INCIDENCE, PRESENTATION AND OUTCOME OF KAWASAKI DISEASE AMONG CHILDREN ADMITTED TO HOSPITAL RAJA PEREMPUAN ZAINAB II

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DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT

OF THE REQUIREMENT FOR THE DEGREE OF MASTER

IN MEDICINE (PAEDIATRICS)

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CHAPTER 1:
THE PRELIMINARIES

Acknowledgement

Firstly, Alhamdulillah to ALLAH ALMIGHTY that bestowed the strength and good health to complete this research. I would like to express my sincere gratitude to Dr Mohd Rizal bin Mohd Zain for his expertise, assistance, guidance and patience throughout the process of this thesis becoming a reality. I want to thank Associate Professor Dr Ariffin bin Nasir, Associate Profesor Dr Najib Majdi bin Yaacob, Dr Nor Fadhilah binti Zahari and Dr Amelia binti Alias for their advice and contribution to this thesis. I am highly indebted to my fellow lecturers, wife, kids, colleagues, supporting staff and friends for the encouragement and support along the ride.

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LIST OF ABBREVIATIONS AND NOMENCLATURE

CA	Coronary Artery
CRP	C-Reactive Protein
ESR	Erythrocyte Sedimentation Rate
ECHO	Echocardiography
Hb	Haemoglobin
HRPZII	Hospital Raja Perempuan Zainab II
IVIG	Intravenous Immunoglobulin
KD	Kawasaki Disease
LAD	Left Anterior Descending
LCX	Left Circumflex Artery
LMCA	Left Main Coronary Artery
MI	Myocardial Infarction
RCA	Right Coronary Artery

ABSTRACT

Introduction: Kawasaki disease (KD) is an acute febrile illness in early childhood characterized by fever for more than five days, accompanied by other symptoms such as a rash, conjunctiva inflammation, oral changes, lymphadenopathy, and extremity changes. KD is the leading cause of acquired heart disease in children. However, there are limited published studies on the disease in Malaysia. Thus, this study was conducted to determine the incidence of KD and its associated risk factors in late resolution of coronary artery dilatation in the Kelantan population.

Methodology: This 12 years study involved 105 KD patients of Hospital Raja Perempuan Zainab II. Socio-demographic characteristics, clinical profile, biochemical evidence and echocardiography were recorded. Single and multiple logistic regression were used to determine the associated risk factors for late resolution of coronary dilatation.

Result: Total of 105 patients were involved (59 were male, 46 were female). Most patients were Malay (96.2%) and the mean age was 28.2 months. Among those patients, 37.1% were complete KD and 62.9% incomplete KD. The hospital incidence of KD during the study period was 93 patients per 100,000 paediatric patients. The study found that almost all patients (99%) presented with a fever lasting more than five days, followed by rashes (80%). Majority of patients had high inflammatory markers. The study revealed that 34.6% of patients required more than 24 months for coronary artery dilatation to resolve. The only variable significantly associated with late resolution of coronary artery dilation was the number of coronary arteries involved (more than 1 vessel during presentation).

Conclusion: This study showed the incidence of KD patient was still high in Kelantan. KD was highly associated with coronary artery abnormality. Involvement of more than 1 coronary artery during presentation was associated with the late resolution of coronary artery in 2 years of follow up.

Keywords: Kawasaki disease, Children, Incidence, Clinical Presentation, Outcome, Risk Factors, Hospital Raja Perempuan Zainab

ABSTRAK

Pendahuluan: Penyakit Kawasaki adalah penyakit demam akut awal pada kanak-kanak yang didefinisikan sebagai kehadiran demam lebih dari 5 hari, disertai dengan gejala-gejala seperti ruam polimorf, kemerahan konjungtiva, perubahan pada mukosa mulut, pembesaran nodal limfa dan perubahan kepada tangan dan kaki. Di Malaysia, penyakit Kawasaki adalah penyebab utama kepada penyakit jantung yang diperolehi (bukan penyakit genetik) dalam kalangan kanak-kanak. Malangnya kajian yang telah diterbitkan adalah terhad. Oleh itu kajian ini bertujuan untuk meneliti kejadian penyakit Kawasaki dan mengenalpasti faktor-faktor yang berkaitan ke atas kelewatan penyembuhan arteri koronari pada kanak-kanak Kelantan.

