

Preverbal visual photo screening Project implementation in Portugal

Implementação de projeto de foto rastreio visual pré-verbal em Portugal

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Abstract

Purpose: To present the design and implementation of an amblyopia risk factors screening project, in a large based Portuguese population. Methods: Two referral centers have been enrolled to assess all children aged 2 under their direct referral area. The photoscreener used was $PlusOptix^{\otimes} A09$. At this age, the cut-off defined for referral was: ≥ 1 Diopter (D) of anisometropia, $\geq 1.5D$ of astigmatism, $\geq 2D$ of myopia and $\geq 1.5D$ of hyperopia. The results were reported to a reading platform that allowed the ophthalmologist to see all exams, and provide timely appointment with a complete ophthalmologic assessment for those who needed. Results: A total of 2867 photo screens were made to the population eligible to both referral centers, which comprises a coverage rate of 55%. Out of 2611 children under one of the referral area, 53% (n=1395) adhered to the screening. Within these children, 17.5% (n=245) were referred and 15.3% (n=214) appointments were performed. The comparison of refraction between Plus Optix® and cycloplegic refraction showed a strong correlation regarding the sphere and cylinder values. From the 214 children observed in consultation, glasses were prescribed in 25.7% (n=55), corresponding to 3.9% of all screened children under one of the referral area. This screening method showed a positive predictive value of 58.4%. **Conclusion:** This screening program may be highly relevant to eradicate untreated amblyopia from our population. The results may lead to the implementation of this project to the whole country.

Keywords: Amblyopia/diagnosis; Mass screening; Risk factors; Portugal

RESUMO

Objetivo: Apresentação da implementação de um projeto de rastreio de fatores de risco de ambliopia, numa população alargada portuguesa. Métodos: dois centros de referência foram selecionados para avaliar todas as crianças de 2 anos, na sua área de referenciação direta. Para o foto rastreio foi utilizado o PlusOptix® A09. Nesta idade, os valores definidos para referenciação foram: ≥1 Dioptria (D) de anosimetropia, ≥1.5 D de astigmatismo, ≥2 D de miopia e ≥1.5 D de hipermetropia. Os resultados foram reportados a uma plataforma de leitura que permitiu ao oftalmologista ver todos os exames e providenciar uma consulta oportuna com uma avaliação oftalmológica completa para aqueles que precisavam. Resultados: Foram realizados 2867 foto rastreios na população elegível para ambos os centros de referência, perfazendo uma taxa de cobertura de 55%. Das 2611 crianças sob uma área de referência, 53% (n = 1395) aderiram ao rastreio. Dentro desse grupo, 17,5% (n = 245) foram referenciadas e 15,3% (n = 214) consultas foram realizadas. Verificou-se uma forte correlação entre a refração do PlusOptix® e a refração cicloplégica. Das 214 crianças observadas em consulta, foram prescritos óculos em 25,7% (n = 55), correspondendo a 3,9% de todas as crianças sob uma área de referência. Este método de triagem mostrou um valor preditivo positivo de 58,4%. Conclusão: Este programa de rastreio pode ser altamente relevante para erradicar a ambliopia não tratada na nossa população. Os resultados podem levar à implementação deste projeto em todo o país.

Descritores: Ambliopia/diagnóstico; Programas de rastreamento; Fatores de risco; Portugual

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Introduction

mblyopia is a public health disease as it is the most common cause of monocular vision loss in children. (1) It may occur secondary to a deviated eye (strabismic amblyopia), an unequal need for refractive correction between the eyes (anisometropic amblyopia), a high refractive error in both eyes (ametropic amblyopia) or a media opacity within the visual axis (deprivation amblyopia). (2) Screening for impaired visual acuity, in primary care settings, could identify children with potentially amblyogenic risk factors, at a critical period of visual development, and lead to earlier detection and earlier treatment.

Finding a cost-effective method and the optimum screening intervals to appropriately screen amblyopia is still a matter of debate and study. Conventional visual screening in preverbal children (cover test, refraction, Hirschberg test, Bruckner reflex, etc) can be difficult due to poor collaboration during the exam. Recent studies have suggested the value of very early photo screening and remote auto refraction to detect refractive error and ocular misalignment. (3,4) Although the validity of photo screening varies by technology, screener experience, and the method of interpretation, many studies have demonstrated high positive predictive value for this technique. (5,6)

Some European countries have already implemented preverbal visual screening but there isn't an established screening project in Portugal. We, therefore, show the preliminary results of a pilot project for preverbal photo screening in Portugal, conducted by the Portuguese Ministry of Health, in partnership with the Portuguese Society of Ophthalmology. The results will be audited to become a screening procedure for the general population.

