

Six-year incidence of ocular hypertension in a South Indian population: the Chennai eye disease incidence study

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ABSTRACT

Aims To report the 6-year incidence and risk factors for ocular hypertension (OHT) in a population-based study in southern India.

Methods 6 years after baseline evaluation, 56.9% subjects (participants:non-participants, 4421:3353) were re-examined at the base hospital. Incident OHT was defined as an intraocular pressure above the 97.5th centile for the population with no evidence of glaucoma in the 2852 phakic subjects, 40 years or older. Subjects with trauma, laser or incisional surgery at baseline or follow-up were excluded (total exclusions: 1569).

Results Incidence of OHT at 6 years was 62/2852 subjects (2.17% (95% CI 1.64% to 2.71%, men: women, 36:26)). Incidence was higher in the rural cohort as compared with the urban cohort (80.6% vs 19.4%, $p < 0.001$). A higher baseline intraocular pressure (with increasing OR: 16–18 mm Hg (OR 4.0, 95% CI 2.1 to 7.9), 19–21 mm Hg (OR 11.4, 95% CI 5.7 to 22.9), 22–24 mm Hg (OR 42.6, 95% CI 11.0 to 164.8, in the urban cohort)) and increasing age (50–59 years (OR 1.9, 95% CI 1.1 to 3.3), 70 years and above (OR 3.6, 95% CI 1.2 to 10.6)) were significantly associated risk factors for incident OHT.

Conclusions A significant proportion of this normal population converted to OHT. A higher incidence of conversion was seen in the rural population.

INTRODUCTION

Glaucoma is the second leading cause of blindness in the world.¹ Intraocular pressure (IOP) remains the only modifiable risk factor for glaucoma.^{2–7} A raised IOP, however, may present without an evident optic disc or visual field damage. The distribution of IOP and prevalence of ocular hypertension (OHT) has been reported^{8–9} but the incidence rates and risk factors are still not well known.^{7–10–11} We report the 6-year incidence and risk factors for OHT from a population based cohort in South India.

MATERIALS AND METHODS

The base hospital in Chennai city (southern India) constituted the urban cohort. The rural population comprised 32 contiguous villages about 65 km from base hospital.¹²

Participants were first examined during the Chennai Glaucoma Study (CGS, 2001–2004).¹² The surviving participants were invited for a repeat examination at the same clinical facility for the

Chennai Eye Diseases Incidence Study (CEDIS, 2007–2010) 6 years after the baseline examination. The study was approved by the institutional ethics review board and conformed to the tenets of Declaration of Helsinki for research involving human subjects. Examination included best corrected visual acuity using logMAR 4 m chart (Light House Low Vision Products, New York, USA), central corneal thickness (CCT) measurement using the ultrasonic pachymeter (DGH 550, DGH Technology, Exton, Pennsylvania, USA), slit lamp biomicroscopy, Goldmann applanation tonometry (Zeiss AT 030 Applanation Tonometer, Carl Zeiss, Jena, Germany), gonioscopy using a four mirror Sussmann lens (Volk Optical, Mentor, Ohio, USA), grading of lens opacities by LOCS II (lens opacification classification system) and LOCS III, dilated retinal examination using +20D lens and binocular indirect ophthalmoscope and stereoscopic optic disc examination using +90D lens at slit lamp in addition to optic disc photography (Zeiss FF450-plus fundus camera (Carl Zeiss, Jena, Germany) with VISUPAC digital image archiving system). One stereo pair of 20° optic disc photographs was taken for each eye. Clinical evaluations including applanation tonometry, slit lamp evaluation, gonioscopy and optic disc and retinal evaluation were carried out by fellowship trained glaucoma specialists.

Applanation tonometry was performed after anaesthetising the cornea with proparacaine eye-drops (Sunways India, Mumbai, India) and the mean of two measurements were taken from each eye. If the IOP differed by more than 2 mm Hg, a third reading was taken and the median of the three readings was used for analysis.