Methodology: Kajian yang berjangka masa 12 tahun ini melibatkan pesakit Kawasaki Hospital Raja Perempuan Zainab II. Maklumat Sosiodemografik, data klinikal, biokemikal dan ekokardiogram direkodkan. Logistik regresi tunggal dan berganda digunakan untuk menentukan faktor-faktor yang menyebabkan kelewatan penyembuhan kepada ketidaknormalan arteri koronari

Keputusan: Seramai 105 pesakit Kawasaki yang terlibat dalam kajian ini (59 adalah lelaki, 46 kanak-kanak perempuan) dengan purata umur pesakit Kawasaki dalam kajian ini adalah 28.2 bulan. Kebanyakan pesakit adalah etnik Melayu (96.2%). Di antara pesakit-pesakit tersebut, 39 (37.1%) orang adalah Kawasaki Penuh dan 66 (62.9%) orang Kawasaki Inkomplete. Kejadian penyakit Kawasaki dalam kajian ini adalah 93 pesakit daripada 100,000 pesakit kanak-kanak yang dimasukkan ke wad dari bulan Januari 2008 sehingga Desember 2019**.** Hampir semua pesakit mempunyai presentasi klinikal demam lebih daripada 5 hari (99%), diikut oleh ruam (80%). Kebanyakan pesakit mempunyai petanda inflamasi yang tinggi. Terdapat 36 pesakit (34.6%)

memerlukan tempoh yang lebih dari 24 bulan (2 tahun) untuk penyembuhan arteri koronari. Dalam kajian kami, didapati bilangan arteri koronari yang terlibat lebih daripada satu semasa diagnosis mengakibatkan kelambatan penyembuhannya arteri coronary.

Kesimpulan: Kajian ini menunjukkan bahawa insiden penyakit Kawasaki masih tinggi di Kelantan. Penyakit Kawasaki menyebabkan ketidaknormalan pada arteri koronari. Bilangan arteri koronari lebih daripada 1 semasa diagnosis mengakibatkan kelambatan penyembuhan arteri koronari dalam tempoh 2 tahun pemerhatian

Kata Kunci: Kawasaki disease, Kanak-kanak, Insiden, Gejala, Hasil, Faktor-faktor resiko, Hospital Raja Perempuan Zainab II

CHAPTER 2:
THE TEXT

2.1 SECTION A:

Introduction

INTRODUCTION

Kawasaki disease (KD) is an acute febrile illness of early childhood, with about 80% of cases occurring between six months and five years. KD was first reported in Japan more than 40 years ago, and the condition has since been described in most populations. KD was first prescribed in Japan in 1967 by Kawasaki.(1) In Malaysia, the first KD case was described in 1979. Subsequently, 19 patients were seen at the University of Malaysia, Kuala Lumpur between 1979-1984.(6) Despite almost 50 years of research, the aetiology of KD remains unknown. An infectious trigger which causes an excessive inflammatory response in genetically predisposed children was widespread hypothesis, but no specific pathogen had been identified yet.

