Original Article

Burden and Spectrum of Amblyopia in a Pediatric Hospital Population Southwest Nigeria

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Abstract

Background: To determine the prevalence, causes and subtypes of amblyopia among children attending pediatric ophthalmology clinic of Eye Foundation Hospital (EFH) and Deseret Eye Centre (DEC) in Ikeja, Lagos.
Methods: The study was a cross-sectional descriptive study, among newly diagnosed and follow up patients of pediatric age group attending the pediatric ophthalmology clinics of Eye Foundation Hospital (EFH) and Deseret Eye Centre (DEC) in Ikeja, Lagos between 15th of November 2014 and 15th of May 2015. Data on socio-demographics, ocular history and ocular examination was collected. Descriptive and comparative analyses were performed. Values of $p<0.05$ were considered statistically significant. **Findings:** A total of 441 children (355 patients from EFH and 86 from DEC) aged 9.4 ± 3.9SD years (range 3 – 17 years) were interviewed and examined. There were slightly more female children 237 (53.7%) with a male to female ratio of 1:1.2. The prevalence of amblyopia in this study was 12.9%. The most common type of amblyopia was ametropic amblyopia (n=18, 4.1%) followed by anisometric (n=10, 2.3%) and sensory deprivation amblyopia (n=10, 2.3%). Strabismic amblyopia was found to be predominant among children less than 5years (n=5, 8.8%). **Conclusion:** The prevalence rate of amblyopia in this study is high with ametropic amblyopia as the commonest subtype. Early vision screening, diagnosis and treatment will reduce the attendant consequence of socio-economic burden following visual impairment in this vulnerable sub-section of Nigerian populace.

Keywords: Amblyopia; Children; Visual impairment; Nigeria

Introduction

Amblyopia is a common pediatric eye condition with both functional and cosmetic consequences. [1] It is a significant cause of unilateral visual reduction worldwide, [2,3] and usually detected when decreased vision is noticed during vision testing in each eye. Amblyopia almost always affects one eye and the amblyopic person usually has difficulty in fixation and binocular view, as well as seeing objects when crowded. [4,5]

Amblyopia is defined as suboptimal vision in one eye, despite best spectacle correction, in the absence of any other ocular or neural abnormality. [1] Amblyopia occasionally occurs bilaterally due to bilateral visual deprivation [5] such as congenital cataract not treated within the first few months of life. It could also be seen in high and uncorrected refractive error. Lifelong visual impairment can result if early diagnosis and appropriate management is not commenced before the age of 8. [1]

A child is defined as every human being below the age of eighteen years, according to article 1, part 1 of the Convention on the Rights of the Child. [6] Children's right require special protection and call for continuous improvement of the situation of children all over the world, as well as their development and education in conditions of peace and security. [6]

Uncorrected or inadequately corrected refractive errors have been shown to be a major cause of visual impairment. A systematic review of published and unpublished surveys from 2000 to 2010, reported an estimate of 285 million people with visual impairment worldwide, of who 39 million were blind. [7] There are an estimated 1.4 million blind children below the age of 15 years. [7] Globally the prevalence of amblyopia among children and teenagers range from 0.20% to 12%. [1,3,8-18] This is often underestimated due to lack of awareness.

Loss of vision due to amblyopia can be permanent if corrective measures are not instituted promptly. [10,15] Early detection of amblyopia and initiation of treatment is believed to improve visual outcomes for children with amblyopia. [16,19]

There is paucity of disorder- specific data on amblyopia in Nigeria. This study sets out to evaluate the burden, specific causes and subtypes of amblyopia in a Nigerian pediatric ophthalmology clinic. While adding to fledgling literature data, findings will provide evidence-based information that will drive

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policy formulation and implementation by all stake holders to effectively reduce the burden of visual impairment and blindness among this vulnerable sub-section of Nigerian rural populace.

Methods

Study area

Eye Foundation Hospital (EFH), is a tertiary private specialist eye care facility located in Ikeja, Lagos. It also serves as a postgraduate training centre for ophthalmology specialty and sub-specialty approved by both West African College of Surgeons and National Post-graduate Medical College of Nigeria. The hospital has four sub-specialty units; Pediatric ophthalmology and Strabismus, Cornea and Refractive surgery, Glaucoma and Vitreoretinal units. Each unit has two clinic sessions and at least one theatre slot per week, with a functional optometry department and low vision clinic.

