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Original Article

Small-for-Gestational-Age Status and the Risk of Kawasaki Disease: A Nationwide Birth Cohort in Japan

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Kawasaki disease (KD) is a pediatric disease of unknown etiology that commonly affects infants in East Asia. Infants born small for gestational age (SGA) have weaker immune systems and are more susceptible to infection. Using data from a nationwide Japanese birth cohort study conducted in 2010 (n = 34,579), we investigated whether SGA increases the risk of KD. SGA was defined as birth weight below the 10th percentile for gestational age. The outcome was hospitalization for KD between 6 and 30 months of age. The association between SGA and hospitalization for KD, adjusted for child and maternal factors, was examined using logistic regression. Of the 231 children hospitalized for KD, 9.5% were SGA. Further statistical analysis showed that SGA did not increase the odds ratio (OR) of hospitalization for KD (adjusted OR 1.12, 95% confidence interval 0.71-1.75). This result was not changed with stratification by early daycare attendance and preterm status. Reasons for the lack of association may include the multifactorial pathogenesis of KD; in addition, the types of infections to which SGA infants are predisposed may differ from those triggering KD. Overall, our large nationwide study found no association between SGA and KD.

Key words: Kawasaki disease (KD), small for gestational age (SGA), cohort, epidemiology

Kawasaki disease (KD) is a disease with major symptoms of fever, bilateral conjunctival redness, flushing of the lips, redness of the pharyngeal mucosa, indeterminate rash, extremity end changes, and cervical lymphadenopathy. It usually occurs in very young children 6 months to 4 years of age, peaking at the age of around one year [1]. Although KD occurs worldwide, it is much more common in Japan, where about 10,000 cases occur annually [2]. KD is thought to be a multifactorial disease influenced by both infectious and genetic factors, as it is more common in East Asians and often runs in families [1]. The history of nationwide epidemics of KD in Japan indicates that an infectious disease is likely involved, but the specific causative organism or virus has not yet been identified.

Small-for-gestational-age (SGA) infants are defined according to the International Classification of Diseases as having a birth weight and height less than the 10th percentile of gestational age for normal birth (https://icd.who.int/browse10/2019/en#/P05.1 [accessed Feb 10, 2024]) [3]. SGA children have weaker immune systems and are more susceptible to infection than appropriate-for-gestational-age (AGA) children [4]. Because infection is suspected to be one of the factors contributing to KD, we hypothesized that SGA children, being susceptible to infection, would be at greater risk of developing KD. Although many previous studies have focused on the factors contributing to KD [5-8], no study has examined the association between SGA and risk of KD.

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Therefore, the purpose of this study was to use data from a nationwide birth cohort in Japan to examine the potential association between SGA and the development of KD.

Methods

Study participants. We used data from the Longitudinal Survey of Babies in the 21st Century (2010 cohort), conducted by the Ministry of Health, Labour and Welfare (MHLW) for all newborns born in Japan between May 10 and May 24, 2010. This longitudinal survey of children's upbringing, including both environment and health status, has been conducted as part of the measures to combat Japan's declining birthrate. When the eligible children were 6 months old, the first basic questionnaire was sent to their parents. Of the 43,767 eligible children, 38,554 parents completed and returned the initial survey form (response rate: 88.1%) (Fig. 1). Parents of children who responded to the initial questionnaire were sent follow-up questionnaires at 1-year intervals (at 18 and 30 months of age). Data were linked to birth records in the Japanese Vital Statistics System. Birth records included birth length, birth weight, gestational age, singleton/twin/other-multiple status, sex, birth order, and age of parents at birth. Of the 38,554 children whose parents responded to the initial questionnaire, 137 were excluded for lack of birth weight information. The 3,838 children with missing hospitalization information in the second and third surveys were excluded, leaving 34,579 children for analysis.