Automated perimetry was done for all subjects with best corrected visual acuity $> 4/16$ who underwent C-20-1 screening frequency doubling perimetry (FDP; Carl Zeiss Meditec, Dublin, California, USA).¹² A reliable test was taken as no false positive or fixation errors and a test was defined as normal if there were no depressed points at any level of sensitivity.

Questionnaires for socioeconomic status, demographics and personal history (smoking, smokeless tobacco, alcohol) were administered during the study.

In the CGS (baseline prevalence study), data from 2532 normal subjects in the urban cohort and 1810 normal subjects in the rural cohort with a normal



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and reliable suprathreshold FDP was taken for estimating the 97.5th centiles for IOP. These were 24 mm Hg and 21 mm Hg for the urban and rural populations, respectively.^{13 14}

Incident OHT was diagnosed in a phakic eye with open angles on gonioscopy if either eye of a participant had an IOP greater than the 97.5th centile for the cohort with no evidence of glaucoma at the 6-year follow-up. All subjects had normal and reliable FDP at baseline and follow-up examinations. If threshold visual fields using the Swedish interactive threshold algorithm standard 24-2 programme (model 750, Carl Zeiss Meditec) were not available or were unreliable, incident OHT was diagnosed if the optic disc findings were stable compared with the baseline visit, and suprathreshold FDP was normal and reliable.

An occludable angle was defined as one in which more than 180° of the posterior trabecular meshwork was not visible in dim illumination. Body mass index (BMI) was defined as weight in kilograms divided by the square of height in metres (kg/m²) and was grouped as underweight (<18.5 kg/m²), normal (18.5–25 kg/m²), overweight (>25.0 kg/m²) or obese (≥30.0 kg/m²).¹⁵ Diabetes mellitus was diagnosed on current use of antidiabetic medications or a random blood sugar level above 200 mg/dL. Hypertension was defined as current use of antihypertensive medications or a systolic blood pressure (BP) ≥140 and/or diastolic BP ≥90 mm Hg.

We included bilateral normal phakic subjects with open angles aged 40 years and above at baseline with IOP within the physiological range (≤97.5th centile) and excluded subjects with trauma, any evidence of glaucoma or a history of laser or incisional surgery either at baseline or at follow-up. Outcome variables included incident OHT and its associated risk factors.

Data analysis

Statistical analysis was done using SPSS for windows V.15 (SPSS, Chicago, Illinois, USA). Statistical significance was assessed at the $p < 0.05$ level for all parameters. Logistic regression was used to investigate the association of incident OHT with age, gender, BMI, CCT, rural or urban residence, diabetes mellitus and hypertension. Multivariable analysis was done to analyse risk factors for incident OHT after adjusting for age, gender and population (rural or urban).

RESULTS

Seven thousand seven hundred and seventy-four subjects (rural: urban 3924:3850) participated in the CGS at baseline. A total of 6022 (rural: urban 3047:2975) subjects who could be contacted or for whom information was available were re-enumerated for CEDIS. After excluding 590 participants who were deceased in the intervening period, 4421 of the eligible 5432 subjects (81.3%, rural: urban 2510:1911) participated in CEDIS. Reasons for non-participation were: 804 (14.8%) had migrated from their original address without a valid forwarding address, 145 (2.7%) refused and 62 (1.1%) were bedridden or too infirm to come for evaluation. There were significant differences between participants and non-participants. Non-participants ($n=3353$) were significantly older (56.4 years vs 52.8 years; $p < 0.001$). Participants were more likely to have lower IOP ($p=0.001$), thinner CCT ($p=0.19$), be rural residents ($p < 0.001$) and illiterate ($p=0.007$), reflecting the higher contribution (56.8% vs 42.2%) from the rural cohort (table 1).

