Epidemiology of Kawasaki Disease in South Korea: A Nationwide Survey 2015–2017

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Background: This study aimed to investigate recent epidemiologic features of Kawasaki disease (KD) in South Korea.

Methods: The ninth triennial nationwide questionnaire survey collected data on the demographic findings, symptoms and signs, treatment patterns and coronary artery complications of acute-phase KD occurred in 2015–2017 from 98 hospitals with pediatric residency programs and 108 community hospitals without residency programs.

Results: We received data from 93 of the 98 hospitals (response rate: 94.9%) with residency programs and 75 of the 108 community-based children's hospitals (response rate: 69.4%) without residency programs. In the 3-year survey period, a total of 15,378 (5449 in 2015, 5171 in 2016 and 4758 in 2017) cases of KD were reported. The mean age at diagnosis was 33.0 ± 24.8 months (range: 0–205 months), and the male-to-female ratio was 1.41:1. The overall KD incidence was 196.9 (202.2 in 2015, 197.1 in 2016 and 191.0 in 2017) per 100,000 younger than 5 years population. Recurrent cases were 4.85%. KD occurred more frequently during winter (December–January) and late spring (May–June). Intravenous immunoglobulin (IVIG) was administered to 95% of the patients; nonresponder rate for the first IVIG was 14.8%. Coronary artery aneurysms and giant coronary artery aneurysms (internal diameter >8 mm) occurred in 1.7% and 19 patients, respectively. Two patients died due to multiorgan failure and hepatic encephalopathy.

Conclusion: Peak incidence of KD in South Korea was 202.2 per 100,000 younger than 5 years population (2015), and the incidence of giant coronary artery aneurysm decreased to 0.09% (2017).

Key Words: Kawasaki disease, epidemiology, surveys and questionnaires, incidence, mucocutaneous lymph node syndrome

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Kawasaki disease (KD) is an acute, febrile, autoimmune, systemic vasculitis that most commonly affects patients younger than 5 years.¹ In most developed countries, KD is a leading cause of acquired heart disease in pediatric patients, with increasing inci-

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dences being reported from epidemiologic studies in these countries.¹⁻⁴ Evaluation of the actual, nationwide epidemiologic data of KD could help understand the pathophysiology or etiology of KD occurrences, facilitate the vigilance on KD among primary healthcare practitioners and parents and thereby reduce the complications of KD.^{2,3}

Epidemiologic data on KD can be obtained primarily through two commonly used methods—(1) active nationwide survey and (2) data from the national health insurance system.^{2,5,6} In South Korea, most KD patients are treated at the resident-training hospitals and the community-based children's hospitals. Therefore, we have conducted triennial nationwide surveys since 1994 using KD patient data that was recorded between 1991 and 1993. The latest reported incidence of KD in 2014 was 194.7 per 100,000 in those <5 years old.^{7–10}

We recently conducted the ninth nationwide survey for data on patients with acute-phase KD who were treated between January 1, 2015, and December 31, 2017. Our primary objective was to identify and quantify the latest epidemiologic features of KD in South Korea.

PATIENTS AND METHODS

We conducted a retrospective nationwide questionnaire survey under the guidance of the Korean Society of Kawasaki Disease to investigate recent epidemiologic features of KD. Data were collected on patients with acute-phase KD who were treated between January 1, 2015, and December 31, 2017. Questionnaires were sent both by regular mail and e-mail to 98 hospitals with residency programs and 108 community-based children's hospitals without residency programs. All patients with KD could receive treatment in these 206 hospitals under the health insurance system in South Korea. We received responses from 93 of the 98 hospitals with residency programs (response rate: 94.9%) and 75 of the 108 community-based children's hospitals without residency programs (response rate: 69.4%).

The questionnaire collected patient' demographic data including sex, body weight and height at diagnosis; date of birth; province of residence; date of KD diagnosis; all symptoms and signs, including pretreatment and total fever duration and recurrence; and acute treatment methods [eg, aspirin, intravenous immunoglobulin (IVIG), steroids, infliximab, plasmapheresis, etc.]. Moreover, we recorded coronary artery complications as well as coronary artery sizes (largest internal diameters) in the acute and recovery phases, recurrent cases and mortality cases. To ascertain the accurate KD incidence, we excluded the duplicated data of patients who had the same birthday, sex and KD-onset date, given the possibility of interhospital transfers.

