



Annual Trend of Myopia and High Myopia in Children in Japan: A Nationwide Claims Database Study

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Purpose: To determine the prevalence and annual trend of the number of incident cases of myopia and high myopia in children.

Design: A nationwide, comprehensive claims database study.

Participants: Of 15 million children aged \leq 14 years, those covered by the universal health insurance were included. The validation study of the claims-based definitions of myopia and high myopia was conducted using 14 654 individuals aged \leq 14 years recruited from 11 diverse medical facilities.

Methods: This study comprises a national claims database analysis and a multicenter validation study. Data from the National Database of Health Insurance Claims and Specific Health Checkups of Japan, which contains the nationwide health insurance claims data, were assessed. All individuals aged \leq 14 years were reviewed, and children with existing and new onset of myopia or high myopia between January 2011 and December 2020 were identified. A validation study was conducted by reviewing electric medical records.

Main Outcome Measures: Prevalence of myopia as of October 1, 2020, and the annual number of incident cases during 2014 to 2020.

Results: According to the 2020 population census, there were 14 955 692 children aged \leq 14 years. Among them, 5 498 764 patients had myopia on October 1, 2020, corresponding to a prevalence of 36.8%. The number of incident cases of myopia was highest at 8 years of age, increasing from 853.3 cases/person-year in 2015 to 910.7 cases/person-year in 2020. The prevalence of high myopia increased with age, peaking at 0.46% among children aged 10 to 14 years; the number of incident cases annually increased in 5- to 9-year-olds and 10- to 14-year-olds. In the year 2020, when the coronavirus disease 2019 pandemic occurred, a discontinuous increase in the number of incident cases of myopia was observed in children aged 8 to 11 years, not 12 to 14 years. The overall sensitivity and specificity of the claims-based definition for myopia were 88.5% and 79.2%, respectively, whereas the corresponding values for high myopia were 41.6% and 99.8%.

Conclusions: This first comprehensive nationwide study revealed the prevalence and annual incidence trends of myopia and high myopia. These findings complement the results of previous high-quality cohort studies, offering a more comprehensive understanding of myopia trends.

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Supplemental material available at www.ophthalmologyscience.org.

Myopia, commonly termed as nearsightedness, is a refractive error with significant worldwide prevalence. It is characterized by the ability to clearly see nearby objects while distant objects appear blurred. The World Health Organization recognizes uncorrected myopia as a major cause of visual impairment worldwide.¹ Furthermore, the degree of myopia is associated with an increased risk of various ocular and systemic diseases.² Pathological myopia, often observed in highly myopic eyes, is among the leading causes of irreversible visual impairment and blindness among middle-aged and older individuals worldwide.^{3,4}

Recently, there has been a steady increase in the prevalence of myopia among children. Prevalence of myopia (spherical equivalent ≤ -0.5 diopters [D]) among 15-year-olds was reported to be >80% among East Asians^{5,6} and 50% of the population in Southern California.⁷ Further, the prevalence of high myopia (spherical equivalent ≤ -6 D) among 14- to 16-year-olds was reportedly 6.69% to 11.3% in Asian countries.^{6,8,9} Meticulously planned and executed cohort studies have provided immense value by obtaining detailed individual-level data with strong population representativeness (Table 1). However, the challenge lies in obtaining such large-scale and detailed data at high frequencies, which affects the speed at which data are generated and their real-time nature. In contrast, national claims database studies, such as the present study, although facing challenges in individual data accuracy, maintain population representativeness and high data velocity. This makes them particularly useful for capturing temporal trends. The limitations in individual data accuracy can be mitigated to some extent through appropriate validation studies. Thus, both cohort studies and national claims database research have their strengths and limitations Combining insights from both approaches can yield a more comprehensive understanding of myopia epidemiology. Nevertheless, although numerous high-quality cohort studies have been conducted, there has been a notable absence of comprehensive national claims database approaches to explore myopia epidemiology. The present study aimed to complement existing high-quality cohort studies by providing annual trends in myopia incidence and prevalence within the pediatric population, utilizing large-scale claims data. This information is crucial for developing and refining effective management and prevention strategies for myopia.

