· Investigation ·

Childhood amblyopia in a tertiary eye care center in western India

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Abstract
● **AIM:** To describe the demographics, clinical characteristics and treatment outcomes of childhood amblyopia in a tertiary eye center in western India.
● **METHODS:** This was a retrospective longitudinal hospital-based study of 1382 children aged ≤12y included in the National Institute of OphthalMology AmBlyopia StUdy in Indian Paediatric EyeS (NIMBUS) Study. Data on patient demographics, treatment approach, and best-corrected visual acuity (BCVA) changes were reviewed.
● **RESULTS:** The mean age of the study cohort was 4.54±2.46y, with males constituting the majority (55.4%). The cause of amblyopia was refractive error in 73.2%, strabismus in 7.3%, and anisometropia in 6.8% of eyes. The majority of therapies comprised glasses (74.4%), followed by occlusion+glasses (10.3%), occlusion alone (7.3%), and surgery+patching+glasses (5.1%). The mean occlusion time was 2.46±1.14h. After a median follow-up of 10.00 (6–85)mo, the mean BCVA significantly improved from 0.85±0.41 to 0.55±0.42 logMAR. Subgroup analysis revealed BCVA gain for all etiologies, including refractive errors (P<0.001), strabismus (P<0.001), cataract (P<0.001), and ptosis (P<0.001). Additionally, eyes with refractive errors showed significantly better BCVA than eyes with cataracts (P<0.001), strabismus (P<0.001) and marginally better BCVA than eyes with ptosis (P<0.05), both at the baseline and final visit.
● **CONCLUSION:** Refractive errors are the commonest cause of amblyopia, followed by strabismus and anisometropia. Timely detection, optimal therapy, and periodic follow-up are crucial in bettering visual acuity regardless of the cause.
● **KEYWORDS:** amblyopia; refractive error; pediatric; epidemiology; prevalence; pattern; ocular morbidities; western India
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INTRODUCTION
Amblyopia is a condition where in visual acuity is reduced in one or both eyes due to deprivation or abnormal binocular interaction, without any detectable organic cause[1-2]. It is a leading cause of childhood vision impairment due to abnormal cortical development during the early stages of development, with a prevalence of 1%-4% that varies depending on age, geographical region, and screening practices[3-4]. Amblyopia can arise from various conditions that result in a discrepancy in visual acuity between the two eyes[3,5]. And the presence of strabismus and/or anisometropia is responsible for roughly 90 percent of cases of amblyopia[3,5]. A Meta-analysis of 97 studies indicated a global prevalence of amblyopia of 1.36%, involving 4 645 274 children and 7706 patients[3]. Amblyopia can affect the economy and society, as individuals with the condition often face limited career opportunities, lower quality of life, and diminished self-esteem[6-7]. The collation of data pertaining to ocular morbidity in children is of utmost importance for developing nations such as India. Early detection plays a role in achieving better outcomes and instituting treatment on detection is of vital importance[8]. In the first report discussing the epidemiology of pediatric diseases, the authors observed that refractive error, allergic conjunctivitis, and strabismus were the most prevalent conditions contributing to ocular morbidity in this population. In this second study report, the NIMBUS study report 2, we discuss the demographics, clinical characteristics, and treatment outcomes of children with amblyopia[1].

PARTICIPANTS AND METHODS
Ethical Approval The study was conducted according to the

Declaration of Helsinki and was approved by the Institute's Ethics Committee (Approval Number: NIO202002). Written informed consent for the use of patient data for research purposes was obtained from the parents or guardians during the initial visit, prior to the start of the study.

The NIMBUS project was a retrospective longitudinal hospital-based study that was carried out at the outpatient department of a tertiary eye hospital located in western India. The study included all children aged 12y or younger who were diagnosed and treated for amblyopia from January 2016 to December 2019 and having a minimum follow up of 6mo' duration. The participants' ages ranged from as young as 2 to 12 years old. Those with less than 6mo of follow up and non-compliant to the treatment were extracted from the study.

Briefly, a retrospective review and analysis of the patient's electronic medical records was done for the following data extraction: demography, best-corrected visual acuity (BCVA), refractive error, diagnosis, cause of amblyopia, management, including the hours and period of patching. A multidisciplinary team of trained optometrists and a single pediatric ophthalmologist with over 17y of expertise evaluated all children. All of the participants underwent a thorough ocular assessment, which encompassed multiple metrics that included lid evaluation, ocular motility, BCVA (Snellen chart/Kay picture test) with cycloplegic refraction, and anterior and posterior segment evaluation.