The annual incidence of KD was calculated by dividing the total number of newly diagnosed KD patients by the total number of the general population of the same age group (<5, 5–9, 10–14 and 15–19 years) in each year from 2015 to 2017. Data on the general Korean pediatric population were obtained from the online database of the Korean Ministry of Security and Public Administration.

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The normal ranges of coronary artery size were defined based on the criteria by the Japanese Ministry of Health and Welfare.¹¹ Coronary artery dilatation, coronary artery aneurysm and giant coronary artery aneurysm were defined by the internal diameter of the coronary artery being smaller than 1.5 times the normal upper limit, 1.5 times or more of the normal upper limit and greater than 8 mm, respectively. For the purpose of this nationwide survey, patients were considered nonresponders to IVIG if they had persistent fever (>38°C) 36 hours or more after the completion of IVIG infusion or required second-line treatment of KD.¹

This survey was approved by the Institutional Review Board of Seoul National University Hospital (approval number: H-1710-109-895, dated November 20, 2017).

Data were analyzed using SAS version 9.2 (SAS Institute, Inc., Cary, NC). In the descriptive analysis, we calculated frequencies and percentages for categorical variables and means and standard deviations for continuous variables.

RESULTS

Demographic Characteristics

A total of 15,378 cases of KD were reported during the 3-year nationwide survey period (5449 in 2015, 5171 in 2016 and 4758 in 2017). The mean age at diagnosis was 33.0 ± 24.8 months (range: 0–205 months, median age: 28.5 months). KD occurred more frequently in male, and the male-to-female ratio was 1.41:1 (1.34:1 in 2015, 1.47:1 in 2016 and 1.40:1 in 2017).

Incidence of KD

The incidence of KD in the younger than 5 years population continuously increased over the past decade since 2000 and then plateaued since 2013 (Fig. 1). The incidence rates of KD by age groups are presented in Table 1, and age-specific distribution KD incidence is presented in Figure 2A. KD incidence was predominantly in the under 5 population (83.5% of all KD patients), although there were reported incidents of KD onset in the adolescent population. Furthermore, 14 patients in the age group of 15–20 years experienced acute KD during the survey period. The overall incidence of KD in the survey period was 196.9 (202.2 in 2015, 197.1 in 2016 and 191.0 in 2017) per 100,000 younger than 5 years population, with the highest incidence of KD in 2015 through all nationwide surveys conducted since 1994 in South Korea. A total of 517 patients (4.85%) were recurrent KD cases during this study



FIGURE 1. Yearly incidence pattern of Kawasaki disease in South Korea. The incidence of Kawasaki disease under 5 years has continuously increased since 2000 and shown plateau since 2013. The peak incidence of Kawasaki disease was 202.2 per 100,000 children under 5 years in 2015. period (5.17% in 2015, 4.32 in 2016 and 5.09% in 2017); of these, 70 patients had multiple KD recurrences and two patients had five episodes of KD recurrence. Age-specific distribution of KD recurrence is presented in Figure 2B.

Monthly Distribution of KD

The monthly KD occurrences from 2015 to 2017 are also shown (Figure, Supplemental Digital Content 1, http://links.lww. com/INF/E50). Although KD occurred throughout the year, KD incidence showed two discrete seasonal peaks: KD occurred more frequently in winter (December–January) and late spring (May– June) in South Korea. In previous surveys, the second seasonal peak of KD incidence was noted in summer in South Korea.^{7,9} KD occurred most frequently in January (10.8%), followed by December (10.1%); the lowest incidence was noted in autumn (7% in September and October) during this nationwide survey period.

