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Performance of the Spot Vision Screener in Children Younger Than 3 Years of Age

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Abstract

PURPOSE—To evaluate the use of the Spot Vision Screener (Spot; Welch Allyn, Skaneateles Falls, New York, USA) for detection of amblyopia risk factors in children aged 6 months to 3 years, as defined by the 2013 guidelines of the American Association for Pediatric Ophthalmology and Strabismus.

DESIGN—Reliability analysis.

METHODS—In this study, children seen from June 1, 2012, to April 30, 2016 were tested with the Spot during a routine visit. Enrolled children underwent a comprehensive eye examination including cycloplegic refraction and sensorimotor testing within 6 months of the testing date by a pediatric ophthalmologist masked to the Spot results.

RESULTS—A total of 184 children were included. The Spot successfully obtained readings in 89.7% of patients. Compared with the ophthalmologist's examination, the Spot had an overall sensitivity of 89.8% and a specificity of 70.4%.

CONCLUSION—The Spot achieved good sensitivity and specificity for detection of amblyopia risk factors in this young cohort, particularly in the older subgroup. Our data offer support for automated vision screening in young children.

AMBLYOPIA IS THE MOST COMMON CAUSE OF PREventable vision loss in children.¹ In a 2016 policy statement by the American Academy of Pediatrics, experts indicate that instrument-based vision screening can be attempted beginning at age 12 months.² The United States Preventive Services Task Force states, however, that current evidence is insufficient to recommend vision screening in children younger than 3 years of age.³

Identifying children at risk for amblyopia, especially in those younger than 3 years, is a great challenge in the primary care setting. The Spot Vision Screener (Spot; Welch Allyn Inc, Skaneateles Falls, New York, USA) is marketed for use starting at age 6 months.⁴ We sought to further evaluate the usefulness of the Spot in this youngest age group for detecting amblyopia risk factors (ARF) as determined by the 2013 report of the American Association

for Pediatric Ophthalmology and Strabismus (AAPOS) Vision Screening Committee (Table 1).⁵

METHODS

THIS PROSPECTIVE RELIABILITY ANALYSIS STUDY WAS approved by the Institutional Review Board and adhered to the US Health Insurance Portability and Accountability Act of 1996. Written informed consent was obtained from the parents or guardians. Patients presenting for examination to the pediatric ophthalmology clinic between June 1, 2012, and April 30, 2016, with appropriate personnel and guardianship available, were asked to participate. Patients aged 6–35 months from a previous report⁶ were included in this study analysis and an additional 111 patients within the age range were recruited beginning July 1, 2015.

The Spot Vision Screener has been previously described.^{6–9} Most screenings were conducted by students and research assistants. Briefly, the examiner chooses the appropriate age range on the home screen of the device. The Spot is held approximately 3 feet from the patient, and twinkling lights and sounds provide a fixation target for the child. With a cooperative patient in a dimly lit room, a reading is obtained in about 2 seconds. Several “retry” attempts were made if a reading was not initially obtained. With a successful reading, the device immediately displays a report of pupillary diameter, ocular alignment, binocular refraction, and referral recommendation. The referral recommendation—“All measurements in range” or “Complete eye exam recommended” —appears in a large horizontal colored blue or red bar, respectively. The age-specific criteria of the Spot software (version 2.0.16) were used for this study (Table 2).

A comprehensive examination was then performed on the same day as Spot screening, including visual acuity, stereopsis, motility evaluation, and examination of the anterior segment. Cycloplegic retinoscopy and fundus examination were performed either on the study date or within the preceding 6 months. Refraction was performed 30 minutes after the instillation of one drop of proparacaine hydrochloride ophthalmic solution USP 0.5%, followed by 1–2 drops of a pediatric “combo drop” of tropicamide 1%, phenylephrine 2.5%, and cyclopentolate 1%. All examinations were performed by a pediatric ophthalmologist masked to the photoscreener results.

