HHS Public Access

Author manuscript

J AAPOS. Author manuscript; available in PMC 2023 September 22.

Published in final edited form as:

J AAPOS. 2021 June ; 25(3): 172–175. doi:10.1016/j.jaapos.2021.01.003.

Normative pediatric visual acuity using electronic early treatment for diabetic retinopathy protocol

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Abstract

There is a lack of normative data for children tested with the electronic Early Treatment for Diabetic Retinopathy Study (E-ETDRS) protocol. In the current cross-sectional study, the mean best-corrected normal and 95% lower tolerance limit for E-ETDRS visual acuity by year in children 7–12 years of age was measured. Our objective was to provide a large normative data set for E-ETDRS visual acuity in children for use in clinical management and clinical trials.

Standardization of visual acuity measurement is essential for accurate monitoring of the response to treatment in individual patients and in clinical trials. For more than 30 years, the Early Treatment for Diabetic Retinopathy Study (ETDRS) logMAR charts[1] have been the preferred method for adult visual acuity testing in clinical trials. In 2003, a computerized version of ETDRS that uses crowded, isolated letters was developed (Figure 1); the new electronic ETDRS (E-ETDRS) has high test-retest reliability and good agreement with ETDRS chart results in adults[2] and in children 7–12 years of age.[3] Originally, the E-ETDRS protocol was implemented on the electronic visual acuity tester (EVA; Jaeb Center for Health Research, Tampa, FL),[2] but it is now available on multiple hardware platforms. Large normative data sets are available for the ETDRS logMAR charts for adults[4] and children,[5,6] and some normative data are available for adults tested with the E-ETDRS.[7] To date, however, there is a lack of normative data for children tested with E-ETDRS. In the present study, we report normative data for 7- to 12-year-old children and adults assessed with the E-ETDRS protocol using the EVA testing system.

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Subject and Methods

Participants included 235 children 7–12 years of age and 37 adults 18–39 years of age recruited from ongoing research studies of normal visual development at the Retina Foundation of the Southwest between July 2004 and July 2020. All participants were born full-term, with no developmental delay, ocular condition, or systemic condition. All participants had normal measured stereoacuity of 60 arcsec or better on the Randot Preschool Stereoacuity Test (Stereo Optical Company Inc, Chicago, IL). Written informed consent was obtained from adult participants and, for children, from a parent or guardian. Written assent was obtained from participants aged 10–12 years. All aspects of the research protocol were approved by the Institutional Review Board of the University of Texas Southwestern Medical Center and complied with regulations of the US Health Insurance Portability and Accountability Act of 1996.

Procedure

For all participants, best-corrected visual acuity (BCVA, based on a comprehensive examination within the last year) testing was completed on each eye monocularly at a viewing distance of 3 meters. Testing followed the E-ETDRS protocol and consisted of an automated presentation of stimuli described previously.[2] Briefly, testing begins with a screening phase to determine an approximate visual acuity threshold using 0.3 logMAR steps with a range of optotype sizes from 1.6 to −0.2 logMAR. Once the screening logMAR level is identified, letters are randomly selected from a pool of letters of the same size as the screening logMAR level and 0.1 logMAR smaller. These levels remain active in the letter pool until 5 letters are tested at that level. Additional logMAR levels of letters in 0.1 logMAR steps are added to the pool as needed to identify an upper logMAR level with 5 of 5 letters correct and a lower logMAR level with 0 of 5 letters correct. The visual acuity is calculated by counting the number of letters correctly identified during post-screening testing, plus 5 letters for each logMAR line above the upper logMAR level through 1.6 logMAR. When converting E-ETDRS letter scores to log-MAR, scores were rounded to the nearest line.

Statistical Analysis

Means and standard deviations were calculated for BCVA and interocular visual acuity difference in each age group; one-sided 95% lower tolerance limits for BCVA and interocular difference were also derived. To account for correlation between the visual acuities of the two eyes of individuals, analyses of BCVA data were conducted on a per-person basis using the interclass correlation model.[8] Post hoc pairwise *t* tests were conducted to compare among age groups. With Bonferroni correction to minimize the risk of type 1 error (n = 21 pairwise *t* tests), only comparisons with $P<0.002$ were considered statistically significant. Differences among age groups in interocular visual acuity difference were evaluated using a one-way analysis of variance (ANOVA).