Symptoms and Signs of KD

The mean total pretreatment duration of fever was 5.13 ± 1.81 days, and the mean total duration of fever was 6.49 ± 2.31 days. The most common symptoms and signs of KD except fever were bilateral conjunctival injection (87.8%), followed by mucosal changes such as red lips, strawberry tongue (82.8%) and polymorphic skin rash (76.4%). Redness and swelling of hands and feet were reported in 65.7% of patients, and cervical lymph node swelling was reported in 57.2% of patients. Erythema at the BCG site was reported in 40.8% of patients. Periungual desquamation was noted in 30.8% of patients during the follow-up period. In this survey period, 44.9% of patients had incomplete KD, with fewer than four symptoms and signs that constitute the diagnostic criteria of typical KD.⁴

Treatment Patterns in Acute-Phase KD

For the treatment of acute-phase KD, IVIG was administered in 95% of patients, which was similar to that of a previous survey.7 The initial dose of IVIG was 2 g/kg in 99.5% of IVIG treatments. The nonresponse rate for the first high-dose IVIG treatment was 14.8% during this survey period. Age-specific distribution of IVIG unresponsiveness of KD is presented in Figure 2C. In patients with resistance to the first dose of IVIG, the second dose of IVIG was administered in 84% of the patients, and intravenous methylprednisolone or oral steroid were administered in 14.1% and 1.4%, respectively. As the third-line treatment, a methylprednisolone pulse therapy was administered in 75.2% of patients, followed by infliximab in 9.3% and the third dose of IVIG in 8.1% of patients. As the fourth-line treatment, infliximab was administered to 52.4% of patients, followed by methylprednisolone pulse therapy in 21.4% of patients. This survey revealed that most centers in South Korea use high-dose IVIG as the first- and second-line treatment for acute-phase KD, whereas intravenous methylprednisolone and infliximab are used for the third and fourth-line treatment. From the multivariate analysis for risk factors of first-dose IVIG nonresponders (Table 2), male sex, total fever duration, more changes in the extremities, BCG site redness, higher neutrophil count, lesser platelet count before IVIG treatment, higher alanine aminotransferase, lower serum sodium and higher platelet count after IVIG treatment were risk factors of IVIG unresponsiveness.

Coronary Artery Complications and Mortality

The coronary artery complications are presented in Table 3. Coronary artery dilatation occurred in 17.1% of patients (18.2% in 2015, 17.7% in 2016 and 15.1% in 2017) and coronary artery aneurysm in 1.7% of patients. Age-specific distribution of coronary artery aneurysm occurrence is presented in Figure 2D. Giant

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	Under 5 years		5 to <10 years		10 to <15 years		15 to <20 years	
	Ν	Incidence*	Ν	Incidence*	Ν	Incidence*	Ν	Incidence*
2015	4583	202.2	601	25.8	47	1.9	4	0.1
2016	4344	197.1	574	24.3	28	1.2	6	0.2
2017	3970	191	569	24.2	34	1.4	4	0.1
Total	12,897	196.9	1744	24.7	109	1.5	14	0.2

TABLE 1.	The Incidence	Rate of Kawasak	i Disease b	oy Age Groups
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*The number of patients with Kawasaki disease per 100,000 subjects in each age group



FIGURE 2. Age-specific distribution for Kawasaki disease characteristics. Age-specific distribution of incidence (A) and recurrence (B) of Kawasaki disease and intravenous immunoglobulin unresponsiveness (C) and coronary artery aneurysm (D) in South Korea. The median onset age of Kawasaki disease was 28.5 months (range: 0–205 months), and peak onset age was 12 months.

coronary artery aneurysms (internal diameter >8 mm) developed in 19 patients (0.17%). For the patients refractory to the first course of IVIG, the percentage of coronary artery dilatation was 27.2% and the percentage of giant aneurysm was 0.27%. From the multivariate analysis for risk factors of coronary artery complication development (Table 4), male sex, higher age at diagnosis, less conjunctival injection, less changes in the lips, less changes in the extremities, less BCG site redness, less cervical lymphadenopathy, lower neutrophil count, lower platelet count before IVIG treatment, higher GPT, lower serum sodium, higher platelet count after IVIG treatment and higher IVIG resistance were risk factors of coronary artery lesion development. Two patients died during the survey period: one patient died due to multiorgan failure at 15 months of age and the other died from hepatic encephalopathy at 83 months of age.

