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A Prospective Analysis of Trabeculectomy in Patients with Primary Open Angle Glaucoma in the Sub-Himalayan Region.

Dr. Yash Pal Sharma, Dr. Vinod Sharma, Prof. Dr. M. L. Pandey, Dr. Kalpana Sharma.

Civil Hospital Rohru, Distt Shimla, H.P. 171214 India.
Correspondence: Dr. Yash Pal Sharma,

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ABSTRACT: Purpose: A Comparative Analysis Of Trabeculectomy On Retinal Nerve Fiber Layer and Optic Nerve Head Parameters In population of clinical patients With Primary Open Angle Glaucoma within 1 week pre-operative and 1week, 1 and 3 month post-operatively In the Sub-Himalayan Region**.**

Methods: Patient sample size consisting of n=27 were accessed for primary open angle glaucoma. The sample age taken was older than 40 years and not more than 80 years. The sample population consists of adults with open anterior chamber angle and with demonstrative RNFL and ONH parameter damage. Average RNFL and ONH measurements were taken on Topcon 3D OCT-1 Maestro within a week before Trabeculectomy and at 1 week, 1 and 3 month post operatively. Pre and post operative value were analyzed using Repeated Measure ANOVA with Bonferroni correction.

Results: It was observed that RNFL Thickness in Inferior Quadrant shows significant improvement in early post-operative period; however other quadrants showed no significant improvement in thickness. In ONH parameter a corroborative positive influence of Trabeculectomy was observed in POAG.

Conclusions: The present study showed that, Trabeculectomy help to reduce intra-occular pressure post-operatively in POAG. IOP-lowering is the only proven treatment for the disease. RNFL and ONH parameters corroborate that there was improvement in the ONH parameters and RNFL thickness for the observation period.

KEYWORDS: Optical Coherence Tomography; Trabeculectomy; Visual Field, Inferior Quadrant, Superior Quadrant, Nasal Quadrant, Temporal Quadrant, Intra Ocular Pressure, Primary Open Angle Glaucoma.

I. INTRODUCTION:

The human eye and its adnexal structures develop from the neuro-ectoderm of the neural groove and the adjoining surface ectoderm, mesoderm and cells of neural crest origin. The eye is a complex anatomical structure consisting of delicate tissues. It is a sense organ which is designed to capture and focus light to form a retinal image which is translated into electrical signals and transmitted to the central nervous system via the optic nerve. The human eye is a precise system, transparency, surface regularity, smoothness, and stable ocular anatomy is important for sight. The constant shape of eye is due to the structure of the sclera and a stable intraocular pressure, higher than the atmospheric pressure [10, 20]. Each eye ball is a cystic structure kept distended by the pressure inside it. Eye ball is not a sphere but an ablate spheroid. The equator of the eye ball lies at the mid plane between two poles. The eye ball comprises three coats: outer (fibrous coat), middle (vascular coat) and inner (nervous coat). Fibrous coat is a dense strong wall which protects the intraocular contents, vascular coat supplies nutrition to the various structures of the eye ball [10, 11].

Glaucoma is a group of acute and chronic, progressive, multi-factorial optic neuropathies in which intraocular pressure (IOP) and other contributing factors are responsible for a characteristic, acquired loss of retinal ganglion cell axons leading to atrophy of the optic nerve with demonstrable visual field defects.

Glaucoma is known to be multi-factorial in origin, with established genetic and biological risk factors [2]. However, the fundamental causes remain unknown for many types of glaucoma. Glaucoma is often classified into primary open-angle (POAG), primary angle-closure (PACG), secondary angle-closure, and secondary open-angle, congenital and juvenile glaucoma's. Vision loss in most forms of glaucoma is related to

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elevated intraocular pressure (IOP) with subsequent injury to the optic nerve.