Deseret Eye Centre (DEC) is a community/public arm of EFH located in Ikeja, Lagos. It is about one kilometer away from EFH and provides clinical services both primary and secondary for individual that cannot afford services provided at EFH.

Created in 1967, Lagos State is the "commercial capital" of Nigeria. It is located in the southwest geopolitical zone, with diverse socio-cultural groups. It has five administrative divisions; Ikeja, Badagry, Ikorodu, Lagos Island and Epe.

Study design

The study was a cross-sectional descriptive study, among new and follow up patients of age 3 to <18 years, that attended the pediatric ophthalmology clinics of both Eye Foundation Hospital (EFH) and Deseret Eye Centre (DEC) in Ikeja, Lagos carried out between 15th of November 2014 and 15th of May 2015. Consenting patients aged <18 years and >3 years were included in the study. However, patients who were mentally challenged were excluded from the study.

The minimum sample size was estimated using the formula for comparative studies.[20] A power analysis with a 95% confidence level showed that 386 participants were required, and a total of 441 participants were enrolled into the study.

Ethics approval

The Health and Medical Research Ethics Committee of Lagos State University Teaching Hospital(LASUTH) Lagos, Nigeria, approved this study, which was compliant with the 1964 Helsinki Declaration (last revised in 2008). Written informed consent was obtained from the parents, guardian or old enough child prior to examination.

Study

For the purpose of this study amblyopia is defined as difference in the Best Corrected Visual Acuity (BCVA) between the two eyes, of two or more Snellen lines or its equivalent in the absence of any significant organic lesion that could result in a decrease vision or a BCVA of less than 6/12 bilaterally on the Snellen chart or its equivalent in the absence of any significant organic lesion that could result in a decrease in vision. A BCVA of 6/12 to 6/36 in the amblyopic eyes is classified as mild to moderate amblyopia and BCVA ≤6/60 as severe amblyopia.[21]

Strabismic amblyopia is defined as amblyopia in the presence of a heterotropia at distant or near fixation, in the absence of any anisometropia meeting the criteria for a combined mechanism amblyopia or patient with strabismus along with refractive errors of less than 1D spherical equivalent (SE) in one or both eyes with regular astigmatism <1.5D in any meridian.

Anisometropic amblyopia is defined as amblyopia in the presence of anisometropia that is ≥1D SE or ≥1.5D difference in astigmatism between both eyes. Combined amblyopia is heterotropia at distance or near along with anisometropia of 1D or more in SE or >1.5 difference in astigmatism in any meridian between both eyes.

Sensory deprivation amblyopia is those with a known cause of sensory deprivation (media opacity) with no primary heterotropia or refractive errors that could be causally related to the amblyopia.

Ametropic amblyopia:patients with refractive errors >1D SE in both eyes resulting in subnormal vision in one or both eyes and no associated strabismus, anisometropia or any other significant ocular pathology.

Meridional amblyopia is defined as patients with regular astigmatism of 1.5D or more in any meridian or those with irregular astigmatism in both eyes, resulting in a decrease in vision in one or both eyes and no associated strabismus or anisometropia.

A pilot study was carried out in another branch of the hospital in Ogun state, where training of the team member was perfected and the questionnaire used was pre- tested and modified accordingly.

Experimental Procedure

All new and follow up patients seen during the study period, who satisfied the study criteria were recruited into the study. A semi-structured questionnaire was administered to all the patients recruited for this study. The patients or their guardians were allowed to freely fill the questionnaire with the support of the research assistance. The second part of the questionnaire was filled by the researcher and his assistant. The questionnaire was designed in English language, interpretation and explanation were given accordingly.

Assessments of distance visual acuity (VA) in each eye were done separately, using Snellen visual acuity chart, with the aid of aurochart at 3 meters. Aurochart is a self- illuminating, multipurpose visual acuity chart, which incorporates Snellen chart, HOTV chart, Kay picture chart, single optotypes chart and many other features that aid in refraction of the patient. Unaided visual acuity (UAVA) was assessed for every patient and spectacle correction in a known spectacle wearer. Patients with UAVA <6/6 were subjected to pinhole VA evaluation, followed by noncycloplegic autorefraction and subjective refraction. Cycloplegic autorefraction was done on all children

less than 10 years and subjective refraction subsequently to obtain the Best Corrected Visual Acuity (BCVA).