SGA status (Exposure). In Japan, according to the International Classification of Diseases (ICD-10), SGA is defined as having both birth weight and height below the 10th percentile for gestational age (https://icd.who.int/browse10/2019/en#/P05.1 [accessed Feb 10, 2024]). However, because of the imprecision in measuring height at birth, many previous studies have defined SGA by birth weight alone (https://www.ncbi.nlm.nih.gov/books/NBK563247/ [accessed Feb 10, 2024]) [9]. In this study, SGA infants were defined as those having a birth weight less than the 10th percentile, depending on gestational week [3, 10, 11]. Birth weight and gestational week data were collected from birth records. A dichotomized variable for SGA status was created, with those having birth weights per gestational week below the 10th percentile defined as SGA and all others as non-SGA.

Hospital admission for KD (Outcome measures). The second and third surveys asked whether the child had been hospitalized for any reason between the ages of 6 and 18 months (second survey) and between 18 and 30 months (third survey). Parents chose the cause of hospitalization from a list of specific disease options. If the reason for hospitalization was KD, the child was

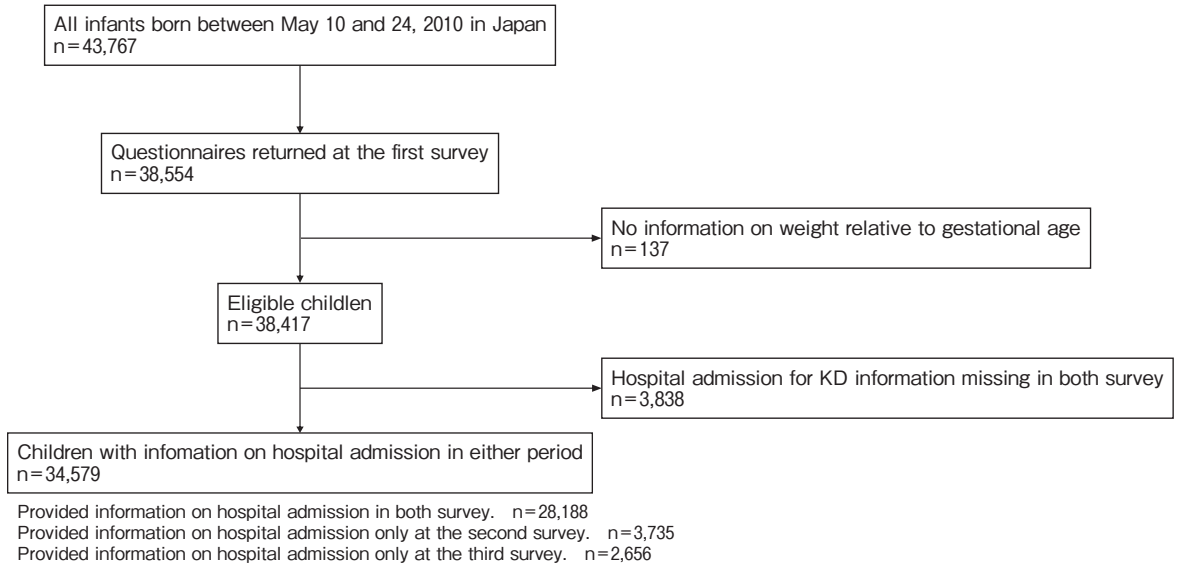

Fig. 1 Flowchart of participants.

considered to have contracted KD during the targeted period. In Japan, the incidence of KD is particularly high between the ages of 6 months and 2-3 years [2], and guidelines essentially require hospitalization for treatment (https://jskd.jp/wp-content/uploads/2022/10/tebiki201906.pdf [accessed Feb 10, 2024]) [12]; thus, at least one hospitalization for KD between 6 and 30 months of age was used as an outcome marker for the development of KD.

