学位論文

Analysis of suspected visual impairment risks based on objective refraction in 3-year-old children

（3 歳児における視力不良リスクとなる他覚的屈折値の解析）

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Abstract

Purpose—To evaluate the relationship between uncorrected visual acuity and non-cycloplegic refractive value among 3-year-old children in a vision screening program in Japan.

Study design—Retrospective, cross-sectional study.

Methods—The participants were 1746 Japanese children who were screened from April 2009 to July 2018, and ranged in age from 36 to 47 months. Visual acuity and handheld refractive values were collected from the clinical records of 3-year-old children in a vision screening program. Multiple logistic regression analysis was used to evaluate the association between 0.3 logarithm of the minimum angle of resolution (logMAR) and > 0.3 logMAR. Correlation analysis was also performed for the presence of myopic shift.

Results—Among the 1746 children (aged [mean ± standard deviation], 37.6 ± 1.6 months; percentage of boys, 50.4%), representing 3492 eyes, 116 eyes (3.3%) had > 0.3 logMAR. Multiple logistic regression analysis revealed that the risk factors for 1.75–2.00 diopter (D) spherical power (odds ratio [OR], 2.51; 95% confidence interval [CI], 1.12-5.64; $P = 0.026$) and 1.25–1.50 D cylindrical power (OR, 5.66; 95% CI, 1.58–20.40; $P < 0.01$) were increased in eyes with > 0.3 logMAR. There was no myopic shift for 10 years (Spearman's rank correlation coefficient; $P = 0.65$).

Conclusion— It is important to set a threshold that considers the characteristics of the autorefractor used in screening, and at population-based refractive values, to ensure that a

thorough eye examination in ophthalmic institutions will help prevent amblyopia.

Keywords: vision screening program, 3-year-old, uncorrected visual acuity, refractive error, multiple logistic regression analysis

INTRODUCTION

Visual deficits in general are an important public health problem. The most common causes of vision problems in children are amblyopia (a neurodevelopmental disorder that arises from the abnormal processing of visual images that results in a functional reduction of visual acuity) and associated risk factors such as strabismus and refractive error [1-4]. In 2011, the United States Preventive Services Task Force recommended screening children at least once between the ages of 3 and 5 years to detect amblyopia or its risk factors [5]. Adequate child vision is key for physical, emotional, and social progress throughout the lifespan. Several studies indicated that screening children's vision is beneficial [6-7].

For a long time, visual deficits have been regarded as a disability worthy of early detection and intervention. The United States Preventive Services Task Force concluded that evidence was insufficient for assessing the balance of the benefits and harm of vision screening for children younger than 3 years [5]. In developed nations, including Canada, the ability to meet the recommendations for screening children between the ages of 3 and 5 years depends on numerous factors such as clinicians' availability, practice patterns, medical training, and community and parental acceptance. Determining whether the recommended visual acuity is acquired is impossible without a national screening program [8]. Since 1991, a vision screening program (VSP) has been officially regulated by the government in Japan [9]. The first automated device for preschool VSPs became commercially available approximately 3 decades

ago, and photoscreening instruments have become easier to use without compromising the accuracy and precision for detecting amblyopia risk factors [10]. In addition, automated vision screening poses several potential advantages over traditional screening techniques such as a shorter time to screen each child and the ability to screen more children who tend to be uncooperative [11]. However, even if a child's vision is normal, based on the guidelines, false-negative results can occur. One of the reasons is that the VSP is done with non-cycloplegic refraction. An examiner should ideally aim to avoid false-negative results. Within the scope of the guidelines, an examiner also needs to be aware of the risks of suspected visual impairment.

This aim of this study was to evaluate the relationship between visual acuity and objective refraction in the VSP in Japan and the risk of suspected visual impairment in order to prevent amblyopia.