Autorefraction was done using KOWA kw-2000 (KOWA Medicals, Japan). Autorefractometer or streak retinoscopy by neutralization for patients that cannot utilize the autorefractometer. Patients with two or more optotypes lines difference of BCVA between the eyes or BCVA ≤6/12 in both eyes were subjected to single optotypes visual acuity (amblyopic) chart to demonstrate crowding phenomenon. Refractive error was quantified as the spherical equivalent refractive error, which is the algebraic sum of the sphere power and half the cylinder power, measured in dioptre. All patients with BCVA of 6/9 or better in both eyes were classified as normal and treated according to their presenting complaint.

General facial appearance in a well illuminated room and ocular alignment was evaluated with Hirschberg cornea light reflex, cover-uncover test at far (3m) and near (40cm) distances and Krimsky test to quantify the degree of deviation. The extra-ocular motility in all directions of gaze was assessed. Pupillary reactions, both direct and consensual, in a dimly illuminated room and near reflexes were evaluated. The anterior segment examination was done with the aid of Bio-microscopic slit lamp and intra-ocular pressure measurement with the Goldmann applanation tonometer, in cooperative patients.

Pupillary dilation was achieved with the aid of 1.0% cyclopentolate eye drops, two drops 5 minutes apart. The Patient kept both eyes closed for 30 minutes. Full pupillary dilation was attained for cyclorefraction. Dilated fundoscopy using +78D condensing lens with biomicroscopic slit lamp to evaluate the posterior pole and Binocular Indirect Ophthalmoscope with +20D lens was used for peripheral fundus examination.

Statistical analysis

Statistical Package for Social Sciences for windows, version 21 (SPSS Inc, Chicago, Ill, USA) was used for statistical analysis. Quantitative data are expressed as means ± standard deviation (SD). Frequency tables and charts were used for qualitative variables. Test of association was determined by Chi-square test at a level of statistical significance set at p-value <0.05.

Results

There were four hundred and sixty nine children seen in the hospitals during the study period. Thirteen children were not cooperative, 8 parents refused to give consent for the study and 7 children did not complete their examination. Hence data of 441 children (355 patients from EFH and 86 from DEC) interviewed and examined were analyzed accounting for 94.0% response rate. The mean age was 9.4 ± 3.9 years with age range from 3years to 17 years. Majority of the study subjects were within ages five and Nine (n=172, 39.0%). There were slightly more female children 237 (53.7%) enrolled for the study, with a male to female ratio of 1:1.2 but this difference was not statistically significant(X^2 2.468, p-value 0.116.).

Majority of the children were from the Yoruba ethnic group (234, 53.1%). Also most of the children were either in primary school (n=188, 42.6%) or secondary school level (n=186, 42.2%). On assessing the school performance of the subjects, 51 children (11.6%) were reported to have poor academic performance as shown in Table 1.

Table 1: Ethnic and class distribution of the subjects

Variables	No of students	Percentage
	N=441	100
Ethnic group		
Yoruba	234	53.1
Ibo	120	27.2
Edo/delta	51	11.5
Efik	11	2.5
Hausa	10	2.3
Others	15	3.4
Educational level		
Nursery	60	13.6
Primary	188	42.6
Secondary	186	42.2
Tertiary	7	1.6
School performance		
Poor	51	11.6
Average	158	35.8
Good	232	52.6

Ocular history of the subjects

Past history of ocular surgery was observed in 35 children (7.9%) while more than a quarter of the children use spectacle (n=116, 26.3%). Family history of poor vision and use of spectacle was reported in 95 and 269 children respectively. Majority of the parents will allow their children to wear spectacle.

Visual status of the subjects

There was a significant improvement in the visual status of children with visual acuity of 6/6 at presentation and following best correction, in the right eye (34% versus 72.1%, p-value 0.01) and left eye (33.8% Vs 72.1%, p-value 0.015) respectively. However, a few subjects had severe visual impairment and blindness (n=11, 2.5%) despite best correction as shown in Table 2.