Statistical analysis. To assess the impact of loss to follow-up, we first compared baseline characteristics of children with hospitalization information between 6 and 30 months of age (eligible children) and those without hospitalization information (lost to follow-up). Then, among children included in the final analysis, we compared the baseline characteristics of the 27,957 children without KD admission and the 231 children with KD admission between 6 and 30 months of age. The association of SGA with KD hospitalization between 6 and 30 months of age was analyzed using a logistic regression analysis with non-SGA as the control group. We calculated crude odds ratios (ORs) and adjusted ORs with 95% confidence intervals (CIs), adjusting for potential confounders. We selected maternal and child factors as potential confounders based on previous findings and prior knowledge of SGA birth, KD onset, and childhood infection [13-15]. In Model 2, we adjusted for maternal factors, and in Model 3, we adjusted for child factors in addition to maternal factors (adjusted models). Maternal factors included maternal age at delivery (categorical) and maternal smoking status (binary). Maternal age at delivery, sex of the child, singleton or multiple birth, number of weeks of gestation, and number of previous deliveries were obtained from birth records. The child factors considered were sex (binary), singleton or multiple birth (binary), preterm birth (binary: ≥ 37 weeks gestation or <37 weeks gestation), parity number (binary: 0 or ≥ 1), breastfeeding status (categorical: formula-fed, partially breastfed, fully breastfed), and early childhood daycare attendance status (binary). The children who mainly had a childcare worker or babysitter take care of them on weekdays at either 6 months (first survey) or 18 months (second survey) of age were considered to be in the early childhood daycare attendance group (*i.e.*, receiving care from a third party).

A sensitivity analysis was performed excluding large-for-gestational-age (LGA) children from the control group. Further subgroup analyses were performed to examine whether the relationship between SGA and KD differed by daycare attendance (third-party care) status. Similarly, we performed subgroup analysis stratified by preterm delivery status. Complete case analysis was conducted, with exceptions for patients with missing data. The statistical software Stata SE version 17 (StataCorp, College Station, TX, USA) was used for the analysis. This study was approved by the Institutional Review Board (No. 1506-073) of the Graduate School of Biomedical Sciences, Okayama University.

Results

Baseline characteristics of children with hospitalization information between 6 and 30 months of age (eligible children) and those without hospitalization information (lost to follow-up) are shown in Table 1. Children with missing hospitalization information were more likely to be formula-fed, to be home-cared, to have a younger mother at birth, and to have a mother who smoked. Of the 28,188 children with hospitalization information in the second and third surveys, we compared the baseline characteristics of the 27,957 who did not develop KD and the 231 who did (Table 2). The 2-year cumulative incidence of KD was 0.82%. Among the eligible children, 5.2% were preterm, 8.3% were SGA children, and 28.5% were in daycare attendance. Children hospitalized with KD tended to be born in multiple births, to be formula-fed, to be second or subsequent children, to attend daycare, to have an older mother, and to have a mother who smoked, compared to children who were not hospitalized.

We performed a logistic regression analysis to evaluate the association between SGA and KD (Table 3). The OR for SGA children compared to non-SGA was 1.16 (95% CI: 0.75-1.81) in the crude model, 1.15 (95% CI: 0.74-1.79) in model 2, which adjusted for maternal factors, and 1.12 (95% CI: 0.71-1.75) in model 3, which adjusted for both maternal and child factors. The sensitivity analysis excluding 2,804 children with LGA did not change the main results (Table 4).

The subgroup analysis stratified by daycare attendance status from 6 to 30 months of age is presented in Table 5. There was no significant difference in ORs when the results were stratified by daycare attendance status. A subgroup analysis stratified by full-term and

Table 1 Demographic characteristics of eligible children with or without KD hospital admission data (n = 38,417)