Amblyopia was determined by assessing the BCVA, which was at or below 20/40 (logMAR≥0.3), or by evaluating the inter-eye difference, which was two or more lines in accordance with the criteria established by the Pediatric Eye Disease Investigator Group (PEDIG)[9]. The parameters analyzed included the etiology of amblyopia, treatment performed, mean hours of patching, and changes in the BCVA till the final visit. The prescribing guidelines for refractive error correction was full correction of astigmatism, myopia, and anisometropia whereas hyperopia is either fully corrected (*e.g*, in cases of esotropia) or under corrected (*e.g*, in cases without esotropia) by no more than +1.50 D spherical equivalent (SE) as per Amblyopia Treatment Study (ATS)[10]. Patching the amblyopic eye for 2h daily for moderate amblyopia (20/40 to 20/80) and 6h of daily for severe amblyopia (20/100 to 20/400) was done. Patients were followed up every 6 monthly and visual acuity noted. Parents were questioned about the compliance to occlusion and children not following the prescribed schedule of occlusion were extracted from the study. Treatment failure was defined as the inability to achieve a BCVA of 20/40 or better in the amblyopic eye, or a lack of significant improvement of at least two lines on the visual acuity chart, despite a minimum of 12wk of appropriate therapy[11].

The data on categorical variables is shown as *n* (%) and the data on normally distributed continuous variables is presented as mean and standard deviation (SD), for non-normally distributed continuous variables median (min–max) is used. The inter-group statistical comparison of distribution of categorical variables is tested using Chi-Square test or Fisher's exact probability test if more than 20% cells have expected frequency less than 5. The inter-group statistical comparison of means of normally distributed continuous variables is done using analysis of variance (ANOVA) with post-Hoc Bonferroni's post-hoc test for multiple group comparisons. The paired comparison of pre-op and post-op means of normally distributed continuous variables is done using paired *t*-test. The underlying normality assumption was tested before subjecting the study variables to ANOVA and *t*-test. All results are shown in tabular to visualize the statistically significant difference more clearly. In the entire study, the *P*-values less than 0.05 are considered to be statistically significant. The entire data is statistically analyzed using Statistical Package for Social Sciences (SPSS ver 24.0, IBM Corporation, USA) for MS Windows.

RESULTS

Demographics A total of 1590 children were diagnosed with amblyopia. Of these, 208 were excluded, 54 due to non-compliance with treatment and 154 due to inadequate follow-up. A total of 1382 children diagnosed with amblyopia were included in the study. The mean age of participants in the study was 4.54±2.46y. The number of males was marginally greater than the number of females (M:F=55.4:44.6). Patients with refractive errors were significantly older (4.85±2.29y) than those with cataract (3.61±2.96y; P<0.001), ptosis (3.44±3.22y; P<0.001), and strabismus (2.91±2.48y; P<0.001; Table 1).

Etiology of Amblyopia Refractive error was the underlying cause of amblyopia in a significant proportion of the study eyes (73.2%; Table 2). This was followed by strabismus (11.9%), and anisometropia (6.8%; Table 2).

Baseline Visual Acuity The mean BCVA at baseline was 0.85±0.41 logMAR (Table 3). The mean BCVA of eyes with refractive error was significantly better than that of eyes with cataracts (P<0.001), strabismus (P<0.001) and borderline superior than eyes with ptosis (P<0.05; Table 3).

Treatment The most common treatment modality provided to patients was the prescription of glasses, accounting for 74.5% of patients (Table 4). Those children not showing an improvement in their BCVA up to 0.2 logMAR even after 3mo of spectacle wear were prescribed occlusion therapy. Among these, 52% had unilateral amblyopia and were instructed to occlude the sound eye, while 48% had bilateral amblyopia and were advised to follow alternating occlusion, in accordance with the ATS recommended schedule[9]. Children who did not

Table 1 Distribution of demographic characteristics including laterality of amblyopia and duration of patching and duration of treatment according to etiology *n* (%), mean±SD