Therefore, we conducted a nationwide claims database study to evaluate the prevalence and the number of incident cases of myopia and high myopia. We utilized the National Database of Health Insurance Claims and Specific Health Checkups of Japan (NDB),²³ which covers >95% of the claims issued in Japan,²⁴ with permission from the Japanese Ministry of Health, Labour and Welfare (MHLW). Claims database analysis has a major limitation in that patients who do not visit hospitals cannot be identified. Accordingly, because patients with nonpathological myopia do not generally visit ophthalmology clinics, claims database analysis may be inappropriate for evaluating the epidemiology of myopia. However, in Japan, all 3-year-old infants as well as elementary and junior high school students (i.e., students aged 6-14 years) are required to undergo ophthalmological health checkups under the Maternal and Child Health Act and the School Health and Safety Act, respectively. Moreover, all children with an uncorrected visual acuity <20 of 20 are required to visit an ophthalmologist and submit their examination results to their school. Therefore, considering the additional compulsory education in Japan, almost all children with myopia visit ophthalmology clinics and are issued the corresponding claims.

Given these unique conditions, we aimed to conduct the first nationwide claims database study on the prevalence and the number of incident cases of myopia and high myopia. Further, we aimed to evaluate the nationwide impact of the coronavirus disease 2019 (COVID-19) pandemic on the incidence of myopia.

Methods

observational study was approved by the ethics committees of Kyoto University Hospital and Kyoto University Graduate School of Medicine (No. R2405 and R2793) and adhered to the tenets of the Declaration of Helsinki. Informed consent was obtained using an opt-out method.

Database

We analyzed the NDB, which is the largest national claims database worldwide and is managed by the Japanese MHLW. Although previously described, $^{25-27}$ we have summarized details regarding the NDB in the Supplementary Note (available at www.ophthalmology science.org). This study was conducted during the MHLW-approved study period between August 23, 2021, and February 22, 2022. On commencement of the study, the NDB contained >14 billion claims generated between 2008 and 2021.

Definition and Validation

Diagnoses of myopia and high myopia were determined based on the NDB diagnostic codes for the corresponding refractive status. Table S2 (available at www.ophthalmologyscience.org) summarizes the correspondence among NDB diagnostic codes, International Classification of Diseases 10th Revision, diagnostic codes, and refractive status. The validity of these definitions was evaluated in the subsequent validation study.

The validation study was conducted by reviewing EMR data from multiple centers, including university and general hospitals, and private ophthalmology clinics, to avoid institutional bias. Finally, we included 11 institutes, which comprised 2 university hospitals (Yamanashi University Hospital and Nagasaki University Hospital), 2 general hospitals (Kurashiki Central Hospital and Japanese Red Cross Wakayama Medical Center), and 7 private clinics (Musashi Dream Clinic, Morooka Eye Clinic, Niimi Eye Clinic, Ray Eye Clinic). We extracted the following patient data from the EMR: date of birth, sex, disease names and their diagnostic codes, date when the disease names were assigned, all refractive indices measured using an autorefractor, and the date of refraction measurement.

The validity of the claims-based definitions was evaluated for participants aged ≤14 years who underwent refraction measurement. First, we specified the earliest date of refraction measurement and excluded individuals without diagnostic codes for refractive errors within the same month. Second, we extracted the earliest measured refractive index and the corresponding diagnostic code for refractive error. In our validation study, we performed 2 distinct analyses. For myopia validation, we dichotomized patients into 2 groups based on their spherical equivalent: nonmyopia (>-0.5 D) and myopia (≤ -0.5 D). Separately, for high myopia validation, we performed another dichotomization: nonhigh myopia (>-6 D) and high myopia (≤ -6 D). This approach allowed us to properly calculate sensitivity, specificity, positive predictive value, and negative predictive value for both myopia and high myopia diagnoses independently. Additionally, we calculated the aforementioned values with age stratification.