DISCUSSION

The ninth nationwide survey revealed specific epidemiologic data of KD between 2015 and 2017 in South Korea. We tried to enroll as many hospitals as possible with facilities to treat acute-phase KD to achieve more accurate analysis of KD epidemiology. One of the most important findings in this survey is the highest incidence rate of KD recorded in 2015 (202.2 per 100,000 under 5 children), which is the second highest in the world after Japan.^{12,13} The overall incidence rate of KD in this survey period is also higher than those in previous nationwide surveys in South Korea (Fig. 1).^{7–10} However, we do not know why the incidence rate of KD has been increased steadily in South Korea. Possible explanations may be whether the true incidence rate of KD is increasing or more patients with KD are being reported in surveys or many physicians are becoming vigilant and diagnosing more patients with KD.

The most important factors in identifying the accurate incidence rate of KD are maximal enrollment of hospitals treating acute-phase KD and increasing the response rate to questionnaires in the nationwide survey.² Every country has a different healthcare system, which affects the characteristic of medical care. In South Korea, most patients with KD are treated at the 98 hospitals with residency programs and some patients with KD are treated at the 108 community-based children's hospitals without residency programs. The last nationwide survey

1014 | www.pidj.com

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TABLE 2.	Risk Factors for	Intravenous	Immunoglobulin	Unresponsiveness	for	Kawasaki
Disease						

	Univariable analysis		Multivariable analysis	
	OR (95% CI)	<i>P</i> -value	OR (95% CI)	<i>P</i> -value
Sex	0.867 (0.777, 0.967)	0.010	0.832 (0.695, 0.996)	0.045
Total fever duration	1.501 (1.463, 1.541)	< 0.001	1.941 (1.836, 2.051)	< 0.001
Change in extremities	1.381 (1.233, 1.547)	< 0.001	1.304 (1.066, 1.595)	0.010
BCG site redness	0.897 (0.805, 1.000)	0.049	1.311 (1.066, 1.612)	0.010
Neutrophil	1.455 (1.401, 1.510)	< 0.001	1.252 (1.161, 1.350)	< 0.001
Platelet before IVIG treatment	0.984 (0.979, 0.988)	< 0.001	0.959 (0.950, 0.969)	< 0.001
ALT	1.021 (1.018, 1.024)	< 0.001	1.010 (1.002, 1.019)	0.018
Na	0.316 (0.261, 0.384)	< 0.001	0.619 (0.446, 0.860)	0.004
Highest platelet after IVIG treatment	$1.035\ (1.032,\ 1.038)$	< 0.001	1.040 (1.034, 1.047)	< 0.001

BCG indicates Bacillus Calmette-Guérin; IVIG, intravenous immunoglobulin; ALT, alanine aminotransferase.

TABLE 3. Coronary Artery Complications of Kawasaki Disease Between 2015 and 2017

	Dilatation N (%)	Aneurysm N (%)	Giant aneurysm N (%)	Total N
2015	736 (18.21%)	67 (1.66%)	7 (0.17%)	4042
2016	671 (17.73%)	64 (1.69%)	9 (0.24%)	3785
2017	531 (15.12%)	60 (1.71%)	3 (0.09%)	3513
Total	1938~(17.09%)	191 (1.69%)	19 (0.17%)	11,340

TABLE 4. Risk Factors for Coronary Artery Lesion After Kawasaki Disease Treatment

	Univariable analysis		Multivariable analysis	
	OR (95% CI)	P-value	OR (95% CI)	P-value
Sex	0.668 (0.601, 0.743)	< 0.001	0.741 (0.637, 0.863)	< 0.001
Age at diagnosis	1.004 (1.002, 1.006)	< 0.001	1.005 (1.002, 1.009)	0.005
Conjunctival injection	0.486 (0.426, 0.555)	< 0.001	0.511 (0.416, 0.627)	< 0.001
Changes in the lips	0.586 (0.519, 0.662)	< 0.001	0.763 (0.630, 0.923)	0.005
Change in extremities	0.707 (0.638, 0.783)	< 0.001	0.839 (0.713, 0.987)	0.034
BCG site redness	0.717 (0.643, 0.799)	< 0.001	0.769 (0.645, 0.918)	0.004
Cervical lymphadenopathy	0.882 (0.798, 0.976)	0.015	0.805 (0.687, 0.942)	0.007
Na	0.516 (0.429, 0.620)	< 0.001	0.530 (0.402, 0.699)	< 0.001
Highest platelet after IVIG treatment	1.013 (1.010, 1.016)	< 0.001	1.011 (1.006, 1.017)	< 0.001
IVIG resistance	$1.933\ (1.715,\ 2.179)$	< 0.001	$1.577\ (1.274, 1.951)$	< 0.001