Etiology	Age (y)	Male/female	Unilateral/bilateral	Hours of patching	Duration of treatment (mo), median (min-max)
Cataract (*n*=69)	3.61±2.96	48 (69.6)/21 (30.4)	18 (26.1)/51 (73.9)	2.44±1.22	9.0 (6-75)
Ptosis (*n*=34)	3.44±3.22	23 (67.6)/11 (32.4)	17 (50.0)/17 (50.0)	2.00±0.00	12.5 (6-67)
Strabismus (*n*=154)	2.91±2.48	60 (39.0)/94 (61.0)	61 (39.6)/93 (60.4)	2.07±1.11	11.0 (6-83)
Refractory error (*n*=1125)	4.85±2.29	634 (56.4)/491 (43.6)	622 (55.3)/503 (44.7)	2.80±1.06	10.0 (6-85)
Total (*n*=1382)	4.54±2.46	765 (55.4)/617 (44.6)	718 (52.0)/664 (48.0)	2.46±1.14	10.0 (6-85)
P					
Cataract *vs* ptosis	0.999	0.999	0.127	0.999	-
Cataract *vs* strabismus	0.252	0.001[c]	0.355	0.999	-
Cataract *vs* refractory error	0.001[c]	0.186	0.001[c]	0.999	-
Ptosis *vs* strabismus	0.999	0.013[a]	0.999	0.999	-
Ptosis *vs* refractory error	0.004[b]	0.999	0.999	0.999	-
Strabismus *vs* refractory error	0.001[c]	0.001[c]	0.001[c]	0.001[c]	-

SD: Standard deviation; *P* for comparing means by ANOVA with post-hoc Bonferroni's test for multiple group comparisons. *P*-value for categorical variables by Chi-square test with post-hoc Bonferroni's test for multiple group comparisons. [a]$P<0.05$, [b]$P<0.01$, [c]$P<0.001$.

Table 2 Distribution of cause of amblyopia *n* (%)

Cause	Cataract (*n*=69)	Ptosis (*n*=34)	Strabismus (*n*=154)	Refractory error (*n*=1125)	Total (*n*=1382)
Stimulus deprived	66 (95.7)	22 (64.7)	0	1 (0.1)	89 (6.4)
Refractive	1 (1.4)	1 (2.9)	0	1009 (89.7)	1011 (73.2)
Stimulus deprived+refractive	2 (2.9)	11 (32.4)	0	0	13 (0.9)
Strabismic	0	0	90 (58.4)	11 (1.0)	101 (7.3)
Anisometropic	0	0	0	94 (8.4)	94 (6.8)
Ametropic	0	0	0	5 (0.4)	5 (0.4)
Refractive+strabismic	0	0	64 (41.6)	5 (0.4)	69 (5.0)

have the refractive error but were amblyopic were advised only occlusion. The mean duration for occlusion was found to be 2.46±1.14h. After the commencement of the treatment, the median duration of follow-up for the patients was 10.00 (6-85)mo and the mean age of starting treatment was 4.54±2.46y. Mean duration of patching was 18mo or till 10y of age for younger children and children more than 10y were asked to patch at least for a year.

Final Visual Acuity After the treatment, there was a significant improvement in the mean BCVA from 0.85±0.41 to 0.55±0.42 logMAR (Table 3). On subgroup analysis, the improvement in BCVA was noted across all etiologies, including cataract ($P<0.001$), ptosis ($P<0.001$), strabismus ($P<0.001$), and refractive errors ($P<0.001$; Table 3). The mean age at the start of treatment in each group was 3.61±2.96y (cataract), 3.44±3.22y (ptosis), 2.91±2.48y (strabismus), and 4.85±2.29y (refractive errors). In our study, the rates of amblyopia treatment failure observed was 7.4% (102) and the distribution among the groups were as follows: 24.6% (17/69) in the cataract group, 14.7% (5/34) in the ptosis group, 16.2% (25/154) in the strabismus group, and 4.9% (55/1125) in the refractive errors group.

Table 3 Distribution of visual outcome according to etiology mean±SD (logMAR)

Etiology	Pre-op	Post-op	*P* (pre-op *vs* post-op)
Cataract (*n*=69)	1.16±0.55	0.85±0.51	<0.001[c]
Ptosis (*n*=34)	0.84±0.32	0.53±0.31	<0.001[c]
Strabismus (*n*=154)	1.11±0.54	0.79±0.32	<0.001[c]
Refractory Error (*n*=1125)	0.67±0.31	0.33±0.13	<0.001[c]
Total (*n*=1382)	0.85±0.41	0.55±0.42	<0.001[c]
P (inter-group)			
Cataract *vs* ptosis	0.013[a]	0.034[a]	
Cataract *vs* strabismus	0.452	0.591	
Cataract *vs* refractory error	0.001[c]	0.001[c]	
Ptosis *vs* strabismus	0.026[a]	0.027[a]	
Ptosis *vs* refractory error	0.045[a]	0.048[a]	
Strabismus *vs* refractory error	0.001[c]	0.001[c]	

SD: Standard deviation. *P*-value for comparing means by ANOVA with post-hoc Bonferroni's test for multiple group comparisons. *P*-value for comparing pre-op *vs* post-op visual outcome by paired *t* test. [a]$P<0.05$; [c]$P<0.001$.