SUBJECTS AND METHODS

After children were evaluated in the VSP, their parents were informed via a document on a website that their VSP data could be used in research conducted at universities. If they did not wish to participate in this study, they submitted a nonparticipation statement in the research consent form and their data were excluded. In addition, an overview of this research was presented in a document on the websites of the facilities where the study was conducted and the Kumamoto University (Kumamoto, Japan). This study was approved by the Epidemiology

and General Research Ethics Committee of the Faculty of Life Sciences at Kumamoto University (Kumamoto, Japan). The committees approved the opt-out consent form for the participants in lieu of written informed consent. This retrospective cross-sectional study was conducted in accordance with the tenets of the Declaration of Helsinki [12].

Study population

The participants were 3-year-old children who were examined in a VSP in Kamiamakusa city (Eastern Amakusa Islands) in Kumamoto, Japan. Children aged 36–47 months who underwent their annual 3-year-old childhood examinations at our local site from April 2009 to July 2018 were included. Children who did not understand the test instructions or who were uncooperative were excluded.

A VSP comprises of 3-steps: in the first step, an inspection is performed at home (family test), in the second step, an inspection is performed in the health center, and in the third step, an inspection is performed in a medical institution. The results of the family test are categorized as: No abnormality, Abnormality, Not administered, and Unknown; and are referenced at the time of the second step. This study used results of the second step.

Screening examination

The second step was performed without cycloplegic effect and uncorrected visual acuity.

The examinations included a visual acuity test at a distance of 2.5 m (oculus dexter [OD], oculus sinister [OS]) (Single Landolt Test Cards and Single PICTUR Optotype Test Cards; Handaya, Bunkyo-ku, Tokyo, JAPAN), the handheld autorefractor (SureSight vision screener; Welch Allyn, Skaneateles Falls, NY, USA), alternate cover test at 1/3 m and 5 m, muscle balance, and Lang Stereo Test I. Children who did not meet the referral criteria for any one test were considered a "refer", whereas only children who passed all five tests were considered a "pass".

Landolt C angular vision or picture optotype was used to measure visual acuity (VA) from 1.0 logMAR to 0.3 logMAR at 2.5 m. This value is the upper limit of the vision value in the medical examination that is defined in Japan. Therefore, the highest vision value in the VSP was 0.3 logMAR. The dot visual acuity (Dot Card For Near Point, Morizane; Handaya Co. Ltd., Bunkyo-ku, Tokyo, JAPAN) was used to measure > 1.0 logMAR.

The SureSight vision screener; takes 5-8 measurements of the eye, after which it displays a measurement of sphere, cylinder, and axis, along with a confidence rating from 1 to 9, indicating the reliability of the reading [13]. The participants sat facing the tester, who attempted to make 3 measurements (without regard to confidence ratings) of each of the non-cycloplegic eyes of the children.

Five orthoptists, who were commissioned by city hall in Kamiamakusa, Japan, performed all examinations.

Definitions of refractive errors

Refractive error was assessed in 0.25 diopter (D) increments for the spherical power and cylindrical power. The spherical power was + 0.75 D or more for hyperopia and - 0.50 D or less for myopia [14,15]. The cylindrical power was 0.75 D or more for astigmatism [16]. In all other cases close to 0 D, the refractive value was treated as emmetropia. The cylindrical power used was a converted absolute value. The spherical equivalent (SE) was calculated as the spherical power minus half of the cylindrical power.

Statistical analysis

The percentage of missing values for all variables was determined, and missing data were excluded from each analysis. The normality of continuous variables was confirmed using the Shapiro–Wilk test. All variables were compared between 2 groups of interest (0.3 logMAR vs. > 0.3 logMAR) by using the Welch's t-test (mean ± standard deviation) for continuous variables and Fisher's exact test for categorical variables. However, a Mann–Whitney U test (median [interquartile range]) was used for the cylindrical power.

For the spherical power, cylindrical power, and SE, we used univariate logistic regression analysis to evaluate visual deficits. Myopia was excluded because of the lack of samples. Multiple logistic regression analysis was conducted, while controlling for confounding factors. Variables that have been associated with VA in previous studies and variables with a value of

P values < 0.001 in the univariate analysis were used for the multiple logistic regression model. Variables previously shown to be associated with VA included age, sex, family test, and the optotype used in a VSP [17,18]. The refractive value category was set to a reference with quarter of the value of the American Association for Pediatric Ophthalmology and Strabismus guidelines [10], from which it can be analyzed in 0.25 D increments.