In the case of multiple refraction measurements within a month, the most positive value was used for participants aged ≤ 8 years and the most negative value for those aged 9 to 14 years. This approach reflects the common clinical practice in Japan, where cycloplegic refraction is commonly performed in younger children (≤ 8 years), typically resulting in more positive refractive values compared with noncycloplegic measurements. In older children, where cycloplegia is less commonly used, we selected the more negative value for 2 reasons: first, the difference between cycloplegic and noncycloplegic measurements becomes minimal in this

We performed a national claims database analysis and validation study of the claims-based definitions of myopia and high myopia using electronic medical records (EMRs). This retrospective

	Location	Cycloplegia	Starting Year	Age at Baseline (Years)	Number of Participants at Baseline	Follow-Up Period	Annual Incidence	Study		
Study Design								Author	Journal	Published Year
Population- based	Netherlands	Yes	2008*	6	6690	3 years	3.5% [‡]	Tideman et al ¹⁰	Ophthalmology	2019
	United Kingdom	Yes	2006	6 12	399 669	6 years	2.2% 0.7%	McCullough et al ¹¹	PLOS One	2016
	Australia	Yes	2003	6^{\dagger} 12^{\dagger}	1765 2353	5-6 years	2.2% 4.1%	French et al ¹²	Ophthalmology	2013
	Hong Kong	Yes	2015 2019	6-8 6-8	1431 923	3 years 8 months	11.6% 29.7%	Zhang et al ¹³	British Journal of Ophthalmology	2021
	Taiwan	No	2009	7-12	1958	4 years	$6.9\%^{\ddagger}$	Ku et al ¹⁴	Ophthalmology	2019
		Yes	2013	7†	11 590	1 years	31.7%	Tsai et al ¹⁵	Investigative Ophthalmology & Visual Science	2016
	mainland	Yes	2006	6-15	3070	5 years	10.6%	Zhou et al ¹⁶	Journal of Epidemiology	2016
	China	Yes	2010	6-17	630	3-4 years	6.3%	Lin et al ¹⁷	British Journal of Ophthalmology	2022
School-based	mainland China	Yes	2010	6-8 [†]	1856	2 years	$18.1\%^{\ddagger}$	Ma et al ¹⁸	Clinical & Experimental Ophthalmology	2018
		No	2010	6^{\dagger} 12^{\dagger}	1975 2670	5 years 2 years	19.1%-30.2% 24.8%-29.1%	Wang et al ¹⁹	JAMA Ophthalmology	2018
		Yes	2012	6-11 [†]	2835	5 years	7.8%-25.3%	Li et al ²⁰	Investigative Ophthalmology & Visual Science	2022
		No	2014	6-10	1103	2 years	13.8% [‡]	Wong et al ²¹	BMJ Open Ophthalmology	2021
		Yes	2016	6^{\dagger} 12^{\dagger}	2432 2346	1 years	33.6% 54.0%	Li et al ²²	BMC Ophthalmology	2018
*Inferred from t [†] Converted grad	the description is des into ages.	n the paper.								

Table 1. Summary of Previous Cohort Studies Reporting the Incidence of Myopia in Children Since 2003

[‡]Calculated by dividing the cumulative incidence by the follow-up period.

age group, and, second, some measurements may have been taken over contact lenses, which typically yield more positive values.

Number of Incident Cases and Prevalence of Myopia and High Myopia

After linking all the claims as previously described,^{26,27} we identified the unique IDs of individuals diagnosed with myopia or high myopia between January 1, 2011, and December 31, 2020.

The prevalence was calculated based on individuals diagnosed with myopia at any time until October 1, 2020, when a census was conducted in Japan. The onset of myopia was defined as the date on which the claim containing the myopia diagnostic code was initially issued. Further, we counted the number of incident cases of myopia after 2014, having reserved 3 years from January 1, 2011, to December 31, 2013, as the washout period to ensure that it was the first diagnosis of myopia. In this study, "the number of incident cases" is reported as the number of new cases occurring per 10 000 individuals. A similar approach was used to calculate the prevalence and the number of children with high myopia, they were evaluated as a group at 5-year intervals in accordance with the Japanese regulations.