During the final examination, it was observed that patients with refractive error exhibited significantly better visual acuity

Table 4 Treatment offered according to etiology *n* (%)

Treatments	Cataract (*n*=69)	Ptosis (*n*=34)	Squint (*n*=154)	Refractory error (*n*=1125)	Total (*n*=1382)
Surgery	0	0	20 (13.0)	0	20 (1.4)
Glasses	10 (14.5)	12 (35.3)	20 (13.0)	987 (87.7)	1029 (74.5)
Patching	0	0	100 (64.9)	1 (0.1)	101 (7.3)
Surgery+patching+glasses	51 (73.9)	13 (38.2)	1 (0.6)	5 (0.4)	70 (5.1)
Surgery+glasses	8 (11.6)	4 (11.8)	2 (1.3)	0	14 (1.0)
Glasses+patching	0	0	11 (7.1)	132 (11.6)	143 (10.3)
Observe	0	5 (14.7)	0	0	5 (0.4)

in comparison to patients diagnosed with cataracts ($P<0.001$), strabismus ($P<0.001$) and marginally better than eyes with ptosis ($P<0.05$; Table 3).

DISCUSSION

The NIMBUS study 2 report focuses on the examination of demographic factors, clinical attributes, and treatment efficacy pertaining to paediatric patients diagnosed with amblyopia. A detailed study of 1382 children diagnosed with amblyopia found that the average age at diagnosis was 4.54±2.46y, with refractive errors being the underlying cause of amblyopia in nearly three-quarters of the cases (73.2%), followed by strabismus (7.3%) and anisometropia (6.8%). The patients with cataract, ptosis and strabismus were significantly younger than patients with refractive error. This is probably due to these conditions coming to the attention of the parents and guardian's sooner, leading to patient being brought to the hospital earlier for treatment. Based on the underlying etiology, the patients received a range of treatments, including combination of glasses, patching, and surgery, and were evaluated on a regular 6 monthly schedule. At one year follow up a significant improvement in the BCVA was noted.

The incorporation of amblyopia screening as a component of regular health monitoring for children aged 3 to 5 is extensively advocated in various nations[11]. A study conducted in Eastern India found that the prevalence of amblyopia was 11.4%, significantly higher than the national average reported in other studies[12]. This discrepancy can be explained by factors like variations in screening practices, socioeconomic status, and access to healthcare services. In a randomized longitudinal study of a population, the implementation of regular early screening was found to be associated with a significant reduction of 60% in the prevalence of amblyopia[13]. The aforementioned study also showed that when therapeutic intervention was started before the age of three years, there was a considerable reduction in persistent amblyopia by 70%[11,13]. We found that the average age of patients diagnosed with amblyopia in our study was 4.54±2.46y and improvement was seen in 92.6%. This observation reinforces the need to detect amblyopia, whether by population-based screening or routine clinic-based methods, as it is crucial for early intervention and improved results. This is also in accordance with the Indian Guidelines for Pediatric Vision Screening and Comprehensive Eye Examination, which suggest that an ophthalmologist ought to conduct at least one ocular evaluation for a healthy newborn child within the first three years of birth[14].

The prevalence of refractive amblyopia alone has been reported to range from 45.29% in India to as high as 84% in Singapore, highlighting the need for focused interventions[15]. A substantial portion of eyes (73.2%) within our cohort exhibited refractive error as the primary etiology of amblyopia. The next most common conditions were strabismus, which affected 7.3% of eyes followed by anisometropia (6.8%). Our results are more consistent with the data from the Rotterdam Amblyopia screening effectiveness study in which refractive amblyopia was the commonest at 42%, followed by combined-mechanism (30%) amblyopia, and strabismic amblyopia (19%)[16]. Likewise, Ganekal *et al*[17] conducted another epidemiological study in Southern India, observed that ametropia was the most prevalent factor contributing to amblyopia, accounting for 50% of cases. This was followed by anisometropia at 40.9% and strabismus at 6.8%[17]. These findings suggest that refractive amblyopia, combined-mechanism amblyopia, and strabismic amblyopia are the most common types of amblyopia worldwide. The growing incidence of refractive amblyopia emphasizes the significance of early identification and management of refractive errors in order to prevent amblyopia, particularly in lower-middle-income countries (LMICs) such as India. This is very different from the Pediatric Eye Disease Investigator Group (PEDIG) study in which, strabismus and anisometropia each accounted for 40% of cases of moderate amblyopia in 409 children aged 3-6.9y, with the remaining 20% of children having both abnormalities at the same time[6]. The possible reason for this disparity could be attributed to the fact that our study was a hospital-based study being located in an urban area with higher awareness and school referrals.