Results

Demographics of the diverse study sample are reported in eSupplement 1 (available at jaapos.org). Mean BCVA and interocular acuity difference and 95% lower tolerance limits, categorized by age group, are presented in Table 1. An ANOVA under the interclass correlation model indicated that there was a significant effect of age on BCVA across the 7 age groups ($F_{6,530}$ = 4.75; P = 0.03; Table 2); post hoc pairwise comparisons suggest that the overall significant difference among age groups could be wholly attributed to significant differences between 7-year-olds and all other age groups (Table 3). None of the age groups between 8- and 12-years differed significantly from each other or from adults. A one-way ANOVA indicated that interocular acuity differences were not significantly different across age groups ($F_{6,321}$= 0.34; P =0.92). Overall, mean interocular acuity difference was approximately one-half logMAR line in all age groups (Table 2).

Discussion

The present study is the first to provide normative pediatric visual acuity data collected using the E-ETDRS protocol. Children aged 7 years have slightly but significantly lower visual acuity measured with the E-ETDRS protocol compared with children aged 8–12 years and adults. Compared to prior ETDRS data for children gathered with retro-illuminated ETDRS charts, the BCVA means and interocular visual acuity differences for 9- and 10-year-olds were similar to those reported by Myers and colleagues,[6] but better across all age groups than those reported by Dobson and colleagues.[5] The adult BCVA data presented here closely agree with prior reports of normal adult controls obtained with both the E-ETDRS protocol and with retroilluminated ETDRS charts.[4,7]

The E-ETDRS protocol provides a standardized approach to visual acuity testing in children and adults. The single surrounded optotype presentation and rigorously developed testing protocol possess a number of advantages over traditional visual acuity tests that make it suitable for clinical practice and clinical research. The data presented here provide normative visual acuity ranges by year for children ages 7–12 years that may be useful in the design and conduct of clinical trials and in the clinical management of pediatric eye conditions.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Financial support:

National Institutes of Health Grant EY022313. The funding organization had no role in the design or conduct of this research.

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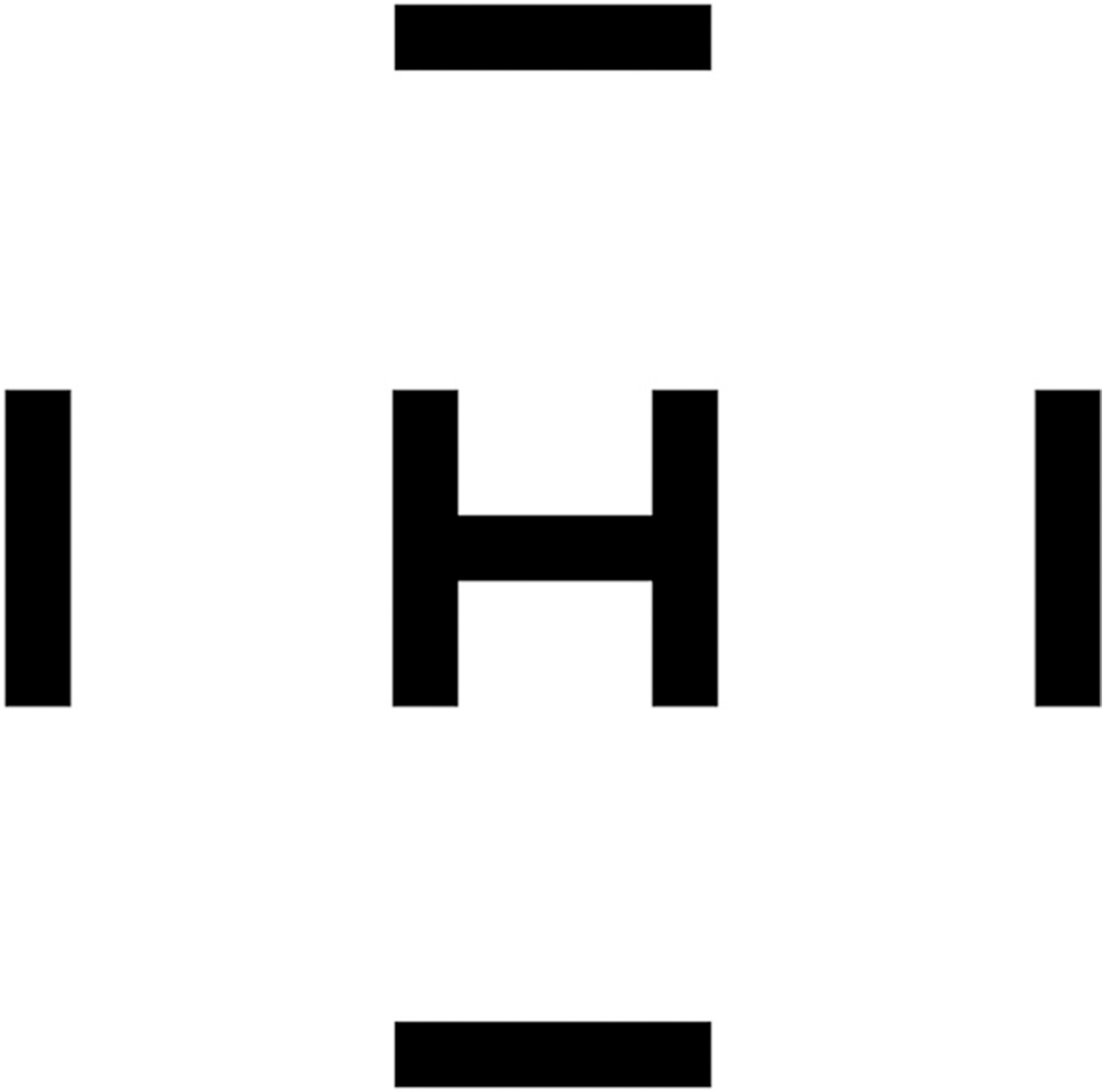