The glaucoma's are classified by the appearance of the irido-corneal angle. There are open angle, closed-angle, and developmental categories, which are further divided into primary and secondary types. Primary open-angle glaucoma can occur with or without elevated intraocular pressure; the latter is sometimes called normal-tension glaucoma. Primary open-angle glaucoma includes adult-onset disease (occurring after 40 years of age) and juvenile-onset disease (occurring between the ages of 3 and 40 years of age), primary open-angle glaucoma, in which the irido-corneal angle is open (unobstructed) and normal in appearance but aqueous outflow is diminished [3].

OPTIC NERVE HEAD: The ONH is defined as the distal portion of the optic nerve that is directly susceptible to Intra-occular Pressure (IOP) elevation. The ONH comprises the nerve fibers that originate in the ganglion cell layer of the retina and converge upon the nerve head from all points in the fundus. At the surface of the nerve head, these retinal ganglion cell axons bend acutely to exit the globe through a fenestrated sclera canal, called the lamina cribrosa. Glaucoma is characterized by progressive atrophy of the ONH secondary to the loss of optic nerve fiber [20].

CUP DISC RATIO IN RELATION TO THE DISC SIZE.

The size of the cup is determined by the size of the optic disc. There is a positive correlation between the vertical diameter and the vertical C: D ratio. A large disc will have a large cup, an average disc will have an averaged sized cup and a small disc will usually have no cup. This fact is important to remember as early or even moderately advance glaucoma may be missed if we judge only using the C: D ratio. Mean area of the optic cup in Indian eyes is 0.98 mm^2. The area of the optic cup is independent of age, refractive error, and sex, axial length of the globe and depth of the anterior chamber. The cup is horizontally oval. The mean horizontal C: D diameter ratio is 0.66 and Mean vertical C: D diameter ratio is 0.56. The configuration and depth of the cup was judged by the stereoscopic examination [1, 20].

THE NEURORETINAL RIM

The neuroretinal rim is the most important parameter of the optic disc evaluation. The rim has a characteristic configuration where the inferior (I) rim is the widest, followed by the superior (S) and nasal rims (N) and the temporal (T) rim is the thinnest [1]. The cardinal feature of glaucomatous optic neuropathy is the loss of NRR from the inner edge of the rim. This loss can occur in all sections of the disc with regional preference depending on the stage of glaucoma. The sequence of loss is usually first in the infero-temporal and supero-temporal disc regions. So for early diagnosis these areas should be carefully evaluated for glaucomatous changes. In moderate disease the temporal part of the horizontal disc is involved and in advanced glaucoma the rim remnants are located mainly in the nasal sectors.

RETINAL NERVE FIBER LAYER

The Retinal Nerve Fibre Layer is formed by the expansion of the fibers of optic nerve; it is thickest near the porus opticus gradually diminishing towards the ora serrata [20]. In normal eyes the RNFL is most visible in the temporal inferior and temporal superior sectors and least visible in the nasal sectors. This has correlation with the histology of the RNFL which is thicker in inferior and superior peripapillary areas than the temporal and nasal. The NRR is wider and the lamina cribrosa pores and diameter of the retinal arterioles is larger in these areas. The visibility of RNFL decreases with age. The normal pattern of the fiber bundles can be detected as bright striations in the retinal reflex. Various studies demonstrate that OCT can measure Peripapillary RNFL thickness. Also observe the vessels as the retinal vessels are normally embedded in the retinal nerve fibers and when there is diffuse RNFL loss, the vessels are covered only by the thin inner limiting membrane so are better visible[1].

OPTICAL COHERENCE TOMOGRAPHY:

Optical coherence tomography (OCT) is the optical analogue to ultra-sonography and measures the echo time delay and magnitude of reflected or backscattered light using the principle of Michelson low-coherence interferometry. Cross-sectional images are obtained by measuring the backscattered light while scanning across multiple sites in a transverse fashion. Echoes from a single point on the retina represent an axial scan (A-scan), and optical cross-sections (B-scans) are obtained by directing the OCT beam in the transverse direction. The data obtained are displayed as false-colour or grey-scale images. Spectral domain OCT allows for unprecedented simultaneous ultrahigh speed and ultrahigh resolution ophthalmic imaging without a loss in image quality, and 2D images can be obtained in 1/29th of a second. Present machine that was used for study was Topcon 3D OCT-1