The primary objective of amblyopia treatment should be to prioritize refractive correction, as this enhances the quality of the retinal image[13]. Moreover, it has been demonstrated that optical correction, when used alone as an intervention, exhibits a resolution rate of amblyopia in roughly 33 percent of previously untreated children after a period of 30wk[18]. As expected, due to a significant proportion of the children exhibiting refractive errors in our study, the most frequently recommended treatment modality was the prescription of corrective eyeglasses. In certain cases, supplementary interventions, such as the use of patches or surgery, may be required in order to attain optimal visual outcomes and enhance binocular capabilities[9]. In our study, we found that around one-fifth of patients were instructed to perform patching with/without glasses. The mean duration of patching of our study cohort was 2.46±1.14h. The correlation between dose and response associated with patching remains uncertain; it is commonly postulated that extended periods of patching may potentially yield greater improvements in visual acuity. However, factors like the severity of the amblyopia, the age at which patching was started, comprehension of the patching method, to name a few, impact the final outcome of amblyopia management. It is important for future research to explore these factors to better understand and improve visual acuity outcomes in patients undergoing amblyopia therapy.

The visual acuity of our cohort improved significantly, regardless of the underlying etiology. These results are encouraging, particularly when considering the noteworthy median follow-up duration of 10.00 (6-85)mo. Furthermore, periodic assessments were conducted to monitor the extent to which children complied with the therapeutic interventions. Compliance with amblyopia therapy has emerged as a critical factor in the success of treatment in recent years and directly impacts visual acuity improvements[19-21]. Factors like parental education and socioeconomic status also influence adherence to treatment protocol[22]. Poor compliance can lead to treatment failure, highlighting the need for strategies like nurse-led counselling[21,23]. Thus, as our results indicate, that with close monitoring and support, parents and children can be encouraged to comply with the therapy, resulting in better treatment outcomes. Having said that, we did not objectively monitor the compliance of patients in our study. However, we relied on self-reported data from both parents and children regarding their adherence to the prescribed therapy. While this method has its limitations, it still provides valuable insights into the overall compliance rates within our study cohort. Future research should consider incorporating objective measures, such as electronic monitoring devices, to provide a more accurate assessment of treatment compliance. Additionally, it is important to acknowledge that self-reported data may be subject to biases and may not fully capture the true extent of adherence to the therapy. Nonetheless, our findings suggest that the encouragement and support provided to parents and children can play a crucial role in promoting compliance.

Some recent advancements in amblyopia treatment include dichoptic training using specialized software[24-25], Active Vision Therapy (AVT) with interactive exercises[26], and Virtual Reality (VR) therapy to promote binocular vision[19,27]. Video game therapy enhances engagement while improving acuity[26,28]. Binocular devices like the Occlu-tab stimulate both eyes simultaneously[29]. Additionally, neuroplasticity-based interventions focus on brain pathways to aid recovery, even in older children and adults[25,30], offering promising alternatives to traditional treatments.

The study's retrospective nature and the possibility of small amounts of data errors resulting from insufficient or missing medical record analysis are its two main limitations. However, despite these limitations, the study still provides valuable insights into the demographics, etiologies, and long-term outcomes of amblyopia management. The retrospective nature allows researchers to analyze a large amount of data and draw conclusions based on real-world patient outcomes. Additionally, while there may be small errors in the medical record analysis, efforts were made to minimize these by ensuring thorough data collection and verification. Therefore, although the study has its limitations, its findings can still contribute to the existing body of knowledge and inform future research and clinical practice.

In conclusion, this second report under the NIMBUS project investigates the influence of demographic variables, clinical characteristics, and treatment effectiveness in pediatric patients diagnosed with amblyopia. The study found that refractive errors were present in 73.2% of eyes, followed by strabismus (7.3%) and anisometropia (6.8%). Patients received treatments such as glasses, patching, and surgery, and after an average follow-up period of roughly a year, they had significant improvements in visual acuity. These findings from one of the largest pediatric ophthalmology epidemiological studies from India accentuates the fact that early detection of amblyopia is essential because it allows for timely intervention and increases the chances of achieving better outcomes. Population-based screening programs can play a significant role in identifying children with amblyopia, ensuring that they receive the necessary treatment at the earliest possible stage. Similarly, routine clinic-based methods, such as regular eye examinations, can also aid in detecting amblyopia and providing appropriate interventions. By implementing these strategies, healthcare professionals can help prevent long-term vision impairment and reduce the burden of amblyopia.

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