METHODS

The screening started on 18th April 2016 and data have been collected until 31st December 2016. Two referral centers have been enrolled in this prospective study: Centro Hospitalar Universitário do Porto (CHUP) and Centro Hospitalar de São João (CHSJ). They have assessed all children aged 2 under their direct referral area (the target population was estimated on 2611 children for CHUP and 2604 for CHSJ). They were called to the screening project by letters, and the measurements were performed in primary care health centers. This study followed the guidelines of the Declaration of Helsinki and local Institutional Review Board designated by Department of Education, Training and Research (DEFI) indicated that approval was not needed.

The photoscreener used was PlusOptix[®] A09, which was placed at a distance of one meter in front of the patient, in a darkroom, and operated by a trained nurse. The fixation target was designed as a smile face on the camera. Once pressing the start button, the smile face was automatically lighted and a warble sound could be heard to draw the child's attention to the camera. The children were asked to gaze at the nose of the smile face on the camera during the test. Then the camera was moved slightly (within 50 mm) until green circles were evident around both pupils on the monitor screen, which was followed by automatic measurement. The results were displayed on the monitor. The PlusOptix® A09 photoscreener has a spherical and cylindrical range of -7.0 to +5.0 Diopter (D), in increments of 0.25D. If the spherical equivalent (SE) is out of the range, the measurement value only displays "Hyperopia" or "Myopia". Ocular misalignment ≥10° could not be measured binocularly, and was changed to a sequential monocular measurement mode. Each patient was tested twice and the average value was the final result.

At this age, the cut-off defined for referral was: $\geq 1~D$ of anisometropia, $\geq 1.5D$ of astigmatism, $\geq 2D$ of myopia and $\geq 1.5D$ of

hyperopia. All asymmetric eye alignment results were referred too. The results were reported to a reading platform that allowed the ophthalmologist to see all exams, and provide timely appointment with a complete ophthalmologic assessment for those who presented abnormal results. According to this pilot project, normal exams have the indication to repeat screening at age 4.

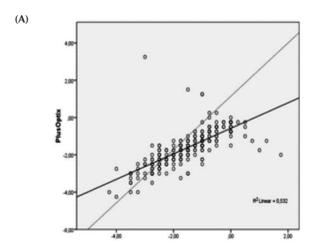
Cycloplegic refraction was performed in every child using cyclopentolate 1% to confirm the photoscreen results.

Statistical analysis was done using SPSS version 17.0. Pearson coefficients were used to correlate refraction values. Significance was set at p<0.05.

RESULTS

A total of 2867 photo screens were made to the population eligible to both referral centers, which comprises a coverage rate of 55%. The median waiting time for screening was 29 days. From the readings performed, 18.2 % (n=431) met criteria for referral and were scheduled an appointment (median waiting time was 44 days).

Regarding the results of CHUP, out of 2611 children under its referral area, 53% (n=1395) adhered to the screening. Within these children, 17.5% (n=245) were referred and 15.3% (n=214) appointments were performed. The mean age of observed children was 28.1 (\pm 2, 2) months and 54.5% were male.



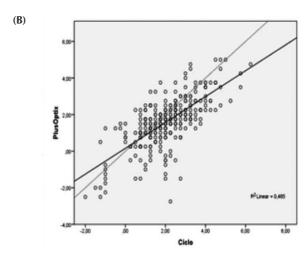
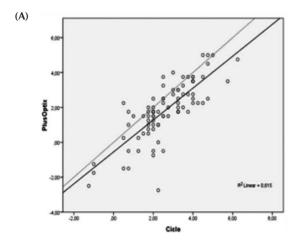


Figure 1: Sphere (A, left) and cylinder (B, right) correlation between PlusOptix and cycloplegic refraction using Pearson correlation. Ciclo denotes cycoloplegic refraction.