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Maestro that is installed at the Department of Ophthalmology I. G. M. C Shimla.
Various study demonstrate that OCT measure RNFL as thinner in older person with decline of 2µm per decade. It is not surprising that RNFL thickness decrease with age. One added advantage of the OCT ONH analysis is that, one can get a cross-sectional view of the ONH rather than the 'enface' view provided by the HRT.[6]

TRABECULECTOMY

With its long-established history, remains widely practiced for glaucoma. Studies are robust in supporting its efficacy in lowering IOP[4]. Trabeculectomy is a surgical operation which lowers the intraocular pressure (IOP) inside the eye in patients with glaucoma. This is achieved by making a small hole in the eye wall (sclera), covered by a thin trap-door in the sclera. The fluid inside the eye known as aqueous humour, drains through the trap-door to a small reservoir or bleb just under the eye surface, hidden by the eyelid. The trap-door is sutured (stitched) in a way that prevents aqueous humour from draining too quickly. By draining aqueous humour the Trabeculectomy operation reduces the pressure on the optic nerve and prevents or slows further damage and further loss of vision in glaucoma. Control of the eye pressure with a Trabeculectomy will not restore vision already lost from glaucoma [17].

II. MATERIALS AND METHODS

The present study was conducted in the Department of Ophthalmology, Indira Gandhi Medical College, Shimla. 27 patients undergoing trabeculectomy were taken into study.

Data was collected from one eye only, if both eyes required surgery then the one with the greater intraocular pressure (IOP) and glaucoma progression was taken in study. The criteria for inclusion were patients aged 40–80 years with diagnosis of POAG. The patients with previous glaucoma surgery, cataract surgery, retinal, or neurological disease affecting VF were excluded from the study. While the patient was under maximally tolerant medication, the indication for surgery was optic nerve head parameter and RNFL which was high risk of glaucomatous progression as well as worsening of the VF. After trabeculectomy, the OCT scans of the patients were repeated at 1- week, 1-month, and 3-month postoperatively. The stimulus for this work was only ophthalmological for the exploration of RNFL and IOP by using the maximum means at our disposal. Informed consent was obtained from all recruited individuals. Each subject underwent extensive examination including Best Corrective Visual Acuity (BCVA) by using Snellen's chart.

Slit lamp bio-microscopy was done to assess the ocular adnexa and the anterior segment **(**AC Depth using Van Herrick's Grading) of eye using a slit lamp bio-microscope (Haag Striet-900). Intra ocular pressure is measured by using a Goldman's applanation tonometer. An open anterior angle chamber using Gonioscopy by Shaffer's system using Goldman Single Mirror Gonioscopic Lens. Optic Disc Examination- for glaucomatous changes was performed in dilated pupil with slit lamp (Haag Striet-900) using 90D lens (Magnification= 0.76). Fundus examination was done by using the direct and indirect ophthalmoscope after pupillary dilatation using 5% phenylephrine and 1% tropicamide drops instilled once or twice as required. Perimetry for visual field analysis using octopus 900 automated perimetry machine.

Optical Coherence Tomography (3D OCT-1MAESTRO) was used for studying RNFL thickness. The RNFL map represents a 6 x 6 mm cube of A-scan data centered over the optic nerve in which a 3.4 mm diameter circle of RNFL data is extracted to create what is referred to as the ISNT map (inferior, superior, nasal and temporal). Each resulting image will consist of RNFL thickness measurements along a 360-degree circle around the optic disc. It is displayed as a false color scale with the thickness values referenced to a normative database.

All OCT scans were acquired by an experienced operator. OCT scans were obtained after pupillary dilatation using 5% phenylephrine and 1% tropicamide drops instilled once or twice as required. All baseline scans was acquired within 1 weeks of the planned surgery. The parameters studied were RNFL Thickness in each quadrant.