DATA COLLECTION AND STATISTICAL METHODS

The following patient data were collected: age, whether or not a Spot reading was obtained, Spot recommendation (“complete eye exam recommended” [refer] and “all measurements in range” [pass] according to manufacturer criteria), and examinations of the pediatric ophthalmologist, including measured strabismus and cycloplegic refraction. Data were entered into a REDCap (Research Electronic Data Capture) database hosted at the Medical University of South Carolina for statistical analysis.¹⁰

We included all patients, even those upon whom the Spot did not obtain a reading. Descriptive statistics were calculated. Patients were considered to have amblyopia or ARF on the comprehensive examination on the basis of the physician’s diagnosis and 2013

AAPOS ARF guidelines⁵ (Table 1). Patients were considered to have met the 2013 AAPOS guidelines for strabismus referral if a constant measurement of >8 PD in primary position at distance or near was found at the time of examination. Children with media opacities of >1 mm or a diagnosis of amblyopia were included as a positive for ARF. Sensitivity, specificity, and positive and negative predictive values (PPV and NPV) of the Spot in detecting ARF were calculated. Children in whom the Spot was unable to obtain a result were included as automatic referrals.

PPV and NPV are affected by the prevalence of disease in the specific population being studied, yet can be estimated for the general population, given a fixed sensitivity and specificity for a diagnostic test. The assumption of a fixed sensitivity and specificity implies that the diagnostic performance test is generalizable to the broader population. In other words, the probability that the test will correctly predict someone as being disease positive (or negative) is the same regardless of whether they are from the population of children at the doctor's office or the more general population. If this assumption is reasonable, then PPV and NPV can be estimated for a given prevalence of disease in a population using sensitivity and specificity according to the relationships shown below^{11,12}:

$$\text{Estimated PPV} = \frac{\text{sensitivity} \times \text{prevalence}}{\text{sensitivity} \times \text{prevalence} + (1 - \text{specificity}) \times (1 - \text{prevalence})}$$

$$\text{Estimated NPV} = \frac{\text{specificity} \times (1 - \text{prevalence})}{\text{specificity} \times (1 - \text{prevalence}) + (1 - \text{sensitivity}) \times \text{prevalence}}$$

Thus as prevalence decreases, the PPV is expected to decrease, but the NPV is expected to increase. Using these relationships, we estimated PPV and NPV of the Spot version 2.0.16 for a general population of young children.

RESULTS

A TOTAL OF 184 CHILDREN WERE INCLUDED IN THIS study. The average age of those enrolled was 23.3 months (median 24 months, range 6–35 months). Fifty-one percent were female. Seventeen percent were Hispanic, 25.5% were African American, 47.3% were white, 0.5% were Asian, and the remainder were not classified.

For the entire age range of 6–35 months, the sensitivity of the Spot to detect the 2013 AAPOS ARF was 89.8% (95% confidence interval [CI] 79.2–96.2), and specificity was 70.4% (95% CI 61.6–78.2). Performance metrics of the Spot by age group are shown in Table 3. Though there is low statistical power and a wide confidence interval, sensitivity was highest in the 6- to 11-month age group (100%), and the positive predictive value was highest in the 24-to-35-month age group (64.3%).

The prevalence of ARFs in our population was 32.1%. For our population, the PPV was 58.9% (CI 48.0–69.2%) and NPV 93.6% (CI 86.6–97.6%). The prevalence of ARFs in the general preschool population is estimated to be 20%.¹³ Using a prevalence of 20% of

children with ARF, the PPV and NPV in a general population of young children can be estimated to be 43.1% and 96.5%, respectively (Figure).

The Spot was unable to obtain a reading for 10.3% (19/184) of the children, who were categorized as automatic referrals. Ten of these 19 children were ultimately found on examination to have ARF.

There were 6 false-negatives. These children were aged 14–33 months. The Spot failed to detect 5 diopters of hyperopia in 1 patient and 4 diopters of anisometropia in the 1 patient with pseudophakia. The Spot underestimated the amount of astigmatism in 1 patient. Two patients demonstrated constant strabismus on examination of >8 prism diopters (PD) (1 exotropia of 25 PD, another esotropia of 30 PD). Table 4 outlines the ages and gold-standard refractive data of these patients.

DISCUSSION

AS YOUNGER CHILDREN HAVE BEEN SHOWN TO BE MORE responsive to amblyopia therapy,¹⁴ the detection of ARF in young children is advantageous. Optotype-based vision screening can be performed in cooperative preschool-aged children, but alternative methods are needed in younger children and others unable to participate in traditional methods.

We know that refractive correction alone results in marked improvement in vision in children with anisometropic amblyopia.¹⁵ Early correction of refractive error is shown to lead to improved visual acuity outcomes.¹⁶ Additionally, children with ARF who underwent photoscreening before age 2 have a better visual outcome than those screened later.¹⁷ All of these factors illustrate the value of detecting eye disease in this young population.