Inclusion and exclusion criteria were met by 2852 subjects (men: women, 1269:1583; rural: urban, 1601:1251). The mean age of the population studied was 55.2 ± 8.2 years. Reasons for exclusion ($n=1569$ subjects) were: cataract surgery in 1010

(rural:urban, 517:493), evidence of glaucoma or laser peripheral iridotomy/incisional surgery (except for cataract) in 464 and IOP above the statistically normal range (as defined) at baseline in 95 subjects.

Over a period of 6 years, 62 subjects (2.17%, 95% CI 1.63 to 2.71) were diagnosed with incident OHT (rural: urban, 50:12; men: women 36:26). The incidence was higher in the rural cohort as compared with the urban cohort (3.12% vs 0.96%, $p < 0.001$). The age and gender adjusted incidence (for the Tamil Nadu population) was 2.52% (95% CI 2.50% to 2.54%). The age and gender adjusted incidence in the rural population was 3.43% (95% CI 3.40% to 3.46%) and 1.32% (95% CI 1.30% to 1.34%) in the urban population. Assuming a linear incidence of OHT, the annual incidence was 0.36%. Incident OHT was bilateral in 25 (40.3%) subjects and unilateral in 37 (59.7%) subjects.

Unadjusted OR for incident OHT showed an association of male gender ($p=0.04$), rural residence ($p < 0.001$) and IOP ($p < 0.001$) (table 2).

After adjusting for age, population, gender and using 40–49 years age as reference population, OR for incident OHT at 50–59 years was 1.9 (95% CI 1.1 to 3.3, $p=0.03$), at 60–69 years was 1.1 (95% CI 0.5 to 2.7, $p=0.84$) and at ≥70 years was 3.6 (95% CI 1.2 to 10.6, $p=0.02$). Baseline IOP (per mm Hg) was a risk factor for incident OHT with OR of 1.4 (95% CI 1.3 to 1.6, $p < 0.001$). We further analysed the relationship of baseline IOP and incident OHT by stratifying IOP at baseline into four groups: ≤15 mm Hg, 16–18 mm Hg, 19–21 mm Hg and 22–24 mm Hg. Keeping IOP ≤15 mm Hg as the reference group in combined cohorts, the OR for incident OHT at baseline IOP of 16–18 mm Hg was 4.0 (95% CI 2.1 to 7.9, $p < 0.001$) and at 19–21 mm Hg was 11.4 (95% CI 5.7 to 22.9, $p < 0.001$). For the urban cohort at baseline IOP 22–24 mm Hg, the OR was 42.6 (95% CI 11.0 to 164.8, $p < 0.001$). Figure 1 shows an increasing trend of incident OHT with higher stratified baseline IOP. As shown, the incidence was higher in the rural cohort at all levels of IOPs.

There was no association of incident OHT with gender ($p=0.17$) and CCT ($p=0.12$) (table 3). We found no association of incident OHT with diabetes mellitus (OR 1.6, 95% CI 0.8 to 3.4, $p=0.21$), BMI (keeping normal as reference, underweight (OR 1.1, 95% CI 0.4 to 3.1, $p=0.91$), overweight (OR 1.6, 95% CI 0.6 to 4.0, $p=0.31$), obese (OR 0.7, 95% CI 0.1 to 5.8, $p=0.75$)) and hypertension (OR 1.4, 95% CI 0.8 to 2.4, $p=0.29$; adjusted for baseline IOP).

DISCUSSION

The age and gender adjusted (for the Tamil Nadu population) incidence of OHT was 2.52% with rural residence, older age and higher baseline IOP as associated risk factors. To the best of our knowledge, the present study reports the incident OHT for the first time from this region. Differences in reported normal IOP or OHT across studies may be influenced by associated risk factors, study methodology, racial differences or differences in CCT.¹⁶

The 'Los Angeles Latino Eye Study' (LALES) reported the 4-year incidence rates of OHT in Latinos from California aged 40 years and above at baseline.¹⁰ The Barbados Incidence of Eye Diseases (BISED I 1992–1997; BISED II 1997–2003), on a predominant African-origin population aged 40–84 years, reported 4-year and 9-year IOP changes.^{11 16 17} The Beaver Dam Eye Study (BDES), on a Caucasian population reported 5-year IOP changes in subjects aged 43–86 years (table 4).⁷