Table 2: Presenting and best corrected visual status of the subjects

Variables	Unaided Visual acuity		Best corrected Visual acuity	
	Right Eye N (%)	Left Eye n (%)	Right Eye N (%)	Left Eye n (%)
6/6	150(34.0)	149(33.8)	318(72.1)	318(72.1)
6/9	74 (16.8)	78(17.7)	55(12.5)	49 (11.1)
6/12	47 (10.7)	57(12.9)	17 (3.9)	23 (5.2)
6/18	59 (13.4)	47(10.7)	12 (2.7)	14 (3.2)
6/24	19 (4.3)	26 (5.9)	8 (1.8)	7 (1.6)
6/36	35 (7.9)	28 (6.3)	9 (2.0)	7 (1.6)
6/60	22 (5.0)	19 (4.3)	4 (0.9)	5 (1.1)
3/60	23 (5.2)	24 (5.4)	7 (1.6)	6 (1.4)
HM	4 (0.9)	6 (1.4)	3 (0.7)	5 (1.1)
PL	8 (1.8)	7 (1.6)	8 (1.8)	7 (1.6)
Total	**441 (100.0)**	**441 (100.0)**	**441 (100.0)**	**441(100.0)**

Prevalence of amblyopia

The prevalence of amblyopia in this study was 12.9% (95% confidence interval 10.0 - 16.3).

The adjusted prevalence for age revealed that amblyopia is more common in younger age group with the highest prevalence recorded among children <5 years (23.2%). This pattern of prevalence was statistically significant (p-value 0.001). However, no statistically significant preference for gender in the prevalence of amblyopia was recorded as shown in Table 3.

Types of amblyopia

The most prevalent type of amblyopia was ametropic amblyopia (n=18, 4.1%) and this was followed by anisometric (n=10, 2.3%) and sensory deprivation amblyopia (n=10, 2.3%)

Demography of the amblyopic children

Strabismic amblyopia was found to be predominant among children less than 5years (n=5, 8.8%), while ametropic amblyopia was most common in older age groups. Among the male children with amblyopia, ametropic subtype was the most common (13, 22.8%), [Table 4].

Laterality and severity of amblyopia

In most of the children, the amblyopia was bilateral in 62 eyes of thirty one children (54.4%). Whereas, in 17 children (29.8%) amblyopia was diagnosed in the left eye only and the remaining 9 children (15.8%) had right amblyopia. Majority of the amblyopic eyes (78, 88.6%) had mild to moderate amblyopia and severe amblyopia in the remaining eyes (10, 11.4%).

Crowding phenomenon

Sixty seven (76.1%) eyes, of the amblyopic eyes demonstrated crowding phenomenon, 1 line gained (37, 42%), 2 lines gained (27, 30.7%) and 3 lines gained (3, 3.4%). However, there was no visual improvement to single optotypes in twenty one (23.9%) of the amblyopic eyes.

Refractive status of the Amblyopic eyes

Myopia was mostly found in pupils with ametropic (83.3%) and meridional amblyopia (100%), while hypermetropia was most common in subjects with combined amblyopia (75.0%).

Previous amblyopia treatment

Thirty three children (57.9%) among the amblyopes had previous amblyopia treatment, while the remaining 24 children (42.1%) were newly diagnosed of amblyopia, Table 5.

Discussion

The mean age of our cohort is 9.4 ± 3.9 years. This is similar to the delayed presentation of children to hospital as reported in similar surveys in Low and Medium Income countries (LMICs). [22-24]. Lack of awareness among parents and guardians about timely vision screening for children, may be responsible for the delayed presentation to the hospital. [17]. The critical period of amblyopia establishment is between the age of 7 and 8 years, after which, the treatment of amblyopia become less effective. [25]. This strongly support the need for early screening of pre-school and primary school children for amblyopia, by primary healthcare workers and trained school teachers or personnel. Similarly, the pediatricians and general practitioners could be trained to evaluate visual status of the children in their clinics.

Table 3: Adjusted prevalence of amblyopia for age and gender.

Variables	n	Presence of Amblyopia n(%, 95% confid interval)	p-value
All children			
Crude rate	441	57(12.9, 10.0 to 16.3%)	0.0001
Adjusted rate by age			
<5yrs	56	13(23.2, 18.1 to 30.1%)	
5-9 years	172	28(16.3, 11.2 to 22.8%)	
10-14years	143	16(11.1, 7.9 to 15.1%)	
15-19 years	54	0	0.001
Adjusted prevalence rate by gender			
Male	204	31(15.2, 10.8 to 19.5%)	
Female	237	26(11.0, 9.1 to 15.4%)	0.187

Fishers exact and Pearson's chi-square test for age and gender respectively

Table 4: Demography of the amblyopic children.