The 2020 population census, which was used to calculate the prevalence, and the annual estimates between 2014 and 2020 were provided by the Japanese Ministry of Internal Affairs and Communications; they were used to define the entire population and each subgroup population (available at https://www.stat.go.jp/en-glish/data/index.html, accessed April 24, 2023).

Impact of the COVID-19 Pandemic

In Japan, the first case and outbreak of COVID-19 were confirmed in January and February 2020, respectively. After the second outbreak in mid-March 2020, the Government of Japan declared a state of emergency on April 7, 2020. The third peak occurred at the beginning of August 2020.²⁸ Accordingly, the lifestyles of Japanese children changed dramatically, including extensive online schooling, less time spent outdoors, and increased screen time. Therefore, we compared the number of incident cases of myopia between 2019 (prepandemic) and 2020 (postpandemic).

Statistical Analysis

Values are presented as 95% confidence intervals where applicable. All analyses were performed using the R statistical software (R Foundation for Statistical Computing; URL: https://www.R-project.org/). Because the target of the current study was not a sampling dataset but a population itself, we did not need a statistical comparison.

Results

Validation Study

The validation study included 14 654 individuals aged \leq 14 years. Patient characteristics are summarized in Table S3 (available at www.ophthalmologyscience.org). There were 7232 males (49.4%), with a mean age of 7.90 \pm 3.57 years (mean \pm standard deviation) and a mean refractive index of -0.68 ± 2.76 D. Tables S4, S5 (available at www.ophthalmologyscience.org) present the validation study results. The overall sensitivity and specificity of the claims-based diagnosis of myopia were 88.5% and 79.2%,

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respectively. The sensitivity was >80% at \geq 4 years old. The specificity was greater than 75% at all ages except for 7, 8, and 14 years. When the myopia prevalence was assumed to be 20%, the positive and negative predictive values were 51.6% and 96.5%, respectively. When the myopia prevalence was assumed to be 80%, the positive and negative predictive values were 94.5% and 63.3%, respectively.

The overall sensitivity and specificity of the claims-based diagnosis of high myopia were 41.6% and 99.8%, respectively. Sensitivity tended to increase with age and was approximately 45% for children aged \geq 10 years. The confidence interval for sensitivity was relatively wide given the small number of children with high myopia. However, the specificity was >98% for all ages. Assuming a 0.5% prevalence of high myopia, the positive and negative predictive values were 53.7% and 99.7%, respectively.

Prevalence of Myopia

According to the 2020 population census in Japan, there were 14 955 692 children aged \leq 14 years. Among them, 5 498 764 patients were identified as having myopia on October 1, 2020, corresponding to a prevalence of 36.8%. When stratified according to age, the prevalence of myopia increased with age, rising to 83.2% at 14 years old (77.1% in men and 89.6% in women). The most rapid increase in the average myopia prevalence (19.4% to 50.4%) occurred between the ages of 6 and 9 years. When further stratified by sex, there were no sex differences up to the age of 7 years. However, from the age of \geq 8 years, the prevalence of myopia among women gradually surpassed that among men (Fig 1 and Table S6, available at www.ophthalmologyscience.org).

Number of Incident Cases of Myopia

Fig 2A and Table S7 (available at www.ophthalmology science.org) present the number of age-stratified incident cases of myopia between 2014 and 2020. There were 3 discontinuous changes in the number of incident cases between the ages of 2 and 3 years, 5 and 6 years, and 11 and 12 years, which corresponded to the beginning of the health checkup for 3-year-old infants, elementary school enrollment, and junior high school enrollment, respectively. The number of incident cases of myopia peaked at the age of 8 years after 2015, with an annual increase from 853.3 cases/ person-year in 2015 to 910.7 cases/person-year in 2020. There were annual increasing and decreasing trends in the number of incident cases of myopia among children aged 3 to 8 years and 10 to 14 years, respectively. Particularly, the largest decrease in the number of incident cases of myopia between 2014 and 2020 occurred among 14-year-old children (743.9 cases/person-year in 2014 to 566.7 cases/ person-year in 2020), followed by among 13-year-old children (794.9 cases/person-year in 2014 to 643.5 cases/ person-year in 2020).