KD is a clinical diagnosis defined as the presence of fever ≥5 days, accompanied by four out of five of the following symptoms: polymorphous rash, bilateral conjunctival injection, oral changes such as cracked, erythematous lips or strawberry tongue, cervical lymphadenopathy, extremity changes such as erythema or palm and sole desquamation. Incomplete Kawasaki disease includes fever ≥ 5days and two or three of the symptoms stated above. The term "atypical Kawasaki disease" was used to describe children who fail to meet the classic KD criteria but have compatible laboratory findings[3]. Some authors believe that this term should be reserved for patient who have a problem that generally is not seen in KD, such as renal impairment, arthritis, aseptic meningitis, pneumonitis, uveitis, gastroenteritis or otitis.(4,6)

Cardiac lesions are hallmark of KD and coronary artery aneurysms developed in 20% of untreated children and can lead to coronary stenosis, myocardial infarction (MI), or sudden death. Pericarditis complicated by cardiac tamponade or myocarditis associated with myocardial dysfunction can also occur during the acute phase. Previous studies showed that medium to long-term prognosis after usual treatment of Kawasaki

disease was excellent and the majority of children did not have any cardiac sequalae or suffer from complication during the follow up.(2) Incomplete Kawasaki disease was more common in children younger than one year, in whom the rate of coronary artery aneurysm was paradoxically higher if not treated.(7) Echocardiography was indicated in all cases suspected KD. The first echocardiography should be obtained when the diagnosis is suspected. Echocardiography provides baseline coronary artery dimensions and morphology and assesses cardiac function. Echo should be repeated at two weeks and six to eight weeks after diagnosis. Some centres were also obtained at six to twelve months follow up study.(6) About half of the coronary artery dilatation associated with KD resolved by echocardiography and angiography within one to two years.(6) Factors of poorer outcome of Kawasaki disease are male gender, atypical age and absence of IVIG infusion during the acute phase.(1,4)

There was no new study regarding Kawasaki disease in Malaysian. There was a study in involving 7 patient reported in March 1987 to February 1995 (8 years).(14) However there were not enough data regarding complication and serial monitoring of patient during follow up. Thus a study need to be carried out to study the complication of the disease to Malaysia population and it factors associated with the outcome.

2.2 SECTION B:

Study Protocol

2.2.1 Documents

Submitted for ethical approval

Dissertation proposal

School Of Medical Science
University Science Malaysia
Prepared in partial requirement fulfilment
For the Degree of Master of Medicine (Paediatric)
2019/2023

INCIDENCE, PRESENTATION AND OUTCOME OF KAWASAKI DISEASE AMONG CHILDREN ADMITTED TO HOSPITAL RAJA PEREMPUAN ZAINAB II

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Research title: Incidence, Clinical Profiles and Outcome of Kawasaki Disease Among Children Admitted to Hospital Raja Perempuan Zainab II

Principal Investigator : Dr Wan Md Hafizi bin Wan Mohamad
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Introduction

Kawasaki disease (KD) is an acute febrile illness of early childhood, with about 80% of cases occurring between 6 months and 5 years. Kawasaki disease was first reported in Japan more than 40 years ago, and the condition has since been described in most populations. Despite almost 50 years of research, the aetiology of KD remains unknown. An infectious trigger which causes an excessive inflammatory response in genetically predisposed children is widespread hypothesis, but no specific pathogen has been identified yet.

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(MI), or sudden death. Pericarditis complicated by cardiac tamponade or myocarditis associated with myocardial dysfunction can also occur during the acute phase. Previous studies showed that medium to long-term prognosis after usual treatment of Kawasaki disease is excellent and the majority of children do not have any cardiac sequalae or suffer from complication during the follow up.(4) Incomplete KD was more common in children younger than one year, in whom the rate of coronary artery aneurysm is paradoxically higher if not treated.(7) Echocardiography is indicated in all case suspected KD.(7) The first echocardiography should be obtained when the diagnosis is suspected. Echocardiography provides baseline coronary artery dimensions and morphology and assesses cardiac function. Echocardiography should be repeated at two weeks and six to eight weeks after diagnosis. Some centres also obtain at six to 12 month follow up study.(7). About half of the coronary artery aneurysm associated with KD resolved within one to two years.(7) Factors of poorer outcome of Kawasaki disease are male gender, atypical age and absence of IVIG infusion during the acute phase.(7,8)

Problem statement and Study rationale:

This study intended to provide local data for factors associated with the resolution of coronary artery dilatation in KD patients. By analysing the result, these findings may help for early diagnosis of Kawasaki disease and to identify the children with risk factors to prevent late resolution of coronary artery abnormalities

Research Question (s)

1) What is the proportion of KD among children admitted to HRPZII?
2) What are the common presentations of KD?