Variables	Ametropic	Strabismic	Anisometropic	Sensory	Medridonial	Combined	Total n(%)
Age distribution							
<5years	3	5	1	1	1	2	13(22.8)
5-9 years	10	2	5	7	2	2	28(49.1)
>10 years	5	1	4	2	1	3	16(28.1)
	18(31.6)	**8(14.0)**	**10(17.5)**	**10(17.5)**	**4(7.0)**	**7(12.3)**	**57(100)**
Gender							
Male	13	6	3	5	3	1	31(54.4)
Female	5	2	7	5	1	6	26(45.6)
Academic performance							
Good	5	3	5	4	2	4	23(40.4)
Average	9	3	3	3	0	3	21(36.8)
Poor	4	2	2	3	2	0	13(22.8)

Fishers exact test (Age group) X^2 = 8.215, p-value 0.608; Gender X^2 =10.97 p-value 0.052

Table 5: Previous amblyopia treatment among the amblyopic children.

Amblyopia	Newly diagnosed	Previous Amblyopia Treatment			
		Spectacle	patching	spectacle & patching	atropine
Ametropic	11	6	0	1	0
Anisometropic	4	1	0	5	0
Sensory deprivation*	0	3	2	3	1
Strabismic	3	0	3	2	0
Combined	2	1	1	3	0
Meridional	4	0	0	0	0
	24	11	6	14	**1**

*Two children had surgical intervention alone; ptosis and cataract surgeries. And a child had combination of spectacle correction with atropinization in addition to cataract surgery

These would promote early referral, early diagnosis and treatment at a younger age and prevent amblyopia.

Majority of the subjects in this study were of Yoruba ethnic group followed by Ibo. This may be due to the location of the hospitals where the study was done which is the predominantly Yoruba and Ibo ethnic southern Nigeria. Eighty five percent of our subjects were either in primary or secondary schools most of who the academic performance is within average. This may be due to the age range of the study population, which is the period for basic primary and secondary education in Nigeria.

The prevalence of amblyopia in this study was 12.9% occurring more among children <5 years old. The older the child the lower the prevalence of amblyopia in the various age group. Various similar hospital-based surveys [22,23,26] has reported variable prevalence rates ranging from 1.4% to 9.1%. In contrast, similar but local community-based studies have reported very low prevalence rates ranging from 0.1% to 0.4%. [27-29] The wide inter-survey discrepancies could be attributed to difference in the study setting. Higher prevalence rates are expected in a hospital setting where the cohorts are mostly children with various ocular complaints. However, majority of the available data from community-based surveys are from schools thereby missing a significant number of children who may be out of school due to poverty or ill health. A community-wide population survey is therefore suggested to evaluate the true prevalence rate of amblyopia in Nigeria.

This study also showed that amblyopia was commoner among younger age group with the highest prevalence reported in children less than 5 years of age. There were more males with amblyopia in this study, but not statistically significant. Similar findings were reported by Bhandari et al., [22] Sethi et al., [30] Adhikari and co-worker [31] and Menon et al. [24] However, Woldeyes et al. [23] and Ejimadu et al. [26] reported that amblyopia was commoner among females and older children. Age of presentation has critical implications on treatment outcome of affected children. Although many studies [32,33] have shown that children may respond to treatment at older ages, but treatment may be less effective than it would have been in younger ages. Recent studies have also found that plasticity in the adult visual system is present and different methods are used to induce such plasticity leading to improvement of VA in older amblyopes. [34]

The dominant cause of amblyopia in this study was ametropia followed by anisometropia. Several similar surveys [22,23,31] have noted the dominant role of uncorrected refractive error in the etiology of amblyopia. In a study conducted among 1100 school children of Kathmandu valley in Nepal 8.1% of ocular morbidity was due to refractive error and 12.4% of those with ocular morbidity had already developed amblyopia. [35] In contrast to our study strabismic amblyopia was a most common subtype (37.88%) in a study conducted at referral strabismology practice in India. [36-38] This is a referral facility for strabismus and is therefore expected to have a relatively higher prevalence of strabismic amblyopia compared to studies done in a general pediatric ophthalmology care facility as ours. Majority (63%) of the amblyopic eyes in this study had myopia, especially among children with meridional, ametropic and anisometropic amblyopia. This could be explained by findings from several local surveys [29,37,38] reporting myopia as a dominant subtype of refractive error in this environment. Contrary to our findings, Woldeyes et al., [23] Sethi et al. [30] and Menon et al. [24] reported more hypermetropia among the amblyopic eyes than myopia in their various studies. The observed discrepancies may be due to different socio-economic setting and ethnicity of study populations of various study settings.