The myopic shift over 10 years was assessed using Spearman's rank correlation coefficient between spherical power and year. The association between SE and uncorrected visual acuity was likewise assessed using Spearman's rank correlation coefficient.

Two-tailed *P* values < 0.05 indicated statistically significant comparisons. All analyses were conducted using the SPSS software package for Windows (version 25.0, IBM Corp., Armonk, NY, USA).

RESULTS

Study participants

After reviewing the data of 1861 children, 115 children were excluded because of incomplete or missing personal information. A total of 101 children (5.4%; 38.3 ± 3.5 months) were excluded due to a lack of visual acuity testing. Thus, 1746 children, representing 3492 eyes, were examined. Among these children, slightly more boys (880, 50.4%) than girls (866, 49.6%) were included. The mean age was similar between the boys (37.6 ± 1.7 months) and

girls (37.7 ± 1.7 months) (P = 0.42; Welch's t-test). Hyperopia was observed in 2712 eyes (77.7%) and myopia was observed in 28 eyes (0.8%). There were 752 eyes (21.5%) with emmetropia. In addition, the complication of astigmatism was noted in 314 eyes (9.0%). There were 7 cases (0.4%) of anisometropia with a spherical power difference of more than 2D between the left and right eyes.

Comparison of the two groups

Table 1 presents the results of each variable between the two groups divided by visual acuity (0.3 logMAR and > 0.3 logMAR). No significant differences existed in age (P = 0.081), sex (P = 0.094), family test (P = 0.17), and orthoptist experience (P = 0.39). However, significant differences were observed in the optotype (P < 0.001).

Table 2 shows the refractive values of the 3492 eyes. The spherical power (P < 0.001), cylindrical power (P < 0.001), and SE (P < 0.001), were all significant.

Multivariable regression analyses

Table 3 shows the results of the univariate regression model and the multivariate regression model. For the spherical power, when a quarter of the American Association for Pediatric Ophthalmology and Strabismus guidelines value was 0.25–1.00 D (the reference), the risk factor of 1.75–2.00 D indicated an increase in "refer" (odds ratio [OR], 2.51; 95%

confidence interval [CI], 1.12–5.64; $P = 0.026$). This increase was similar to that of the cylindrical power of 1.25–1.50 D (OR, 5.66; 95% CI, 1.58–20.40; $P = 0.008$) and SE of 2.01–3.00 D (OR, 14.05; 95% CI, 3.79–52.04; $P < .0001$). The OR was increased when the frequency was strong in all.

Correlation analysis

The relationship between refractive values over the 10 years from 2009 to 2018 had a correlation of - 0.008 ($P = 0.65$, 95% CI: - 0.001–0.017) with no significant difference (Fig. 1). The relationship between SE and uncorrected visual acuity was significant, with a correlation of 0.140 ($P < 0.001$, 95% CI: 2.25–2.84) (Fig. 2).

DISCUSSION

In this study, we investigated the relationship between visual acuity and refractive errors among 3-year-old children in a VSP in Kamiamakusa in Kumamoto, Japan. The threshold value for uncorrected visual acuity was spherical power + 1.75 D, and the visual acuity was reduced at higher values. The same was also the case when the cylindrical power was less than - 1.25 D. Essentially, the evaluation of refractive values in children's eyes requires eye drops for cycloplegia. However, screening usually does not include eye drops for cycloplegia. A difference of 0.68 D in the refractive value between non-cycloplegic and cycloplegic refraction

has been reported in 3-year-old children [19]. Furthermore, the results obtained vary depending on the proficiency of the measurer [20]. This should be considered when assessing refractive values in unregulated paralysis. The results of the SE were not significantly different, until reaching the refractive value of + 2.00 D. If the spherical power and cylindrical power are both high, then the SE may be less than + 2.00 D. Screening may increase false-negatives when assessed with SE values. Therefore, SE evaluation is not recommended for VSP.