3) What are the percentage of patients that having resolution of coronary abnormalities in KD?
4) What are the risk factors associated with late resolution of coronary dilatation in patients with KD?

Objectives

General:

To determine the proportion, associated factors and outcome of KD among children in Hospital Raja Perempuan Zainab II.

Specific:

1) To determine the hospital incidence of KD in HRPZII
2) To describe clinical profile of patients with KD at HRPZII
3) To determine the percentage of resolution of coronary dilation in KD at 2 years of follow up
4) To determine factors associated with late resolution of coronary dilatation in patients with KD within 2 years follow up

LITERATURE REVIEW

Aleksandra Stasiak and Elzbieta Smolewska conducted a single-centre retrospective study at the Paediatric Cardiology and Rheumatology Medical University of Lodz, Poland. The study aimed to describe the clinical course with special interest in cardiac involvement, treatment and follow-up of Polish patients with KD. Clinical features (including coronary involvement), laboratory results and treatment were evaluated. Twenty four patients were diagnosed with coronary artery abnormalities. Mean day of treatment equalled 9th day of the disease. They found that it is important to start treatment within first 10 days of disease due to the high risk of cardiovascular complications. Each patient should have echocardiography on admission, around 14th day of the disease, after 4-6 weeks from the onset of symptoms as well as long-term observation atleast once year due to the fact that the inflammatory process and changes in the lipid profile increase the risk of atherosclerosis. Children with coronary dilatation should undergo check-ups every 6 months.

Marion de La Harpe, Stefano di Bernardo, Michael Hofer and Nicole Sekarski reviewed retrospectively the medical records of all patients with diagnosis of KD at University Hospital of Lausanne Switzerland diagnosed between 1981 and 2014. Among 207 patients included in the study, 96 patients had coronary diameter anomalies (46.4%) at diagnosis and children with atypical ages for KD (<1 year or >10year of age) were more often affected with aneurysms during the follow up (87.5%). Absence of immunoglobulins in the acute phase was associated with less regression rate (57.1 vs 92.2%) and boys had greater z-scores at last echocardiography, statistically significant for the left anterior descending artery. They found rare complications after the acute phase documented in patients chart (only 3.8%). Recurrence of the disease occurred in 5 children (2.4%) and myocardial ischemia in patients (1.4%), all with initial coronary

aneurysm. They concluded that medium to long term prognosis after Kawasaki disease is excellent. Boy, absence of IVIG infusion during acute phase or atypical age range are more at risk for an unfavourable outcome.

Teiji Akagi, Vera Rose, Lee N. Benson, Alice Newma and Rober M. Freedom studied the outcome of coronary artery aneurysm after Kawasaki disease in their Hospital for Sick Children Toronto. From 1974 through 1991, a total of 583 children with Kawasaki disease were seen at the Hospital whom 80 (13.7%) had coronary artery involvement. There were 55 boys and 25 girls, whose mean age at 2.9 ± 2.5 years, followed by mean period of 4.0 ± 3.6 years. Giant aneurysm (maximum diameter ≥8mm) were found in 22 children, moderate-sized aneurysms (≥4 to <8mm) in 44, and dilatation lesion (<4mm) in 14. Myocardial infarction occurred in 9 (1.5%), all of whom had giant aneurysms. The persistence rate for aneurysms was 72% at 1 year and 41% at 5 years of follow-up. In multivariate analysis, the regression of an aneurysm was significantly related to the severity of coronary artery lesions, initial treatment, and gender. Although >80% of small or moderate-sized aneurysms regressed within 5 years, giant aneurysms did not regress during the follow-up period. In patients who received immune globulin therapy, coronary lesions tended to resolve more rapidly than in those treated with salicylate therapy alone, because 91% of the lesions in the former were small or moderate. These findings suggest that the severity of coronary artery involvement during the initial stages of Kawasaki disease influences the regression of these lesions, and that immune globulin treatment may improve outcome by reducing the incidence of severe lesions.

