickness.

Discussion

Chronic glaucoma is one of the main causes of loss of vision due to damage to retinal ganglion cells. Although in advanced stages, glaucomatous damage is irreversible, it has been observed that timely intervention and lowering of intraocular pressure can reverse changes in visual fields and prevent permanent damage to retinal nerve fibre layer. Consequently, there may be improvement in the appearance of optic nerve head [7-8]. Several studies have documented reversal of optic disc cupping in congenital and developmental glaucoma's after surgical intervention [9]. However, cupping reversal in childhood glaucoma may lead to nerve fibre layer thinning post-operatively and deserves further study in adults with glaucoma as well [10-11].

The present prospective study evaluated changes in RNFL thickness, ONH parameters (rim area and volume) and visual fields (mean sensitivity and mean deviation) in patients with chronic open angle glaucoma following trabeculectomy. The study also evaluated the correlation between these structural and functional parameters. The results revealed that there was a significant decrease in IOP and a significant increase in rim area over 12 months into surgical intervention. Repeated measure ANOVA revealed that although rim area significantly increased at all time points, IOP significantly reduced at 1-month postoperative followed by slight paradoxical rise at 3 months. The increase in IOP from 3 to 6 months was not significant. The study also revealed statistically significant changes in RNFL 3, 6 and 12 months after glaucoma filtering surgery. On regression analysis, there was structural and functional correlation as well (IOP and RNFL thickness and rim area and mean deviation) that is changes in RNFL thickness were pressure dependent (0.4microns change in RNFL for 1mm of IOP reduction).

Some studies report total lack of structural and functional correlation after trabeculectomy. In a study by Chang., et al. twenty-one eyes of patients who underwent medical or surgical intervention to lower IOP, change in the overall RNFL thickness after IOP reduction was not significant despite an increase (mean+/-SD, 1.02 +/-10.3 micron; P = 0.653) [12]. In contrast, a study by Saif., *et al.* in 58 eyes of patients with primary open angle glaucoma, medical reduction of IOP resulted in a significant change in the RNFL and ganglion cell complexes layer as shown by spectral-domain OCT at 6 months. This observation agreed to the present study. Moreover, there was a significant ($P < 0.01$) correlation between IOP changes and rim volume ($r = 0.81$) [13].

In primary open angle glaucoma patients with more than 30% reduction in IOP following trabeculectomy, Yamada., *et al.* found that postoperative nerve fibre layer thickness was significantly greater than the preoperative thickness in the super temporal and inferotemporal quadrants of the optic disc ($P < 0.05$). These changes were relevant in early stages of glaucoma with a better mean deviation in visual fields. In the present study, there was a mean increase in RNFL thickness after 44% reduction in IOP at 12-months; none of the cases had advanced glaucomatous changes [14].

In contrast, in adult patients with glaucoma (n = 17), Raghu., *et al.* found that there was a mean increase in RNFL thickness and cup area 1-week postoperatively. However, RNFL thickness and cup area reverted to pre-operative levels at 3 months. The authors attributed these observations to shift in anatomic structures (reduction in stretch force on lamina cribrosa of optic disc) instead of reversal of damage caused by sustained rise of IOP. There was no correlation between RNFL change and IOP change [15].

Baumane., *et al*. evaluated short-term changes in structural and functional eye parameters following glaucoma filtration surgery in different stages of glaucoma. The authors evaluated c/d ratio, RNFL thickness and MD in early, moderate and advanced cases of glaucoma, respectively. The authors found that mean RNFL thickness increased in of all four quadrants after the surgery in patients with moderate glaucoma; in contrast, there was a decrease in the mean RNFL thickness for all four quadrants in advanced glaucomatous patients. The horizontal and vertical c/d ratio improved more in moderate (66.1%) than in advanced stages (55.6%), respectively [16].

Waisboard., *et al*. evaluated structural and functional changes in open angle glaucoma patients following intraocular pressure reduction in patients using Spectral Domain Optical Coherence Tomography and automated perimetry. Seventy-six glaucomatous eyes were allocated into three groups; group 1 (IOP > 32 mmHg), group 2 (IOP between 22 - 32 mm Hg) and control group (IOP < 22mm Hg), respectively. The authors found that there was a significant decrease in the average cup to disc ratio ($p < 0.05$) following the intervention in groups 1 and 2. The changes in cup-disc ratio were not related to the amount of intraocular pressure lowering [17]. In contrast, Lesk., *et al*. found that patients with less than 25% IOP reduction after glaucoma surgery, there was worsening of all parameters in comparison to those with greater than 40% IOP reduction. However, improvement in mean deviation in visual fields was correlated with the degree of improvement of cup: disc ratio ($P = 0.025$).

Conclusion

The effect of lowering of IOP by surgical intervention in open angle glaucoma may be variable and dependent on several factors like age of the patient, the height and the amount of intraocular pressure reduction, the stage of glaucoma when the patient receives intervention and the duration of follow up.

The most important outcome of the present study was that IOP could statistically influence changes in RNFL as measured by OCT. However, the important question that needs further evaluation is that the target IOP achieved after surgical intervention would be adequate to prevent further glaucomatous damage, nerve fibre layer thinning and visual field loss. Further studies on a large sample size of patients with long term follow up are needed to improve our knowledge and our ability to prevent glaucomatous damage.

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Declaration of interest statement

We do not have any conflict of interest.

Funding

This project was not funded. Plus-minus values are means ± SD. Baseline values were the means of the values obtained during screening and eligibility confirmation visits. Snellen vision was converted to Log MAR units for comparison. Rim area was measure in millimetres and Mean deviation in decibels. Retinal nerve fibre layer (RNFL) was measured in microns.

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