Fig 2B, C present the comparisons of the number of age and sex-stratified incident cases of myopia between 2014 and 2019. In both 2014 and 2019, there was a sex difference in the number of incident cases of myopia among children aged \geq 7 years. In 2014, the number of incident cases of myopia exhibited a bimodal peak for both sexes, with the



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Figure 1. Prevalence of myopia in Japan stratified by age and sex in 2020. The prevalence increased with age from 19.4% at 6 years to 83.2% at 14 years. A rapid surge in prevalence was observed between the ages of 6 to 9 years, increasing from 19.4% to 50.4%. Although there were no sex differences in the prevalence up to the age of 7 years, the prevalence among women exceeded that among men from the age of 8 years onward.



Figure 2. Number of age- and year-stratified incident cases of myopia from 2014 to 2020 (**A**); number of age- and sex-stratified incident cases of myopia in 2014 (**B**) and 2019 (**C**). (**A**) Three discontinuous changes corresponded to the beginning of health checkups for 3-year-old infants, elementary school enrollment, and junior high school enrollment, respectively. There was an annual increasing and decreasing trend in the number of incident cases of myopia from 2014 to 2020 was observed in children aged 3 to 8 years and 10 to 14 years, respectively. Particularly, the largest decrease in the number of incident cases of myopia from 2014 to 2020 was observed in children aged 14 years. A decrease and increase in the number of incident cases in 2020 compared with that in 2019 were observed in children aged 3 to 6 years and 8 to 11 years, respectively. *Elementary school enrollment. †Junior high school enrollment. (**B**, **C**) In both 2014 and 2019, there were sex differences in the number of incident cases among children aged \geq 7 years. A bimodal pattern of the number of incident cases was observed in both years: (**B**) in 2014, peaks occurred at ages 9 and 12 years, (**C**) whereas, in 2019, peaks occurred at ages 8 and 12 years, with the peak in 2019 showing a lower rate than that in 2014.



Figure 3. For both high myopia (A–D) and myopia (E–H): Age- and sex-stratified prevalence in 2020 (A, E); number of age-stratified incident cases from 2014 to 2020 (B, F); Number of age- and sex-stratified incident cases in 2014 (C, G) and 2019 (D, H). The prevalence of high myopia increased with age and tended to increase in women with increasing age (A), which was similar to the trend observed for myopia (E). The number of incident cases of high myopia increased from 2014 to 2020 in both the 5 to 9 years and 10 to 14 years age groups (B). Contrastingly, the number of incident cases of myopia showed an increasing and decreasing trend for ages 5 to 9 years and 10 to 14 years, respectively (F). Comparing the number of sex-specific incident cases of high myopia and myopia in 2014 and 2019 revealed that the aforementioned trends were observed in both men and women (C, D, G, and H).

first and second peaks occurring at the ages of 9 and 12 years, respectively. Another bimodal peak was observed in 2019, with the first and second peaks occurring at the ages of 8 and 12 years, respectively; however, the number of incident cases was lower than that in 2014 (Fig 2B, C, and Table S8, available at www.ophthalmologyscience.org).

Prevalence and Number of Incident Cases of High Myopia

Fig 3 shows the comparison of the age and sex-stratified prevalence, the number of age-stratified incident cases from 2014 to 2020, and the number of age and sex-stratified incident cases in 2014 and 2019 between high myopia and myopia. The prevalence of high myopia increased with age to 0.46% (0.42% in men and 0.51% in women) in the 10 to 14 years age group. Although it was similar between men and women in the 5 to 9 years age group, it was higher among women in the 10 to 14 years age group.