Childhood amblyopia has a reported prevalence of approximately 1%–3% [21-23]. This figure includes developing countries that do not have VSPs. Many different VSP strategies have been installed globally to screen young children for amblyopia so that treatment can begin at a young age. Visual screening is recommended in many countries, but the use of a photoscreener is extremely effective because photoscreening devices have good sensitivity and specificity [24-26].

In preschool children, a spherical power of + 3.00 D and cylindrical power of - 1.50 D are the references for minimum optical correction, based on the American Association of Pediatric Ophthalmology and Strabismus guidelines [27]. The revised guidelines in 2013 suggested correcting for spherical power of + 4.00 D and cylindrical power of - 2.00 D [10]. However, the results of this study indicate the need for stricter standards for spherical and for cylindrical corrections. In fact, one study, reported of a boy who had a refractive error of + 2.50 sphere in the right eye and + 2.25 sphere in the left eye and that he already had amblyopia [28].

The guideline states: “Refractive amblyopia risk factors persist toward the end of this age range are less likely to spontaneously resolve and are more likely to be associated with amblyopia.” However, this criterion does not compensate for a certain vision value, even if it is less than the reference value. The need for tighter standards is indicated for the spherical power and cylindrical power. The example of amblyopia as described by the aforementioned investigators may be rare; however, it indicated that refractive values lower than those of the 2003 guidelines are risk factors for amblyopia.

To date, no report exists regarding the OR, based on multivariate analysis, of the relationship between VA and the objective refraction measurement. In our study, the results showed a higher risk with VA values > 0.3 logMAR, even if the refractive value was less than the normal value reported as the current guideline cutoff value. In the case of normally developing children aged 3 years (36 to 47 months), 62.8% of children will reach 0 logMAR uncorrected visual acuity [29]. The > 0.3 logMAR of this study was a small percentage of 116 eyes (3.3%), and refraction testing was important in the VSP. In the case of a VSP without refraction testing, the cutoff value for visual acuity needs to be re-examined.

One limitation of this study was that we did not examine different machine types. Different objective refraction values are used worldwide; therefore, unifying the measurement results is difficult. In addition, the machines used for screening are not necessarily a photoscreener. If it is a stationary type, the type of difference that will appear will need to be

considered. In one report, the SureSight vision screener had a mean difference of approximately - 1 D when compared to the stationary type of autorefractor (AR-820; NIDEK) [30]. Therefore, if it was + 1.75 D with the SureSight, it would be approximately + 2.75 D with the stationery type of autorefractor. Thus, it is essential to investigate the characteristics of the specific machine being used. The number of myopic eyes in this study was very low (0.8%), and due to the characteristics of the machine we used, the prevalence of myopia may actually have been even lower. The prevalence of myopia in the Japanese population at the age of 6 years has been reported to be 63.1% [31]. Rapid myopia is thought to occur between the ages of 3 and 6 years, when children are undergoing rapid physical development; changes over time between the ages of 3 and 6 years should be observed over these 3 years of development.

The prevalence of anisometropia of at least 2 D was found in 0.4% of participants, similar to the findings in Dirani et al.'s Singaporean study from 2010 (0.6%) [32].

The VA value used in this study was 0.3 logMAR. The VA of 0.2 logMAR recommended in the guidelines of the American Pediatric Ophthalmology and Prosthetic Society could not be used because this value was the upper limit of the vision value in the medical examination that is defined in Japan. However, it was consistent with the finding that the refraction value, which is a risk factor in Japanese children with suspected visual impairment, was lower than the refraction value mentioned in the guidelines of the American Pediatric Ophthalmology and Prosthetic Society.

In summary, it is important to set a threshold that considers the characteristics of the autorefractor used in screening, and at population-based refractive values, to ensure that a thorough eye examination in ophthalmic institutions will help prevent amblyopia.