In our limited study, the Spot demonstrates good sensitivity and specificity for detecting the 2013 AAPOS ARF criteria in children between the ages of 6 months and 35 months. The “out-of-the-box” Spot manufacturer criteria can be modified by the user as indicated for desired sensitivity and specificity in each screening situation. Criteria with a higher specificity may be preferable in some screening situations.

Limitations of our study include its small size and the use of an enriched population in a clinical setting. Although sensitivities and specificity are often assumed to be test-specific across populations, PPV and NPV do vary with prevalence of disease. Our estimates for the general population indicate that the PPV is only moderate at 43.1%, with an excellent NPV of 96.5%. However, estimates and results from an ophthalmology office setting population, and with experienced personnel, will not necessarily correlate to results out in the field. Further studies in the general population setting would be needed to support or adjust these values.

Although the false-negative results are few, they remind us that no vision screening system is perfect. Indeed, repetition of screening is expected and a comprehensive examination is recommended should teachers, doctors, or caretakers have concerns about a child’s vision, even if the child passes a screening test. However, identifying ARF in children less than 3

years old provides the opportunity to improve vision for a lifetime. Our study adds further support to the use of automated vision screeners in young children.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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FIGURE.

Estimation of positive predictive value (PPV) and negative predictive value (NPV) using sensitivity of 89.8% and specificity of 70.4% as found for the Spot Vision Screener in the current study.

TABLE 1

Amblyopia Risk Factors Targeted With Automated Preschool Vision Screening

Age (Months)	Refractive Risk Factor Targets (Cycloplegic Refraction)			
	Astigmatism	Hyperopia	Anisometropia	Myopia
12–30	>2.0 D	>4.5 D	>2.5 D	> –3.5 D
31–48	>2.0 D	>4.0 D	>2.0 D	> –3.0 D
>48	>1.5 D	>3.5 D	>1.5 D	> –1.5 D
All ages	Nonrefractive Amblyopia Risk Factor Targets: Manifest strabismus >8 PD in primary position Media opacity >1 mm			

D = diopters; PD = prism diopters.

TABLE 2

Manufacturer Criteria for Spot Vision Screener, Version 2.0.16

Age (Months)	Anisometropia	Astigmatism	Myopia	Hyperopia	Anisocoria	Gaze Vertical, Degrees	Gaze Nasal, Degrees	Gaze Temporal, Degrees	Gaze Asymmetry, Degrees Difference
6–12	1.5	2.25	2	3.5	1	8	5	8	8
12–36	1	2	2	3	1	8	5	8	8
36–72	1	1.75	1.25	2.5	1	8	5	8	8
72–240	1	1.5	1	2.5	1	8	5	8	8
240–1200	1	1.5	0.75	1.5	1	8	5	8	8

TABLE 3

Performance Metrics of the Spot Vision Screener by Age Group

Age Groups	ARF+	ARF-	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)
Patients 6–11 months						
Spot referral/positive	3	7	100 (29.2–100)	63.2 (38.4–83.7)	30 (6.7–65.3)	100 (73.5–100)
Spot pass/negative	0	12				
Patients 12–23 months						
Spot referral/positive	14	10	82.4 (56.6–96.2)	68.8 (50.0–83.9)	58.3 (36.6–77.9)	88.0 (68.8–97.5)
Spot pass/negative	3	22				
Patients 24–35 months						
Spot referral/positive	36	20	92.3 (79.1–98.4)	73.0 (61.4–82.7)	64.3 (50.4–76.6)	94.7 (85.4–98.9)
Spot pass/negative	3	54				

ARF = amblyopia risk factors; CI = confidence interval; NPV = negative predictive value; PPV = positive predictive value.

TABLE 4

Children With False-Negative Screen

Patient Code	Age (Months)	Right Eye			Left Eye		
		Sphere, D	Cylinder, D	Axis	Sphere, D	Cylinder, D	Axis
1	33	+5.00	+0.75	90	+5.00	+0.75	90
2 ^a	20	0	0	0	+4.00	0	0
3 ^c	24	+0.75	0	0	+0.75	0	0
4 ^b	24	+1.25	+0.75	90	+1.25	+0.50	90
5 ^c	14	+1.50	0	0	+1.50	0	0
6	14	-1.00	+2.5	110	-0.5	+2.00	70

D = diopters.

^aOne patient included with pseudophakia, left eye.

^bDiagnosis of strabismic amblyopia left eye.

^cDemonstrated constant strabismus on examination of >8 prism diopters.