In CHUP appointments, refractive errors were found in 80% (n=152) children. Regular astigmatism only was found in 61.2% (n=93), hyperopia with regular astigmatism in 15.9% (n=24), hyperopia in 15.2% (n=23), myopia in 2.6% (n=4), myopia with regular astigmatism in 1.9% (n=3), anisometropia in 1.9% (n=3) and hyperopia with esotropia in 1.3% (n=2). Non refractive disorders were found in 7 children (4 pseudo-strabismus, 1 esotropia, 1 iris nevus and 1 anisocoria).

The comparison of refraction between PlusOptix and cycloplegic refraction showed a strong correlation regarding the sphere values (r=0.485; p<0.001; Figure 1A) and cylinder values (r=0.532; p<0.001; Figure 1B) in the population analyzed. From the 214 children observed in consultation in CHUP, glasses were prescribed in 25.7% (n=55), corresponding to 3.9% of all screened children under CHUP referral area. The distribution of the potential refractive errors was astigmatism in 94.5%, followed by hypermetropia in 81.1% and finally myopia in 12.7%. Anisometropia accounted for 5.4% of these cases.

In the sub-group of children who received glass prescription, a comparison of refraction between PlusOptix and cycloplegic refraction also revealed a strong correlation regarding the sphere values (r=0.615; p<0.001; Figure 2A) and cylinder values (r=0.416; p<0.001; Figure 2B) in the population analyzed.



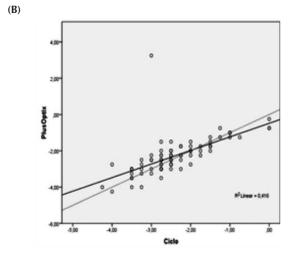


Figure 2: Sphere (A, left) and cylinder (B, right) correlation between PlusOptix and cycloplegic refraction in glass prescription sub-group, using Pearson correlation. Ciclo denotes cycloplegic refraction.

The study shows that this screening method has a positive predictive value of 58.4%. From the 1395 children screened, 64.2% (n=122) will need a follow-up visit, from which some kind of treatment (glass prescription with/without occlusion treatment) was deemed necessary in 36.9% (n=45) of them.

DISCUSSION

The Portuguese National Vision Health Program emphasizes the importance of a timely diagnosis of visual deficits. Concerning preverbal children, this is the first time that an objective visual screening pilot project is implemented in Portugal.

Proponents of widespread community photoscreening have demonstrated high positive predictive value for this technique. (6) Our study shows that there is a strong correlation between PlusOptix® and cycloplegic refraction, with PlusOptix® being able to give similar results to cycloplegic refraction in the group of children who received glass prescription. We also found that the accuracy of the PlusOptix® A 09 is higher in myopic children than hyperopic children and it tends to underestimate higher orders of hyperopia.

Recent population-based studies among younger preschool 6 years old children have reported prevalence rates of amblyopia ranging from 0.8 to 2.6% in their samples. (7-9) In our study, glasses were prescribed in 3.9% of all screened children under CHUP referral area, which might indicate an over prescription attitude.

The positive predictive value was only 58.4%. However, considering that the predictive value depends on population prevalence and that amblyopia and refractive errors are infrequent in 2 years old children, this may explain this low positive predictive value. (10)

After analysis of the first cycle of screening, it was proposed to change the criteria for reference to: $\geq 1D$ of anisometropia, $\geq 2D$ of astigmatism, $\geq 2D$ of myopia and $\geq 2D$ of hyperopia. With the new criteria, none of the children who need treatment would be excluded and we expect to reduce by 26.3% the number of appointments.

There are considerable weaknesses and limitations to our study. In particular, the coverage rate was only 55%. In this sense, based on the photo screening images, we do not suspect a different severity of amblyogenic factors in individuals with whom we had no compliance and no follow-up. In addition, examinations and treatment plans were performed by five different pediatric ophthalmologist and there wasn't a universal criteria for glasses prescription.

Additional studies are needed to better understand effects of screening compared with no screening, to clarify the risk for potential unintended harms from screening, to define the optimal time at which to initiate screening and to define the direct monetary cost. In order to consolidate the cut-offs defined for reference, we aim to repeat the process with the new cohort that makes 2 years-old in 2017, to screen children who reach 4 years-old in 2018 and to do a comparative study between this last group and the group screened in 2016.

Previous studies had shown that infants and toddlers younger than 2 years who had amblyopia detected by photoscreening had treatment successes averaging about 1 logMAR line better than children who had amblyopia detected between ages 2 and 4 years. (11) The final goal our study will be define the necessity of a screening project at 2 or 4 years old, or both.

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