The number of incident cases of high myopia increased from 2014 to 2020 in both the 5 to 9 years and 10 to 14 years age groups (1.21 cases/person-year in 2014 to 1.75 cases/person-year in 2020 and 12.4 cases/person-year in 2014 to 13.7 cases/person-year in 2020, respectively). Comparisons of the number of sex-specific incident cases of high myopia and myopia in 2014 and 2019 confirmed the aforementioned trends in both men and women.

Impact of the COVID-19 Pandemic on the Number of Incident Cases of Myopia

Fig 2A shows a comparison of the number of age-stratified incident cases of myopia between 2014 and 2020. Within this dataset, we conducted a focused comparison between 2019 and 2020. The number of incident cases of myopia decreased and increased in 2020 compared with 2019 among children aged 3 to 6 years and 8 to 11 years, respectively. The number of incident cases of high myopia increased from 2019 to 2020 in all age groups (0–4 years, 0.59 cases/person-year in 2019 to 0.68 cases/person-year in 2020; 5–9 years, 1.51 cases/person-year in 2019 to 1.75 cases/person-year in 2020; and 10–14 years, 13.5 cases/person-year in 2019 to 13.7 cases/person-year in 2020).

Discussion

We conducted a nationwide claims database study to assess the epidemiology of myopia in Japan. Further, we clarified the epidemiology of early-onset high myopia, which is often associated with irreversible visual impairment in the middle or later stages of life. Given the public health threat of myopia, this study provides significant implications with respect to public health and the elucidation of the epidemiology of myopia because it is the first nationwide claims database study on the prevalence and incidence of myopia and early-onset high myopia.

Myopia is caused by the combined influence of genetic and environmental factors.²⁹⁻³² However, recently, there has been an increase in the prevalence of myopia, especially among young individuals,^{33,34} which could be attributed to factors such as prolonged reading of books and the widespread use of digital devices, which increases screen time and reduces the time spent outdoors.35-37 Because the myopia-related decrease in uncorrected visual acuity affects daily life and academic performance, some Asian countries with a high prevalence of myopia have implemented myopia prevention programs.³ Women are considered to have a higher prevalence of myopia than men; however, the age at which sex differences emerge remains unclear. Our results demonstrated that the myopia prevalence started gradually showing sex differences after the age of 8 years, reaching a difference of >10% by the age of 14 years. These findings could inform future policymaking and educational campaigns. Further studies are warranted to elucidate the pathogenesis of myopia.

Although several studies have investigated the incidence of myopia among schoolchildren, this is the first nationwide comprehensive study. Table 1 summarizes the literature published over the past 2 decades. There are considerable variations in the reported prevalence rates, even in Asia. For example, the incidence rates ranged from 31.7% in Taiwan¹⁵ to 10.6% in China.¹⁶ This discrepancy can be attributed to various factors, including geographical distinctions within the same country (such as urban or rural areas) and even variances within the same urban locality (such as areas with higher and lower rates of educational advancement). In our study, the number of incident cases of myopia was highest at the age of 8 years, with 868.5 cases per 10 000 person-years, which is consistent with previous reports. Because this was a nationwide comprehensive study, the validity of the results can be considered high.

Consistent with the progressive decrease in the age of myopia onset, the number of incident cases of myopia showed an upward and downward trajectory among children aged <8 years and \geq 10 years, respectively (Fig 2A). When stratified by sex, a divergence in the number of incident cases emerged at the age of 7 years, consistent with the sex differences observed in the number of incident cases from the age of \geq 8 years (Fig 1, Fig 2B). Furthermore, there was a gradual decrease in the age of myopia onset in both sexes, indicating the absence of sex differences in this trend. The current nationwide surveys, when interpreted alongside other epidemiological evidence, provide insights into myopia trends and may serve as one of the monitoring indicators.