FIG 1.
The electronic ETDRS test displays single letters from the Sloan letter set framed with crowding bars that are spaced a letter width around the letter.

Table 1.

Mean and lower limit for visual acuity and interocular difference by age group

	Visual acuity					Interocular difference	
Age group, years	**No. of participants[a]**	**Mean logMAR**	**Mean Snellen**	**95% lower limit, logMAR**	**95% lower limit, Snellen**	**Mean**	**95% upper limit IOD**
7	58	−0.02	20/20	0.12	20/25	0.04	0.13
8	45	−0.06	20/16	0.06	20/25	0.04	0.13
9	35	−0.06	20/16	0.05	20/25	0.04	0.13
10	37	−0.06	20/16	0.07	20/25	0.05	0.13
11	30	−0.06	20/16	0.06	20/25	0.06	0.16
12	30	−0.07	20/16	0.07	20/25	0.05	0.13
Adults	38	−0.08	20/16	0.06	20/25	0.04	0.12

LogMAR, logarithm of the minimum angle of resolution.

[a]Each participant contributed data from two eyes; statistical analysis considered the correlation between the visual acuities of the two eyes of individuals.

Table 2.

Overall ANOVA results comparing best-corrected visual acuity for different age groups using the intraclass correlation model

Source of variation	Sum of squares	df	Mean square	F Statistic	*P* Value
Between age groups	0.189	6	0.032	4.75	0.03
Between eyes	0.047	7	0.007	1.01	0.42
Within age groups	3.493	530	0.007		

Table 3.

Value of *t* statistics and *P* values for pairwise comparisons

Age, years	No. participants[a]	Mean	Comparison group, age, years[b]					
			8	9	10	11	12	Adult
7	58	−0.02	*t* = 3.50 0.0006	*t* = 3.49 0.0006	*t* = 3.15 0.002	*t* = 3.10 0.002	*t* = 3.24 0.001	*t* = 4.45 0.0008
8	45	−0.06	—	0.23	0.94	0.96	0.51	0.13
9	35	−0.06	—	—	0.64	0.67	0.86	0.35
10	37	−0.06	—	—	—	0.98	0.56	0.19
11	30	−0.06	—	—	—	—	0.59	0.22
12	30	−0.07	—	—	—	—	—	0.49
Adult	38	−0.08	—	—	—	—	—	—

[a] Each participant contributed data from two eyes; statistical analysis considered the correlation between the visual acuities of the two eyes of individuals.

[b] For the 21 pairwise comparisons, Bonferroni correction requires $P \leq 0.002$. *P* values are given for all pairwise comparisons, along with the value of the t-statistics for comparisons associated with a *P*-value that met this criterion.