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Table 1. Characteristics of the population of 3-year-old children in a vision screening program

Characteristic	Visual acuity		*P*-value
	0.3 logMAR (n = 1658)	> 0.3 logMAR (n = 88)	
Age (month)	37.6 ± 1.7	37.7 ± 1.9	0.081*
Sex			
Boy	828	52	0.094**
Girl	830	36	
Family test			
No abnormality	593	36	0.17**
Abnormality	372	12	
Not administered	519	33	
Unknown	174	7	
Orthoptist experience (number of years)			
< 1	474	23	0.39**
1-2	476	21	
≥ 3	708	44	
Optotype (screening)			
Landolt rings	1142	46	< 0.001**

Picture optotype	516	40
Other	0	2

Values are presented as the mean ± the standard deviation, unless otherwise indicated. The sample comprises 1746 children. The logMAR indicates logarithm of the minimum angle of resolution.

* Based on the Welch's t-test.

** Based on Fisher's exact test.

Table 2. Comparison of refractive values

Refraction	Visual acuity		*P*-value
	0.3 logMAR	> 0.3 logMAR	
Spherical power (M ± SD)	1.25 ± 0.64	2.59 ± 1.92	< 0.001*
Cylindrical power (median [IQR])	0 [0, 0]	0 [0, 0.25]	< 0.001**
Spherical equivalent (M ± SD)	1.19 ± 0.65	2.31 ± 1.99	< 0.001*

Values are presented as the mean ± the standard deviation or median [IQR] unless otherwise indicated. The logMAR indicates logarithm of the minimum angle of resolution; M ± SD: median ± standard deviation; IQR: interquartile range.

* Based on the Welch's t-test.

** Based on Mann-Whitney U test.

16 Table 3. Association between the refractive value category and refractive errors.

17

	Univariate analysis		*P*-value	Multivariate analysis		*P*-value
	OR	(95% CI)		OR	(95% CI)	
Spherical (diopter)						
0.25-1.00	1	(Ref.)	-	1	(Ref.)	-
1.25-1.50	1.65	(0.79–3.45)	0.18	1.66	(0.80–3.47)	0.18
1.75-2.00	2.49	(1.11–5.59)	0.027	2.51	(1.12–5.64)	0.026
2.25-2.50	8.82	(3.01–25.91)	< 0.001	8.66	(2.94–25.53)	< 0.001
2.75-3.00	43.24	(15.06–124.14)	< 0.001	40.06	(13.77–116.51)	< 0.001
> 3.00	146.00	(67.19–317.69)	< 0.001	129.57	(58.80–285.48)	< 0.001
Cylindrical (diopter)						
0.25-0.50	1	(Ref.)	-	1	(Ref.)	-
0.75-1.00	1.71	(0.49–5.92)	0.40	1.68	(0.48–5.87)	0.42
1.25-1.50	5.61	(1.57–19.82)	0.007	5.68	(1.58–20.40)	0.008
1.75-2.00	15.75	(4.07–61.02)	< 0.001	13.22	(3.31–52.73)	< 0.001
> 2.00	23.63	(6.41–87.05)	< 0.001	25.15	(6.68–94.66)	< 0.001
SE (diopter)						
< 0	1.30	(0.35–4.88)	0.70	1.58	(0.40–6.23)	0.52
0.00-1.00	1	(Ref.)	-	1	(Ref.)	-

1.01-1.50	0.82	(0.25–2.66)	0.74	0.87	(0.2– 2.88)	0.82
1.51-2.00	2.65	(0.69–10.19)	0.16	3.31	(0.83–13.24)	0.091
2.01-3.00	8.82	(2.65–29.32)	< 0.001	14.05	(3.79–52.04)	< 0.001
> 3.00	19.21	(5.95–62.07)	< 0.001	29.52	(7.92–110.11)	< 0.001

Multivariate analysis is adjusted for age, sex, family test, and optotype.

OR: odds ratio; CI: confidence interval; Ref.: reference; SE: spherical equivalent

Figure legends

Fig. 1 Correlation between the Spherical power and examination of year

Fig. 2 Correlation between the visual acuity of logarithm of the minimum angle of resolution (logMAR) and the spherical equivalent (diopter)

These figures were created using SPSS Version 25