RESEARCH DESIGN

This was a Retrospective study conducted at Hospital Raja Perempuan Zainab II, a tertiary centre located at East Coast Peninsular Malaysia. All records of children less than 18 years old that were admitted to HRPZII which diagnosed as KD from January 2008 until December 2019 and follow-up until 2 years after diagnosis. The medical records retrieved were reviewed retrospectively and follow-up records reviewed using data collection sheet containing patient's information and determinants. Among children diagnosed with Kawasaki disease, their echocardiography findings were recorded, data of their risk factors and its outcome were recorded

RESEARCH AREA

Tertiary Centre in Kelantan

1) Hospital Raja Perempuan Zainab II

STUDY POPULATION

Reference Population

Children with Kawasaki disease in Kelantan

Source Population/Sampling pool

Kawasaki disease patient that having follow up for echocardiography in pediatric cardiology clinic in HRPZII which diagnosed from January 2008 till December 2019

Subject Criteria

Inclusion Criteria

Children with Kawasaki disease and Atypical Kawasaki disease based on criteria from 1st January 2008 until 31st December 2019

Exclusion Criteria

1) Records with inadequate "crucial data". Crucial data include the date of diagnosis and lack of follow-up records.
2) Outcome occurs after end of study period

Sample Size Estimation

$$n = \frac{Z^2 p(1-p)}{d^2}$$

n = min. required sample

Z = value of standard normal distribution = 1.96

d = precision = 0.05%

p = 0.1% (reference: Prevalence of Kawasaki Disease in Tertiary care Hospital: A descriptive cross-sectional study, Nepal, 2018)

n: 15, 351

Reference: Sample not calculated because no information or study regarding this objective available

Sample Size Calculation For Objective Number 2 (Clinical profile of Kawasaki disease):

This objective involves a description of all patients with Kawasaki disease from 2018 to 2019. No sample size need to be calculated as all Kawasaki disease patient identified from 1st objective will be included

Sample Size Calculation For Objective Number 3:

n = min. required sample

Z = value of standard normal distribution = 1.96

d = precision = 7.5%

p = 87.5% (reference: Thirty years of Kawasaki disease: a single-center study at Univeristy Hospital Lausanne. 2018, Poland)