The reported incidence of OHT in LALES was 3.5% (95% CI 2.9% to 4.1%) at 4 years.¹⁰ The IOP increased by 2.5

Table 1 Baseline differences between participants and non-participants in the Chennai Eye Disease Incidence Study along with baseline and follow-up characteristics of the population studied for incident ocular hypertension

Parameter studied	Participants (N=4421)	Non-participants (N=3353)	p Value	Complete cohort (N=7774)	Population studied (N=2852)		p Value (baseline vs 6 years)
					Baseline	Follow-up at 6 years	
Age (years)*	52.8±9.7	56.4±11.3	<0.001	54.3±10.6	49.5±8.2	55.2±8.2	<0.001
Male: Female	1972:2449	1500:1853	0.91	3472 (45.7%): 4302 (53.4%)	1269 (44.5%): 1583 (55.5%)		
Rural: Urban	2510:1911	1414:1939	<0.001	3924 (50.5%): 3850 (49.5%)	1601 (56.1%): 1251 (43.9%)		
IOP (mm Hg)*	15.2±4.3	15.5±4.4	0.001	15.3±4.3	14.7±3.2	14.1±3.5	<0.001
CCT*	510.4±34.9	511.4±37.1	0.19	510.8±35.9	508.9±45.3	509.1±88.5	0.91†
VCDR*	0.42±0.2	0.44±0.2	<0.001	0.4±0.2	0.4±0.2	0.4±0.2	<0.001
Literate vs illiterate	2705:1716	2152:1201	0.007	4857:2917	1828:1024		
BMI‡							
Normal	1179	1088	0.41	2267	775	1335	<0.001
Lean	276	293		569	169	454	
Overweight	637	603		1240	435	615	
Obese	234	205		439	160	201	

*Mean±SD.

‡BMI values not available for all subjects.

BMI, body mass index; CCT, central corneal thickness; IOP, intraocular pressure; VCDR, vertical cup-to-disc ratio.

±3.9 mm Hg in BIASED I.^{11 16} Using the 80th centile (21 mm Hg) values, incidence was 12.9% (95% CI 11.7% to 14.3%) and ranged from 1.5% to 11% for other criteria.¹¹ In BIASED II, IOP decreased by 0.4±4.0 mm Hg; this was explained based on selective mortality in subjects with diabetes or hypertension.¹⁷ Besides, 6.5% of subjects with IOP 21 mm Hg or below at baseline had an elevated IOP of more than 21 mm Hg.¹⁷ These differences may arise due to differing population groups and methodology and differing interplay of factors over a period of time. If the same criterion of IOP above 21 mm Hg was considered as incident OHT in our study sample, an additional 10 subjects would be classified as OHT and the incidence rates for OHT would be 2.52% (72/2852, rural:urban, 69%:31%).

Increasing age was noted to be a consistent risk factor in our study similar to LALES and BIASED.^{10 11 17} We found the odds for incident OHT at 50–59 years to be nearly double (p=0.03) and ≥70 years to be 3.5 times (p=0.02) with 40–49 years as reference. In BIASED I, an increasing trend of IOP >21 mm Hg with age was seen and in BIASED II an increase of IOP at 50–59 years (0.1±3.6 mm Hg) and a decrease of IOP (–0.6

±4.2 mm Hg) at ≥70 years was noted.^{11 17} An increased incidence (15 times) in subjects 80 years and above as compared with 40–49 years was noted in LALES.¹⁰ Similar results were obtained from a large Japanese longitudinal study in men and women.¹⁸