BCG indicates Bacillus Calmette-Guérin; IVIG, intravenous immunoglobulin.

in South Korea (2012–2014) included 19 community-based children's hospitals without residency programs.⁷ However, we contacted 108 community-based children's hospitals without residency programs in this survey, because community-based children's hospitals have been increasingly established since 2015 and started treating patients with KD during this survey period. As we did not obtain data from all of the 206 hospitals that were potentially treating patients with acute-phase KD, this study might underestimate a little the actual incidence rate of KD in South Korea.

Another method to acquire the accurate incidence rate of KD is to use national health insurance data as if almost all of the population is covered under national health insurance systems, such as in South Korea and Taiwan.^{14,15} Although we could get more incidence data of KD by this method compared with nationwide survey, national health insurance data also have the possibility of over- or underestimation of KD. Moreover, national health insurance data include only simple indices, such as incidence, age, sex, province of residency and months of occurrence.² Because epidemiologic studies of KD in each country have shown changes of

KD occurrence and given evidences to deduce the risk factors and pathophysiology of KD, efforts to reveal the true epidemiology of KD should be continued in every country by the methods of questionnaire surveys or using national health insurance data, or a combination of these methods according to the medical environment in each country.²

In this survey, we noted new findings on seasonal occurrence of KD. KD occurred most commonly in the cold winter season (December–January), as shown in most epidemiologic studies from countries with four discrete seasons.^{7,16–19} The second seasonal peak of KD occurrence in South Korea moved from summer (June, July and August) to late spring (May and June) compared with the previous surveys.^{7,9} This change of seasonal distribution of KD could give potential clues on the pathophysiology of KD associated with the climate change or infectious etiology.^{16,20} The geographic patterns of KD occurrence, wherein the incidence rates of KD in Northeast Asian countries including Japan, South Korea, China and Taiwan are 10–30 times higher than in the Unites States and Europe, and the seasonal differences of KD occurrence reported by the previous epidemiologic studies imply that infectious agents

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could provoke particular immunologic reactions in genetically susceptible patients.^{1–3,20,21}

In this survey, we investigated sequential treatment patterns for KD refractory to the initial IVIG treatment. A 14.8% of patients were nonresponders to the initial IVIG treatment. For the nonresponders to the initial IVIG treatment, most patients (84%) were treated with the second dose of IVIG. As the third-line treatment, methylprednisolone pulse therapy was administered to 75.2% of patients. As the fourth-line treatment, infliximab was administered most commonly to 52.4% of patients. These treatment patterns for acute-phase KD differ from country to country according to medical environments. Furthermore, there are no data with strong evidence from clinical trials to guide clinicians to choose the right therapeutic options for patients with initial IVIG resistance.1 Compared with previous nationwide surveys in South Korea,7,9 more patients were treated with infliximab as the rescue treatment for IVIG resistance in this survey. Because there is no definite guideline to recommend to rescue treatment for IVIG resistance, the cost and effectiveness of each therapeutic option should be considered according to each country's medical environments.

During this survey period, coronary artery dilatation occurred in 17.1% of patients,¹¹ whereas coronary artery aneurysm occurred in 1.7% of patients and giant coronary artery aneurysms developed in only 19 patients (0.17%). Since the last nationwide survey, the proportion of giant coronary artery aneurysm decreased to <0.2% of KD patients in South Korea.⁷ This decrease seems to be associated with recent KD treatment patterns in South Korea. Increased awareness of KD among the public and primary-care physicians might lead to earlier diagnosis and treatment.

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