Surgical Technique: No pupillary dilatation and a bridle suture/corneal Traction Suture were inserted (commonly superior cornea). Site of Trabeculectomy was supero-nasal or supero-temporal.

A fornix based flap of conjunctiva and Tenon capsule was fashioned superiorly. Epi-scleral tissue was cleared and major vessels cauterized. An incision was made through about 50% of sclera thickness to create a trap-door lamellar sclera flap. This flap was triangular according to preference. The superficial triangular flap was dissected forwards until clear cornea is reached. A paracentesis was made in temporal peripheral clear cornea and air injected. The

anterior chamber was entered along most of the width of the trapdoor base.

Sclerotomy incision was 1mm clear of either side of sclera flap. After the initial linear incision into anterior chamber sclerotomy is fashioned with sclera punch. A fistula 0.5mm to 1mm in height and 1.5 to 2mm in width created. Peripheral iridectomy was created. Superficial scleral flap was sutured to its underlying bed tightly with Apex sutures, using nylon 10-0 suture. Balanced salt solution was injected through the paracentesis to deepen the anterior chamber and test the patency of the fistula. Conjunctiva/Tenon capsule flap was sutured. Irrigation through the paracentesis was repeated to produce a bleb. Steroid and antibiotic was injected under the inferior conjunctiva. Postoperative analysis of IOP and RNFL were done at 1 week, 1 and 3 month respectively. All data was collected on data forms.

III. STATISTICAL ANALYSIS:

Data collected during the study was tabulated and analyzed by using Repeated Measure ANOVA with Bonferroni correction. The probability value ('p'-value) was calculated and a value of <0.05 was implied to be statistically significant.

IV. RESULT:

The number of patients in age group 40-50 years were 7, 51-60 year age group had 9 patients, 61-70 year age group showed 9 patients whereas 71-80 age group had 2 patients. The mean age was found to be 57.9 years. . Out of the total study group 18 were male members which contributed to a total of 66.7% of the total study group. Out of 27 individuals 9 were females who composed about 33.3% of the total study group.

The Mean IOP in the pre-operative period was found to be 26.93 ± 2.786. There was a decrease in the post-operative first week and the Mean was observed to be 9.07± 3.43 ($p < 0.05$). In the first month of the post operative period was to be 11.41± 4.254 ($p < 0.05$). In the third month of the observation period the Mean was observed 11.81± 3.552 ($p < 0.05$). Disc Area was analyzed pre-operatively and the mean was observed to be equal to 2.5493 ± 0.34513. The Disc Area post-operatively at 1 week was found 2.6181 ± 0.39821 (p=1.000). At one month the Mean Disc Area was found to be 2.7281 ±.45585 (p=0.259). The Mean Disc Area at the third month post-operatively was 2.6307 ± 0.60255 (p=1.000).

The reading for the Rim Area was taken 1 week post operatively it was observed that the mean values was 0.587 ± 0.26172 (p=0.124). The Rim Area was then observed in the follow-up period of 1 month post operatively in this period it was seen that the mean value is 0.6452 ± 0.25913 (p=.044). Mean Rim Area in the 3 month post operatively of follow up period was observed to be 0.6707 ± 0.29319 (p=.008). The Mean value of Rim Volume Pre-Operatively was found to be 0.0463 ± 0.01904. The Mean Rim Volume Post Operatively at 1 week was 0.0541 ± 0.02438 (p= 0.039). The Mean value of the Rim Volume Post Operatively at 1 month was at 0.0630 ± 0.02383 (p=0.000). The Mean value of the Rim Volume at 3 month came to be 0.0630 ± 0.03361 (p=0.036). The pre-operative Cup Area was observed to be 2.064±0.5043. The mean Cup area during the first week of post-operative period came to be 1.996±0.5082 (p=0.951). The Cup Area observed during the first month of the follow-up was 2.029±0.5336 (p=1.000). During the third month of the follow-up the Mean Cup Area was observed to be 1.9393±0.58619 (p=0.027). The Mean Cup Volume Pre-Op was observed to be 0.6981 ± 0.33874. The Mean Cup Volume 1 week Post-op was found to be 0.6515 ± 0.32375 (p=0.003). The Mean of Cup Volume at 1 month was found to be 0.617 ± 0.31518 (p=0.001). The Mean Cup Volume at 3 month Post-op was observed to be 0.5933 ± 0.31274 (p= 0.000).