Gender was not associated with incident OHT in our study, similar to most other incidence studies.^{7 10 11} In BIASED II, however, men were found to have a larger (p=0.04) mean increase in IOP (0.52 mm Hg) than women (0.21 mm Hg).¹⁷ These differences may be due to an actual higher risk of raised IOP in men or due to selective losses to follow-up.¹⁷ As expected, a higher baseline IOP was noted as a risk factor for incident OHT in our study. This risk increased proportionately with increasing levels of IOP with the odds increasing from 4 to above 40. BIASED I showed a positive association of all levels of baseline IOP to incidence of raised IOP.¹¹ No association with CCT was noted in our study as in BIASED I.¹¹

Table 2 Risk factors (unadjusted) for incident ocular hypertension (OHT)

Risk factors (n=2852)	Incident OHT (n=62)	No OHT (n=2790)	p Value
Age (years)*	51.2±9.2	49.4±8.2	0.09
Gender (men:women)	36:26	1225:1559	0.04
Rural:Urban	50:12	1551:1239	<0.001
Intraocular pressure* (mm Hg)	17.5±3.1	14.7±3.2	<0.001
	16.7±2.8 (Rural)	13.8±2.9 (Rural)	<0.001
	20.7±2.3 (Urban)	15.8±3.2 (Urban)	<0.001

*Mean±SD.

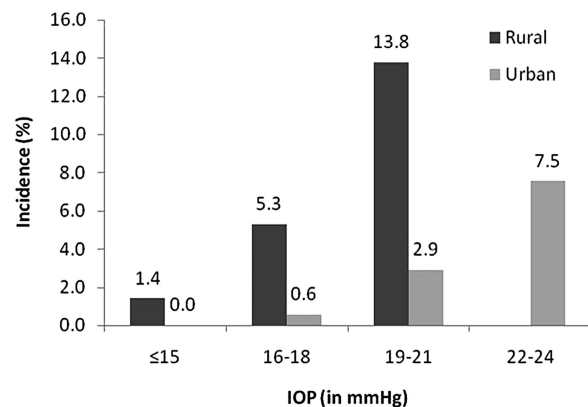
**Figure 1** Relationship between baseline intraocular pressure (IOP) and risk of developing incident ocular hypertension (as a percentage) for rural and urban cohorts.

Table 3 Risk factors (adjusted) for 6-year incident ocular hypertension

Risk factors	Number of subjects	Adjusted OR* (95% CI)	p Value
Age			
40–49 years	1653	1.0	
50–59 years	801	1.9 (1.1 to 3.3)	0.03
60–69 years	344	1.1 (0.5 to 2.7)	0.84
≥70 years	74	3.6 (1.2 to 10.6)	0.02
Gender			
Male	1269	1.0	0.17
Female	1583	0.7 (0.4 to 1.2)	
Cohort			
Urban	1601	1.0	<0.001
Rural	1251	4.4 (2.3 to 8.6)	
CCT (40 μ increase)	2852	1.3 (0.93 to 1.81)	0.12
IOP at baseline†			
≤15 mm Hg	1768	1.0	
16–18 mm Hg	716	4.0 (2.1 to 7.9)	<0.001
19–21 mm Hg	315	11.4 (5.7 to 22.9)	<0.001
22–24 mm Hg	53	42.6 (11.0 to 164.8)	<0.001

*Adjusted for age, population and gender.

†IOP at baseline also adjusted for CCT.

CCT, central corneal thickness; IOP, intraocular pressure.

Diabetes was not found to be an associated risk factor in this study. It was noted to be a risk factor for higher IOP change in BDES and BISED I and BISED II.^{7 11 16–17} The mechanism by which diabetes potentially influences IOP remains complex and associated autonomic neuropathy may play a role in IOP change with diabetes.¹⁷

No association with hypertension was noted in our study. In contrast, BDES had a positive association with hypertension at 5 years (0.21 mm Hg and 0.43 mm Hg increase in IOP for a 10 mm Hg increase in systolic or diastolic BP, respectively).⁷ Subjects on antihypertensive medications at baseline were at risk of raised IOP and raised BP at follow-up.⁷ BISED I and II showed positive associations with systolic and diastolic BP.^{11 16 17} Overall, 22% (244 of 1088) subjects with systemic hypertension in our study were on medications for BP control

at baseline (rural: urban, 13% (49/380): 28% (195/708). Hypertension showed an association prior to adjustment in our cohort, but failed to be so after adjusting for baseline IOP.