	Eligible children (n = 38,417)		Included in the Analyses (n = 34,579)		Without KD Admission Information (n = 3,838)	
Characteristics of children						
Sex, n (%)[a]						
Male	19,776	(51.5)	17,805	(51.5)	1,971	(51.4)
Female	18,641	(48.5)	16,774	(48.5)	1,867	(48.7)
Singleton or multiple birth, n (%)[a]						
Singleton birth	37,695	(98.1)	33,948	(98.2)	3,747	(97.6)
Multiple birth	722	(1.9)	631	(1.8)	91	(2.4)
Term or preterm birth, n (%)[a]						
Term birth	36,321	(98.5)	32,734	(94.7)	3,587	(93.5)
Preterm birth	2,096	(5.5)	1,845	(5.3)	251	(6.5)
Parity, n (%)[b]						
0	17,971	(46.8)	16,133	(46.7)	1,838	(47.9)
≥1	20,446	(53.2)	18,446	(53.3)	2,000	(52.1)
Breastfeeding status, n (%)[b]						
Formula feeding without colostrum	1,340	(3.5)	1,125	(3.3)	215	(5.7)
Partial breastfeeding	23,906	(62.8)	21,433	(62.5)	2,473	(65.6)
complete breast-feeding	12,836	(33.7)	11,752	(34.3)	1,084	(28.7)
SGA status, n (%)[a]						
SGA	3,243	(8.4)	2,906	(8.4)	337	(8.8)
Non-SGA	35,174	(91.6)	31,673	(91.6)	3,501	(91.2)
Daycare attendance, n (%)[b,c]						
Not Attending	23,918	(72.0)	23,612	(71.9)	306	(84.5)
Attending	9,309	(28.0)	9,253	(28.2)	56	(15.5)
Maternal characteristics						
Maternal age at delivery, n (%)[a]						
<25	3,761	(9.8)	2,919	(8.4)	842	(21.9)
25–30	10,844	(28.2)	9,642	(27.9)	1,202	(31.3)
30–35	14,169	(36.9)	13,088	(37.9)	1,081	(28.2)
≥35	9,643	(25.1)	8,930	(25.8)	713	(18.6)
Maternal smoking status, n (%)[b]						
Nonsmoker	35,631	(93.0)	32,414	(94.0)	3,217	(84.3)
Smoker	2,676	(7.0)	2,077	(6.0)	599	(15.7)

[a]Obtained from the birth record, [b]Obtained from the first survey (at age 6 months), [c]Obtained from the second survey (at age 18 months).

preterm birth is presented in Table 6. There was no significant association between SGA and KD hospitalization within the full-term or preterm birth groups, but the point estimate for the OR tended to be lower for preterm births.

Discussion

In this study, we examined the association between SGA births and the development of KD in early childhood using data from a nationwide longitudinal birth cohort in Japan. The results showed that SGA status was not associated with the risk of hospitalization for KD between 6 and 30 months of age. Sensitivity analysis excluding LGAs did not change the main results. The absence of an observed association between SGA children and KD was consistent with the clinical impression that intrauterine growth restriction may not significantly increase the risk of developing KD in early childhood, possibly due to distinct pathogenic mechanisms involved. Previous studies have shown that SGA children have a higher risk of hospitalization for gastro-

Table 2 Demographic characteristics of eligible children with data of KD hospital admission from 6 to 30 months of age (n=28,188)

	Total (n=28,188)		No Admission (n=27,957)		Admission (n=231)	
Characteristics of children						
Sex, n (%)[a]						
Male	14,582	(51.7)	14,451	(51.7)	131	(56.7)
Female	13,606	(48.3)	13,506	(48.3)	100	(43.3)
Singleton or multiple birth, n (%)[a]						
Singleton birth	27,684	(98.2)	27,460	(98.2)	224	(97.0)
Multiple birth	504	(1.8)	497	(1.8)	7	(3.0)
Term or preterm birth, n (%)[a]						
Term	26,728	(94.8)	26,511	(94.8)	217	(93.9)
Preterm	1,460	(5.2)	1,446	(5.2)	14	(6.1)
Parity, n (%)[b]						
0	13,157	(46.7)	13,066	(46.7)	91	(39.4)
≥1	15,031	(53.3)	14,891	(53.3)	140	(60.6)
Breastfeeding status n (%)[b]						
Formula feeding without colostrum	842	(3.0)	827	(3.0)	15	(6.5)
Partial breastfeeding	17,410	(62.2)	17,271	(62.2)	139	(60.2)
complete breast-feeding	9,759	(34.8)	9,682	(34.9)	77	(33.3)
SGA status, n (%)[a]						
SGA	2,345	(8.3)	2,323	(8.3)	22	(9.5)
Non-SGA	25,843	(91.7)	25,634	(91.7)	209	(90.5)
Daycare attendance, n (%)[b,c]						
Attending	8,042	(28.5)	7,960	(28.5)	82	(35.5)
Not Attending	20,137	(71.5)	19,988	(71.5)	149	(64.5)
Maternal characteristics						
Maternal age at delivery, n (%)[a]						
<25	1,982	(7.0)	1,971	(7.1)	11	(4.8)
25–30	7,627	(27.1)	7,576	(27.1)	51	(22.1)
30–35	10,969	(38.9)	10,881	(38.9)	88	(38.1)
≥35	7,610	(27.0)	7,529	(26.9)	81	(35.1)
Maternal smoking status, n (%)[b]						
Nonsmoker	26,727	(95.0)	26,516	(95.0)	211	(92.5)
Smoker	1,404	(5.0)	1,387	(5.0)	17	(7.5)

[a]Obtained from the birth record, [b]Obtained from the first survey (at age 6 months), [c]Obtained from the second survey (at age 18 months).