The cup area and disc area were analyzed to find the ratio between the both. It was observed that the C/D Ratio in patients during the pre-operative period came out to be 0.7896 ±0.7004. In the first week post operatively it was observed that the C/D Ratio came to be equal to 0.7563 ± 0.13342 (p=0.021). During the first month observational period it came equal to 0.73 ±0.1321 (p=0.020). In third month the C/D Ratio came to be 0.7004 ±0.18039 (p=0.000).

Mean value of Inferior Quadrant came to be equal to 63.3 ± 8.978. The Mean values of inferior quadrant observed at 1 week post operatively came to be 69.48 ± 9.002 (p= 0.000). The consecutive period of observation was at 1 month in which the Mean value of Inferior Quadrant came to be 68.93 ± 11.19 (p = 0.096). The final readings of the Inferior Quadrant were observed to be equal to 66.67 ± 9.919 (p=0.144).

V. DISCUSSION

Detection of optic nerve head and retinal nerve fiber layer damage is, crucial for the early diagnosis and management of glaucoma.[8]

Hence one of the main reasons for a perceptible improvement in optic nerve appearance with IOP reduction is a reduction in the posterior bowing of the lamina cribrosa, giving relief to the compressed nerve fibre bundles. Similarly increase

in RNFL thickness postoperatively is the reversal or rebound of the physical compressive effect on the RNFL by the elevated pre intervention IOP, leading to a recovery of normal shape and size by the retinal ganglion cell axons. [5, 6, 7, 8, 12, 14.]

In our study IOP decreased from 26.93 ± 2.786 mm Hg pre-operatively to 9.07 ± 3.43 mm Hg ($p < 0.05$) at one week Post-operatively. IOP then reduced to 11.41 ± 4.254mm Hg ($p < 0.05$) at one month to 11.81 ± 3.552mm Hg ($p < 0.05$) at third month respectively after Trabeculectomy. This corresponds to reduction of IOP to about 33.7% at one week and 42.3% and 43.8% at one month and third month respectively as compared to pre-operative IOP. The reduction in IOP was statistically significant in all post operative follow-up period.

Similar results were also observed by Figus et al (2011) they studied that IOP decreased at 3 and 6 months after trabeculectomy; this corresponded to a reduction of 48 ± 18% at 3 months and of 54 ± 20% at 6 months [15]. Bertrand et al (2014) observed in his study that trabeculectomy resulting in at least 36% reduction in IOP and was effective in considerably reducing the rates of change in the visual field in his study population [19]. Yildirim[17], Sarkar [8], Kotecha[12], Lazaro [18] Raghu[5] appear to support the idea that pressure reduction in glaucoma patients invariably prevents the long-term progression of visual field defects.

Mean Rim value at 1 month was 0.6452 ± 0.25913 (p=.044). Mean Rim Area at 3rd month post operatively of was 0.6707 ± 0.29319 (p=.008). The Rim area showed statistically significant improvement at 1st month and 3rd month post operatively. The Rim Area showed improvement in the follow-up period though significant improvement was observed at 1 month and 3rd month post-operatively. Similarly Rim Volume was analyzed and showed significant improvement during the follow-up period after Trabeculectomy. Similar results were observed by Figus et al (2011) he observed that borderline ONH changes and negligible functional changes were found. The lack of an absolute structure–function correlation may be due to the different levels of measurement noise displayed by the devices used to detect change, and it has been suggested that structural and functional methods can be considered as independent indicators of glaucoma damage. Irak et al (1996) observed that mean rim area and rim volume increased significantly after trabeculectomy.