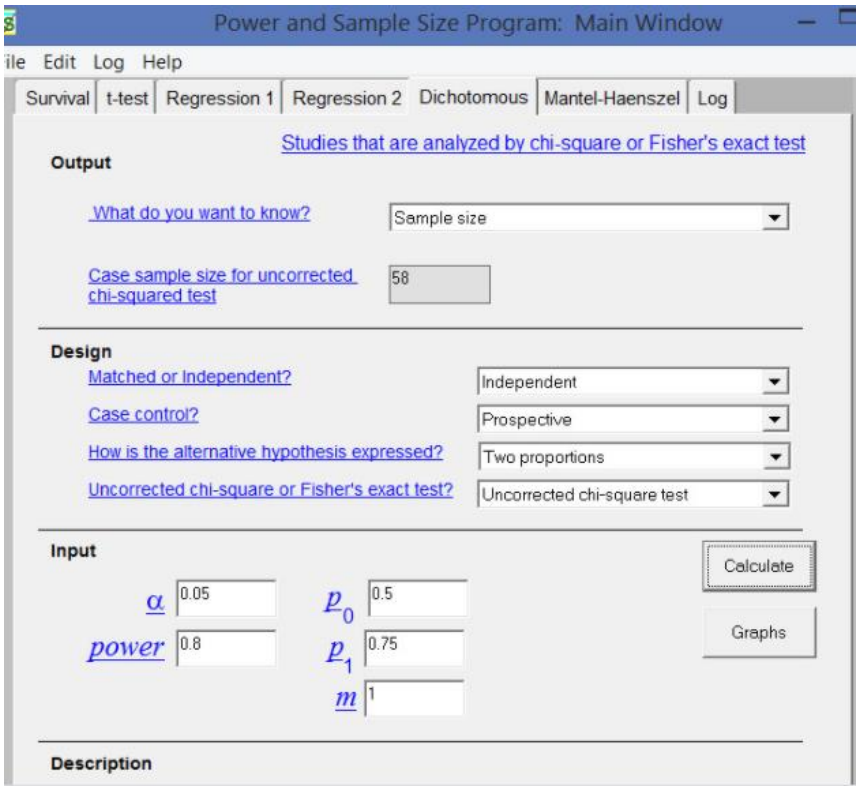
n = 75

Considering 20% drop out, minimum required sample **94**

Sample Size Calculation For Objective Number 4:

Using Power and Sample size program

-comparison of two independent proportion (for logistics regression analysis)



Gender (male)	0.28 (Risk factors and implications of progressive coronary artery dilatation in KD children, Taiwan 2017)	0.99	0.77	48 x2 =96
Larger size of aneurysm	0.23 (Outcome of coronary artery aneurysm after Kawasaki disease, 1992,Canada)	1	2.6	3 x2 = 6
Received IvIG	0.1 (Thirty years of KD: A single-center study at University Hosp Lausanne, 2018, UK)	0.27	10	37x2= 74
IvIG unresponsive	0.8 (Effectiveness of ivig alone vs ivig combined with	0.29	1.2	13x2=26

	hig dose aspirin in acute stage of KD: study protocol for a randomised trial, Taiwan, 2016)			
IvIg with without dose of aspirin	0.15 (Effectiveness of IVIG alone vs IVIG combined with high dose aspirin in acute stage of KD: study protocol for a randomised trial, Taiwan, 2016)	0.36	1.8	50 x2 =100
Hypoalbuminemia (less 35g/L)	0.13 (Risk factors and implications of progressive coronary artery dilatation in KD children, Taiwan 2017)	1	0.2	7x2 = 14
High initial CRP (≥30mg/dl)	0.25 (Risk factors and implications of progressive coronary artery dilatation in KD children, Taiwan 2017)	0.75	23	6x2=12
Thrombocytosis ≥450x10^9 -normal value	0.28 (Risk factors and implications of progressive coronary artery dilatation in KD children, Taiwan 2017)	0.45	3.4	78=156
Leucocytosis more 15 x 10^9	0.13 (Risk factors and implications of progressive coronary artery dilatation in	0.45	6.3	15x2=30

	KD children, Taiwan 2017)			

Considering 20% drop out, minimum required sample **171**

Operational Definition

Kawasaki disease:

Acute, self-limited, systemic vasculitis that presented with fever lasting more than 5 days, accompanied by four out of five of symptoms: polymorphous rash, bilateral conjunctival injection, oral changes such as cracked and erythematous lips and strawberry tongue, cervical lymphadenopathy, extremity changes such as erythema or palm and sole desquamation

(Malaysian pediatric protocol, 2018)

Incomplete Kawasaki disease

Clinical presentation includes fever lasting ≥5 days, fewer than 4 principle clinical features and compatible laboratory or echocardiographic findings. Also patient with atypical presentation generally not seen in KD

Atypical age:

Atypical age of Kawasaki disease is less than 1 year (≤1 year old) or more than 10 years (≥10 years old)

(Thirty Years of Kawasaki Disease: A Single-Center Study at the University Hospital of Lausanne, 2019)

Intravenous Immunoglobulin (IVIG)

The mixture of antibodies to reduce the production of inflammatory cytokines and chemokines thus reduce inflammatory process

(Thirty Years of Kawasaki disease: A Single-Center Study at the University Hospital of Lausanne, 2019)

Coronary artery aneurysm:

Giant aneurysm (maximum diameter ≥8mm), moderate-sized aneurysms (≥4 to <8mm) and dilatation lesion (<4mm)

(Outcome of coronary artery aneurysms after Kawasaki disease, Teiji Akagi, Vera Rose, Lee N. Benson, Alice Newma and Rober M. Freedom . 1992, Hospital of Sick Children, Toronto, Ontario, Canada)

Late Resolution:

Resolution of coronary artery abnormalities occur after 2 years[4]

(Thirty Years of Kawasaki Disease : A Single-Center Study at the University Hospital of Lausanne. Harpe MD La, Bernardo S, Hofer M, Sekarski N. 2019; University Hospital of Lausanne

Anemia

Anemia defined as Haemoglobin (Hb) less than 10g/dl

(Risk Factors and implications of progressive coronary dilatation in children with Kawasaki disease. 2017, Taipei Taiwan)

Thrombocytosis

Thrombocytosis defined as platelet count more than 450 $x10^9$

(Risk Factors and implications of progressive coronary dilatation in children with Kawasaki disease. 2017, Taipei Taiwan)

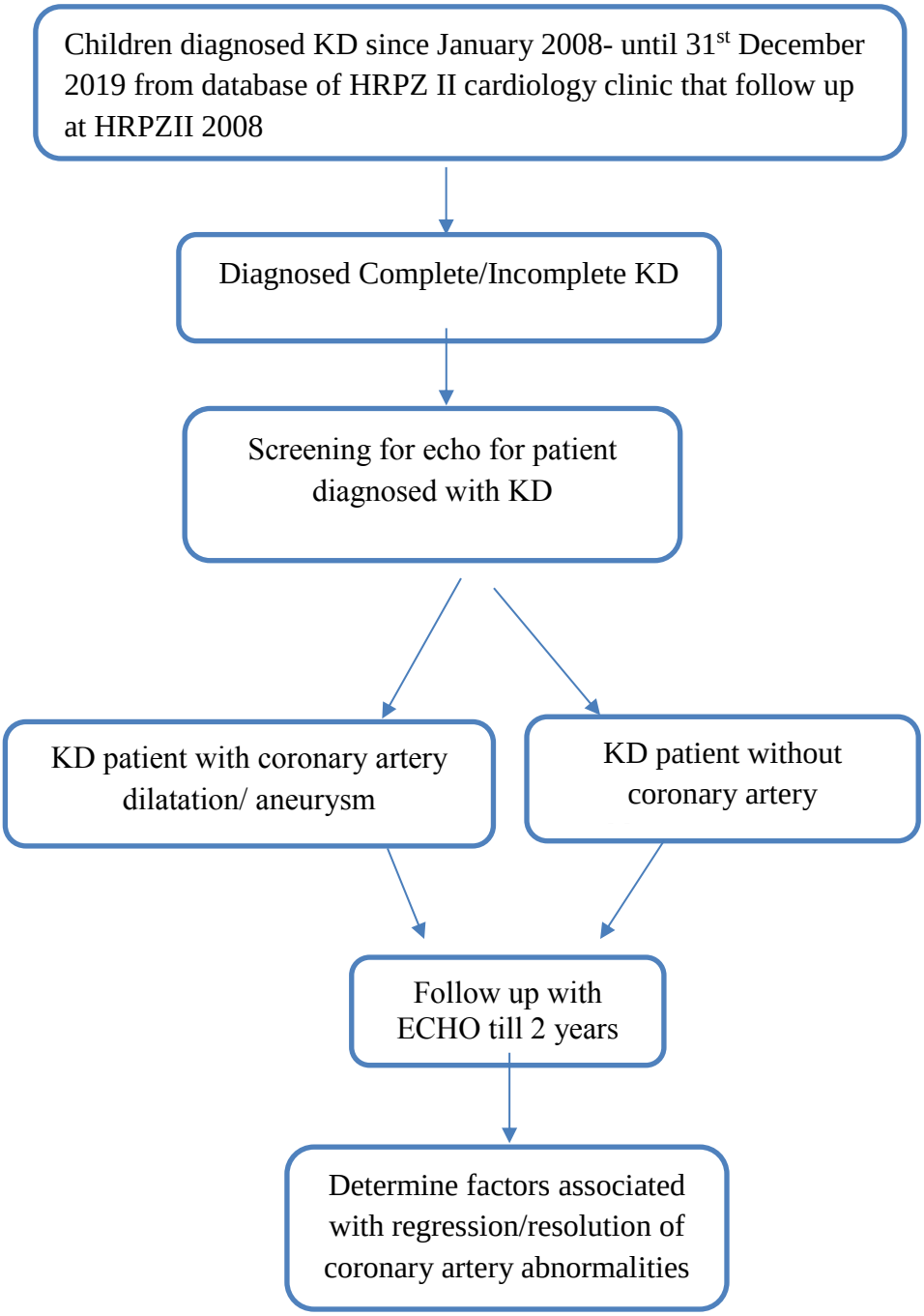
Data Collection Method

Patient will be identified from database at Cardiology pediatric clinic and Unit records of HRPZII. All children under 18 years old admitted to HRPZII in between January 2008 till December 2019 and having follow up at Pediatric Cardiology Clinic HRPZII until 2 years. Those who fulfilled inclusion criteria will be included in the study

All relevant data were obtained, included:

- Baseline demographic characteristics: age, gender, weight, age detected with Kawasaki disease
- Baseline clinical examination: weight, height, clinical presentations
- Baseline laboratory findings: full blood count, CRP, ESR, renal function test, liver function test
- Diagnosis of Kawasaki Disease (Typical Kawasaki disease, Incomplete/Atypical Kawasaki disease
- Findings of Echocardiography and outcomes after 2 years of follow up

STUDY FLOW CHART



DATA ANALYSIS