The amblyopia resulting from sensory deprivation noticed in this study was comparable to 15% reported in Nepal [22] and relatively higher compared to 13.1% reported in Ethiopia. [23] Improved peri-natal care and early identification and surgical treatment of congenital and developmental cataract and optimal visual rehabilitation is critical to reducing the burden of amblyopia in this sub-section of children.

Twenty four (42.1%) of the amblyopic children had strabismus in this study, 8 (33.3%) children among them have strabismic amblyopia and seven (29.7%) children with combined amblyopia. Though, the prevalence of strabismic amblyopia in this study was 14.0%. This is lower than what was reported in Ethiopia [23] 69.9%, India [24] 62.2% and in Khyber [30] 55%, because in our study the commonest subtype of amblyopia was ametropic unlike strabismic amblyopia in these studies. However, the three studies reported esotropia as the most common form of strabismus and strabismic amblyopia, as reported by this study.

In this study, the amblyopes predominantly (54.4%) had bilateral amblyopia. This is higher than the 12% reported in an Ethiopia [23] study, where only 12% of the amblyopic children had bilateral amblyopia, and unilateral amblyopia involving the right eye in 43.7% and the left eye in 44.3%. The disparity in our findings may be due to increase prevalence of ametropic amblyopia (36.1% vs. 13.7%), which often occur bilaterally,

compared to strabismic amblyopia in Ethiopia (39.3% vs. 14.0%).

Among the amblyopic eyes (78, 88.6%) had mild to moderate amblyopia, while (10, 11.4%) had severe amblyopia. Similar findings were reported by Sethi et al. in Khyber [30]. (87%) mild to moderate amblyopia and severe amblyopia in 13% of the amblyopes. However, more severe amblyopia (57.5%) was reported by Bhandari et al. [22]. The BCVA better than 6/18 was recorded in fourty eyes (45.4%) among the amblyopic eyes, 45% of these were due to ametropic amblyopia. However, Adhikari and co-worker in Nepal, [31]. recorded 68% BCVA of 6/18 or better. The lower value recorded in this study compared to Nepal study is due to difference in visual acuity setting of both studies. In our study, we consider BCVA better than 6/18, while Nepal study use BCVA of 6/18 or better. Seventy five percent of the amblyopic eyes in this study demonstrated crowding phenomenon, by achieving at least one line gain on single optotype snellen visual acuity.

Thirty three children (57.9%) among the amblyopes had previous amblyopia treatment, while the remaining 24 children (42.1%) were newly diagnosed of amblyopia. Similar findings were reported in Nepal by Bhandari et al. [22]. Treatment modalities included spectacle, patching, combination of spectacle and patching and atropine penalization. In addition, cataract, squint and ptosis surgeries were done for those requiring it. The optimal management of these patients therefore required enormous specialized training, equipment and within-specialty collaboration which may be grossly lacking in an underserved LMICs eye care settings.

Limitations

The conclusion drawn from this study is limited by its hospital-based setting since only very few visually normal children come to eye clinic, for routine eye examination. There is also possibility of participants' inaccurate recall of the details of their previous ocular history.

Conclusion

The prevalence of amblyopia in this study is high. Uncorrected refractive error is the dominant cause, which could be avoided simply by detecting and correcting error on time. Lack of knowledge and awareness about amblyopia and its appropriate timely management has been the cause for late presentation and significant visual impairment associated with amblyopia. This study underscores the need for effective implementation of pre-school and school screening along with the awareness programs on the need of early eye checkup for children. Policy making it compulsory for every child to receive basic eye examination before admission to school is suggested. This will help in reducing the prevalence of visual impairment in children due to amblyopia.

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Conflict of interest

All authors disclose that there was no conflict of interest.

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