Table 3 SGA and KD hospital admission from 6 to 30 months of age

		OR (95% CI)		
	case/total	Model1 crude n=28,188	Model2[a] n=28,131	Model3[b] n=27,954
Non-SGA	209/25,843	1 (reference)	1 (reference)	1 (reference)
SGA	22/2,345	1.16 (0.75–1.81)	1.15 (0.74–1.79)	1.12 (0.71–1.75)

CI, confidence interval; KD, Kawasaki disease; OR, odds ratio; SGA, small for gestational age.
[a]Adjusted for maternal factors (maternal age category, maternal smoking status), [b]Adjusted for maternal factors (maternal smoking status, maternal age category), children's factors (sex, parity, preterm birth, singleton or multiple birth, daycare attendance, breastfeeding status).

Table 4 Relationship between SGA and KD hospitalization from 6 to 30 months of age, stratified by daycare attendance

		OR (95% CI)		
	case/total	Model1 crude n=28,179	Model2[a] n=28,122	Model3[b] n=27,946
Not Attending				
Non-SGA	134/18,448	1 (reference)	1 (reference)	1 (reference)
SGA	15/1,689	1.05 (0.48–2.30)	1.05 (0.48–2.28)	0.98 (0.44–2.15)
Attending				
Non-SGA	75/7,388	1 (reference)	1 (reference)	1 (reference)
SGA	7/654	1.22 (0.71–2.09)	1.21 (0.71–2.08)	1.20 (0.70–2.07)

CI, confidence interval; KD, Kawasaki disease; OR, odds ratio; SGA, small for gestational age.
[a]Adjusted for maternal factors (maternal age category, maternal smoking status), [b]Adjusted for maternal factors (maternal smoking status, maternal age category), children's factors (sex, singleton or multiple birth, parity, preterm birth breastfeeding status).

Table 5 SGA and KD hospital admission from 6 to 30 month of age (Exclude LGA)

		OR (95% CI)		
	case/total	Model1 crude n=25,384	Model2[a] n=25,331	Model3[b] n=25,170
Non-SGA	182/23,039	1 (reference)	1 (reference)	1 (reference)
SGA	22/2,345	1.18 (0.76–1.86)	1.18 (0.76–1.84)	1.14 (0.73–1.80)

CI, confidence interval; KD, Kawasaki disease; LGA, Large for Gestational Age; OR, odds ratio; SGA, small for gestational age.
[a]Adjusted for maternal factors (maternal age category, maternal smoking status), [b]Adjusted for maternal factors (maternal smoking status, maternal age category), children's factors (sex, parity, preterm birth, singleton or multiple birth, daycare attendance, breastfeeding status).

Table 6 Relationship between SGA and KD hospitalization from 6 to 30 months of age, stratified by full-term and preterm birth

		OR (95% CI)		
	case/total	Model1 crude n=28,188	Model2[a] n=28,131	Model3[b] n=27,946
Full term bith				
Non-SGA	197/24,636	1 (reference)	1 (reference)	1 (reference)
SGA	20/2,092	1.19 (0.75–1.90)	1.19 (0.75–1.90)	1.20 (0.75–1.91)
Preterm birth				
Non-SGA	12/1,207	1 (reference)	1 (reference)	1 (reference)
SGA	2/253	0.79 (0.18–3.57)	0.78 (0.17–3.53)	0.68 (0.14–3.24)