In our study Cup Area pre-operative value within 1 week was 2.064±0.5043. The mean at first week post-operative period was 1.996±0.5082 (p=0.951). The Mean value at first month was 2.029±0.5336 (p=1.000). At third month the Mean Cup Area was observed to be 1.9393±0.58619 (p=0.027). Cup Area showed significant improvement at 3rd month post-operatively. Cup Area decreased during the post-operative follow-up period but statistical significance was observed at third month.

In the present study cup area and disc area were analyzed to find the ratio between them. The C/D ratio decreased significantly after surgery during the follow-up period. Previous studies done showed similar results, Irak et al (1996) defines Mean cup area, cup volume, and cup/disc area ratio decreased significantly after surgery. In adult patients, reversal of glaucomatous optic disc cupping is not generally recognized in clinical practice. However, reports have noted evidence of optic disc cup reversibility after intraocular pressure reduction in some adult patients using a variety of diagnostic methods including qualitative evaluation of stereo-photographs and quantitative assessment using photogrammetric or computer video-graphic imaging methods. Similar study was done by Raghu et al (2012) in his study Among the ONH parameters he observed that the cup area decreased significantly[5]. Figus et al (2011) studied borderline ONH changes. He also adds that, ONH changes are usually short-lived and one would not expect them to be present at 3 and 6 months [15]. Paranhos et al (2006) studied ΔIOP and ΔIOP% had a statistically significant effect on Δ cup disk area, Δ cup volume and Δ mean cup depth. Changes in cup shape size were influenced significantly only by ΔIOP. Some optic disc parameters measured by HRT presented a significant improvement after filtering surgery, depending on the amount of IOP reduction. Long-term studies are needed to determine the usefulness of these findings as outcome measures in the management of glaucoma [13].

RETINAL NERVE FIBRE LAYER:

The Retinal Nerve Fiber Analyzer designed for the objective and quantitative in vivo relative measurement of RNFL thickness [16]. A possible explanation suggested for the immediate increase in RNFL thickness postoperatively is the reversal or rebound of the physical compressive effect on the RNFL by the elevated pre intervention IOP, leading to a recovery of normal shape and size by the retinal ganglion cell axons. Another explanation that has been postulated may be retinal swelling from acute postoperative reduction in IOP [5].

In the present study all the four quadrants were analyzed, differences between normal and

Glaucomatous eye has been well documented. The changes in four quadrants Inferior, Superior, Nasal and Temporal were analyzed. Inferior Quadrant of RNFL pre-op Mean value was 63.3 ± 8.978, 1 week post operatively was 69.48 ± 9.002 (p= 0.000), 1 month the Mean value of Inferior Quadrant was 68.93 ± 11.19 (p = 0.096) and at 3rd month reading of Inferior Quadrant was66.67 ± 9.919 (p=0.144). Hence Inferior quadrant thickness showed significant improvement in the first week post operatively, but were tending to pre-operative values in the 1 month and 3rd month of follow-up. Similar results were observed by N Raghu et al (2012) in their study the RNFL parameters, average and inferior and temporal quadrant RNFL thickness measurements increased significantly at 1 week after surgery, but reverted to baseline levels at the subsequent follow-up visits. Aydin et al (2003) in his study found a significant increase in the peripapillary NFL thickness, as determined by OCT, after glaucoma filtration surgery.

VI. CONCLUSION:

Thus we conclude that the Trabeculectomy help to reduce intra-occular pressure post-operatively in POAG. While IOP is a major risk factor for glaucoma and IOP-lowering is the only proven treatment for the disease. Visual acuity deterioration was withheld or slightly improved in our study. RNFL thinning and ONH parameters corroborate that there was improvement in the RNFL thickness. Inferior Quadrant showed significant improvement in early post-operative period which started coming towards pre-operative value in subsequent follow up period. Thus data needs to be collected and analyzed for long term effects of Trabeculectomy.

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Conflicts Of Interest
There are no conflicts of interest.

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