Statistical analyses were performed and analysed using SPSS version 26. Numerical data were presented as mean ± standard deviation (SD) and median and interquartile range (IQR) for skewed data. Categorical variables were expressed as frequencies and percentages. The resolution of coronary artery abnormalities and factors associated with delay resolution of coronary artery were analysed by using simple and multiple logistics regression analysis. A probability value (P-value) of less than 0.05 was reported as statistically significant.

EXPECTED RESULTS

DUMMY TABLES

Table 1: Socio Demographic Data for Kawasaki disease patient

Variables	Coronary artery dilatation n (%)	Typical Kawasaki Disease	Incomplete/Atypical Disease
Age	Mean (SD)		
Gender Male Female			
Race Malay Chinese Indian Others			

Table 2: Type of KD

Coronary artery	n (%)
• Complete KD • Incomplete KD	

Table 3: Clinical Presentation of KD

Contributing Factors	n (%)	Mean (SD)
Fever more than 5 days		
Rash		
Conjunctival injection		
Oropharynx changes (erythematous lips/strawberry tongue		
Cervical Lymphadenopathy		
Extremities changes (erythema or palm and sole desquamation		

Table 4: Laboratory results associated with KD

Laboratory results	n (%)	Mean (SD)
Anaemia (Hb <10g/dl)		
Thrombocytosis (>450000)		
High ESR ≥ 40 mm/hr		
High CRP ≥ 3.0 mg/dL		

Hypoalbuminemia <35g/L		
Elevated ALT		
High CK value		
High Troponin I		
ECG changes		

Table 5: Contributing Factors for Outcome of KD

Contributing Factors	n (%)	Mean (SD)
Male gender		
Atypical age of presentation		
Timing of iv human immunoglobulin given from onset of fever i.Less than 10 days ii.More than 10 days		
Giant/Large aneurysm at first presentation		

Table 6: Outcome of Kawasaki disease

Outcome	n (%)
Normal coronary artery	
Mild dilatation of coronary artery (diameter <4mm)	
Moderate dilatation of coronary artery (diameter ≥4mm to 8mm)	