Nationwide surveys are beneficial for both policy evaluation and natural experiments. In the present study, the COVID-19 pandemic provided the context for a natural experiment. Generally, a decrease in the number of incident cases was observed in 2020, particularly in preschool children aged 3 to 6 years. This likely reflects strong reductions in medical visits due to the pandemic rather than an actual decrease in myopia onset. It is presumed that, for young children, there was a stronger tendency to refrain from seeking medical attention for less urgent symptoms during this period. Nevertheless, despite the tendency to avoid health care visits, the number of incident cases of myopia exhibited a discontinuous increase in 2020 in children aged 8 to 11 years, which deviated from the previous annual trend (Fig 2A). This can be attributed to the aforementioned unique conditions of the COVID-19 pandemic (i.e., a reduction in the time spent outdoors and an increase in the screen time).

High myopia can cause complications and irreversible visual impairment. It is known to increase the risk of glaucoma by 7.3 times,³⁹ retinal detachment by >21.5 times,⁴⁰ and myopic macular degeneration by 60 times.^{40,41} Complications of high myopia are a significant cause of blindness in developed countries, making it a significant public health issue. Despite the increasing prevalence of high myopia among school-age children, there have been no nationwide surveys, with several cohort studies being the only reference for its prevalence and incidence rates. The largest study evaluating the prevalence of high myopia in children was the Beijing Childhood Eye Study in 2014, which reported that the prevalence of high myopia was 3.1% among children aged 10 to 14 years.⁴² Additionally, a survey conducted in Hong Kong between 2005 and 2010 reported a high myopia prevalence of 3.8% among 12year-olds.43 These findings may reflect the characteristics of urban areas, which may have resulted in higher numbers. In the current study, the prevalence of high myopia was 0.46% among children aged 10 to 14 years, which was lower than previously reported values. However, despite the relatively low prevalence of high myopia, an increasing trend was observed between 2014 and 2019 for both the 5 to 9 years and 10 to 14 years age groups, with increases by 1.45 times and 1.10 times, respectively.

Despite the aforementioned strengths of this nationwide claims database study, there are claims database analysisspecific limitations. First, the accuracy of the diagnosis is generally a major limitation. To address this issue, we conducted a validation study covering various regions and institutional scales. The validation study revealed good diagnostic accuracy (Table S4), indicating the reliability of our findings. Second, the claims database analyses cannot account for patients who did not visit the hospital. Although Japan's school health system encourages ophthalmic examinations for children with reduced visual acuity, the voluntary nature of compliance means we cannot assume complete coverage of all myopic children. This, combined with variations in examination procedures such as the use of cycloplegic refraction, introduces uncertainty into our prevalence estimates. Moreover, caution is warranted when interpreting data from the pandemic period. This is because changes in health care seeking behavior may have influenced the results. Third,

although Japan's universal health insurance system provides standardized coverage and predictable costs nationwide, we acknowledge that economic factors may still influence health care-seeking behavior as well. Finally, although the NDB serves as a comprehensive administrative database encompassing most medical care services across the entire Japanese population, it does not incorporate medical care expenses covered by social welfare programs or industrial accident compensation insurance. Consequently, we may have overlooked some myopia cases. Nevertheless, given

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the infrequency of such cases, we posit that their impact on the overall findings is minimal.

In conclusion, this is the first comprehensive nationwide claims database study on myopia and high myopia that evaluated their prevalence and the number of incident cases. Because myopia and high myopia are public health threats, understanding their epidemiology is of great importance. The current study offers valuable information for future myopia prevention strategies and policy-making in various countries, particularly in Asia.

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HUMAN SUBJECTS: Human subjects were included in this study. This retrospective observational study was approved by the ethics committees of Kyoto University Hospital and Kyoto University Graduate School of Medicine (No. R2405 and R2793) and the study adhered to the tenets of the Declaration of Helsinki. Informed consent was obtained using an opt-out method.

No animal subjects were used in this study.

Author Contributions:

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Abbreviations and Acronyms:

COVID-19 = coronavirus disease 2019; D = diopters; EMR = electronic medical record; MHLW = Japanese Ministry of Health, Labour and Welfare; NDB = National Database of Health Insurance Claims and Specific Health Checkups of Japan.

Keywords:

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