CI, confidence interval; KD, Kawasaki disease; OR, odds ratio; SGA, small for gestational age.
[a]Adjusted for maternal factors (maternal age category, maternal smoking status), [b]Adjusted for maternal factors (maternal smoking status, maternal age category), children's factors (sex, singleton or multiple birth, parity, daycare attendance, breastfeeding status).

enteritis and respiratory infections in early childhood [16]. Meanwhile, findings suggest that the risk of developing KD is higher in situations where the risk of infection is higher, such as late birth order and early daycare attendance [8]. The intensification of hygiene behaviors and maintenance of social distance resulting from the COVID-19 pandemic [17,18] caused a reduction in viral infections [18,19] and a decrease in KD cases worldwide [17,19-22]. Taken together, these findings strongly suggest an association between KD incidence and infectious diseases. On the basis of these previous studies, we hypothesized that KD may be more likely to occur in SGA children, who are at increased risk for infection. However, our study, which examined the association between SGA and KD hospitalization in a large Japanese birth cohort, showed that SGA did not increase the risk of KD. The results did not change when stratified by early daycare attendance status and preterm birth status. Although KD is found worldwide, evidence for genetic factors in the etiology of KD includes the high incidence rates in East Asian populations such as those of Japan, Korea, and Taiwan, particularly in Japanese, where the incidence rate is 10-15 times that of Caucasians, and the high relative risk among siblings. Environmental factors have been shown to include the presence of epidemics, regionality, and seasonality [23]. Indeed, one of the reasons why this study found no association between SGA and KD may well be this multifactorial etiology of KD [23].

Although the causes of KD have been studied throughout the world, the specific factors leading to the development of KD have not been elucidated. As mentioned above, the higher risk of infection that SGA children carry may not have had a significant effect on the risk of KD because multiple factors are involved in the development of KD. Furthermore, infections with a high risk in SGA children may not necessarily be the same infections that are likely to cause KD [24]. Pathogens that have been reported as possible triggers of KD include *Staphylococcus aureus* and *Streptococcus pyogenes* [14], adenovirus, herpes virus, and parainfluenza virus [14]. The susceptibility of SGA children to these pathogens remains uncertain [23,25]. The results of this study have important implications for elucidating the cause of KD.

The principal strength of this study is that it was conducted on a large scale, including approximately one-twentieth of the children born in Japan in 2010. Therefore, we had a relatively large number of KD cases and considered the data sufficient to identify an association between SGA children and the development of KD, had there been any. In addition, the incidence rate of KD reported in Japan [2] is similar to that found in this study population, suggesting the representativeness of this study population among Japanese children as a whole. Furthermore, the results of this study can be said to be representative of Japanese births. The high response rate at baseline (88.1%) strengthens the validity of our findings. Moreover, we were able to adjust for a wide range of potential confounders, including child and parental factors.

Limitations. The cohort included children born during a specific period (May 10-24, 2010); thus, the seasonality of KD and infection may have affected the age of onset and number of KD cases in the current cohort. In Japan, the incidence of KD has been shown to be higher in January [2]. The generalizability of the results of this study is unclear, as the possibility of an increased risk of KD onset for SGA children born at other times of the year cannot be ruled out. Second, the questionnaire was answered based on parental recall and had no medical validation. However, recall bias is unlikely because the survey asked specifically about hospitalizations for KD in the most recent year. In Japan, diagnostic criteria for KD are standardized based on the Kawasaki Disease Diagnostic Guidelines (Revised: 6th Edition) [26], and patients are hospitalized for treatment according to the guidelines. Third, it was not possible to distinguish between typical, atypical, and incomplete KD and to obtain information on treatment and evaluation. Whether or not patients respond to IVIG is an issue of great importance, but this issue could not be evaluated due to lack of information. Finally, because of the lack of family history information, we could not correct our data for family history of KD, despite several studies having reported an association between KD and genetic factors, with a higher incidence of KD in the siblings of patients with the disease [27].

In the present study, we examined SGA and development of KD, focusing on susceptibility to infection, but found no association. The effect of the higher risk of infection in SGA children may have been diluted by the multifactorial nature of KD [28]. On the other hand, the infections associated with SGA and those that trigger KD may be different. Future studies should further

investigate the differences in infections associated with SGA children and those with KD.

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