At the 4 year follow-up and the 9 year follow-up, BISED showed no association of BMI with IOP changes which is similar to our results but in contrast with two large Japanese studies which showed a positive association.^{11 16–19} Possible explanations on differences in ethnicity and/or baseline differences in BMI between subject groups could account for observed effects.¹⁶

Interestingly, there was an increased incidence in the rural cohort which was nearly four times that of the urban cohort (table 4) within the same geographical region. These differences may have arisen due to baseline differences in disease pattern, age (urban being 1 year older; 54.8 years vs 53.8 years), CCT or systemic diseases.²⁰ The mean vertical cup-to-disc ratios at follow-up were 0.38 ± 0.18 for normal subjects and 0.45 ± 0.22 for subjects with incident OHT. Exclusions due to cataract surgery were more likely in urban subjects at baseline (rural: urban, 157:323) and in rural subjects at follow-up (rural:urban, 360:170). This may cause an underestimation of the observed rural-urban differences and may secondarily reflect better access to healthcare for the rural population in intervening period.

We defined subjects as normal or ocular hypertensive at baseline and follow-up based on centile values for normal subjects with normal and reliable suprathereshold FDP in the CGS.¹² This approach appears more feasible as it is based on IOP distribution rather than on an arbitrarily fixed value.

Raised IOP is the only modifiable risk factor for glaucoma.^{2–7} The association with increasing age is similar to that seen for prevalent and incident primary open angle glaucoma (POAG). It is possible that some of those with incident OHT could convert to POAG over time. This could help identify subjects needing relatively closer follow-up.

We confined our data to phakic subjects at baseline and at follow-up to avoid interplay of other confounding factors. This may influence true incidence as some excluded subjects may have converted to OHT at follow-up.

Other potential limitations include the fact that single visit IOP recordings were available. Besides, the nature of chronic diseases with a protracted course and consequently requiring a longer follow-up is still unknown. There may be differences in

Table 4 Incidence of ocular hypertension (OHT) or raised intraocular pressure (IOP) as reported in other studies

Study details (Baseline) (Follow-up)	Age at baseline	Follow-up (years)	Number of subjects studied	Incidence of OHT or raised IOP (as defined)
Los Angeles Latino Eye Study (LALES) ¹⁰ (2000–2003) (2004–2008)	≥40 years	4	3939	3.5% (95% CI 2.9% to 4.1%)*
Barbados Incidence Study of Eye Diseases (BISED I) ¹¹ (1987–1992) (1992–1997)	40–84 years	4	2495	12.9% (95% CI 11.7% to 14.3%)+ +2.5±3.9 mm Hg (average increase in IOP)
BISED II ¹⁷ (1987–1992) (1997–2003)	40–84 years	9	2298	–0.4±4.0 mm Hg (average decrease in IOP)
Current study (2001–2004) (2007–2010)	≥40 years	6	2852	2.17% (95% CI 1.63% to 2.71%)

*Defined incident OHT as IOP >21 mm Hg (or ≤21 mm Hg if on medications or had IOP lowering laser or incisional surgery in that eye) with no optic disc or visual field changes suggestive of glaucoma.

†Using 80th centile (21 mm Hg) values.

evaluating the reasons for an IOP change over a short-term period and a long-term period. These may partly be affected by participation rates which in turn may be affected by systemic illnesses. Non-participants in our study were more likely to have diabetes and hypertension, similar to other studies;^{10 11 17} this may affect true incidence due to the reported association with long-term changes in IOL.¹⁰ Thus, a significant proportion of the normal population converted to OHT at 6 years. Higher baseline IOP and increasing age were associated risk factors with an increased incidence noted in the rural population.

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