A Cost-Benefit Analysis of Intravenous Immunoglobulin Treatment in Children with Kawasaki Disease

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Abstract

To determine the long-term cost-benefit of intravenous immunoglobulin (IVIG) treatment in Children with Kawasaki Disease (KD), a model was made to compare the total cost for management of these children with and without the use of IVIG. Long-term (10-21 years) follow-up of 594 KD patients treated in the pre-IVIG era reported by Kato, et al. was used to calculate cost using previous cost studies from Chulalongkorn Hospital. Reduction of CAA from 25 per cent to 4 per cent with IVIG treatment was assumed based on previous published data. Total cost was slightly lower for the non-IVIG treatment group compared to the IVIG treatment group (33,451,129 baht *vs* 35,001,195 baht) for the duration of follow-up in Kato's model. Cost per effectiveness analysis showed more effectiveness in the IVIG treatment group (359,576 baht *vs* 383,614 baht). Net cost analysis similarly demonstrated lower costs in the IVIG treatment group (25,365,215 baht *vs* 33,451,129 baht). Incremental cost-effectiveness analysis demonstrated supplementary costs of 13,663 baht for one case in the reduction of coronary involvement and 387,517 baht for one life saved in the IVIG-treated group. Estimation of total costs for follow-up and treatment for healthy life (until 60 years old) was more expensive in the non-IVIG treatment than the IVIG treated group (75,482,803 baht *vs* 29,883,833 baht). The authors conclude that treatment of all KD cases in Thailand with IVIG is likely to result in lower cost and better outcome when compared to no treatment with the IVIG policy.

Key word : Kawasaki Disease, Intravenous Immunoglobulin, Coronary Artery Aneurysm, Cost

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Kawasaki disease (KD) is an acute inflammatory disease of unknown etiology with a potential for serious morbidity and mortality attributable to coronary artery aneurysms (CAA)[1-11]. Approximately 25 per cent of untreated patients develop CAA [8,10-11], with giant CAA occurring in 2 per cent to 5 per cent[4,8]. Treatments with intravenous immunoglobulin (IVIG) at 2 g/kg and high dose aspirin during the acute phase reduce the incidence of CAA to 4 per cent[12-20]. Although most CAA regressed spontaneously[19], the affected coronary continues to have abnormal response to the coronary vasodilators[11]. Some of these CAA develop stenosis, resulting in long-term sequelae in adult life. Despite being the best medication to prevent CAA in patients with KD at the present time, IVIG is very expensive. Because of in high cost, the value of IVIG in treatment of KD in developing countries like Thailand is often a topic for debate. There are no previous reports available on cost-benefit analysis of IVIG treatment of KD. The purpose of this study was to compare the overall cost of management in patients with KD over a long-term period, using either IVIG-for-all or a no IVIG policy.

METHOD

The cost-benefit analyses of KD patients were compared between 2 groups: the control group represents patients with KD without IVIG treatment and the IVIG-treated group represent patients with KD who received IVIG treatment.

The data on the long-term follow-up (10-21 years) of 594 KD patients reported by Kato, et al[19] were used as the model to calculate costs in this study. This study represented the clinical course and outcomes of patients with KD in the pre-IVIG era (KD without IVIG treatment), and is the largest long-term

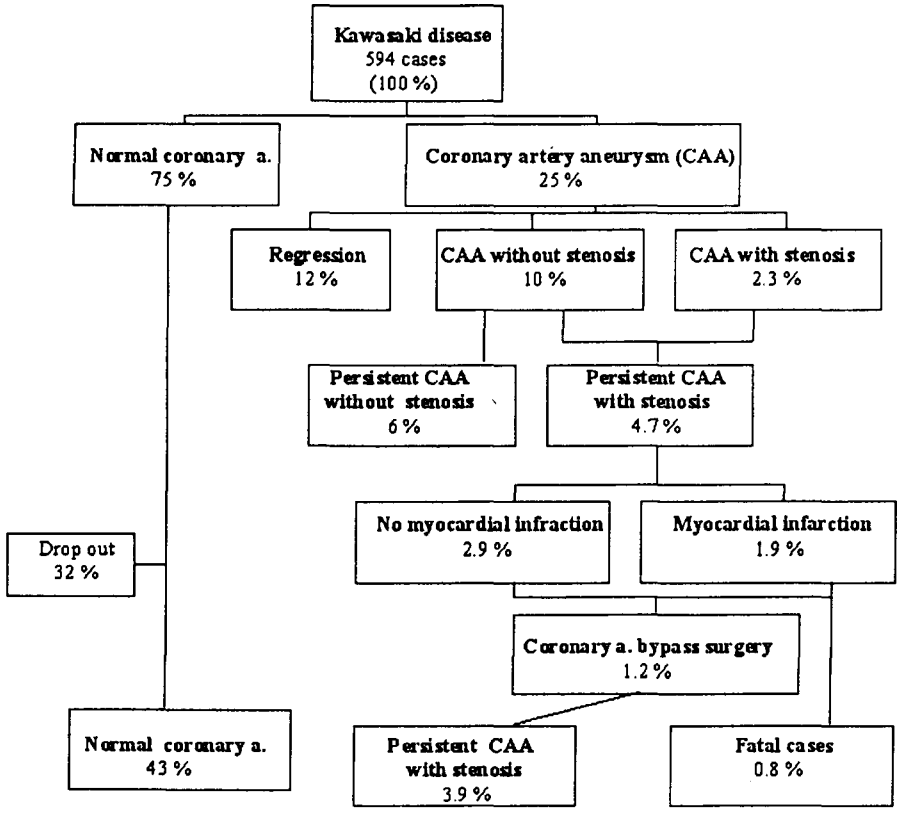

Fig. 1. Long-term outcomes of Kawasaki Disease in 594 patients; a 10 to 21 years follow-up study. (Kato's model: non-IVIG treatment group)

Abbreviations: CAA = Coronary artery aneurysm, MI = Myocardial infarction, Bypass Sx = coronary artery bypass graft surgery.

study available for the consequences of Kawasaki Disease. No patient in this study received IVIG treatment and all were examined by coronary angiography (CAG) for evidence of CAA during acute illness and follow-up. Aspirin was the only medication used if the patient was found to have CAA. Complete follow-up data were available in 65.8 per cent (395 cases) of all cohort and 91 per cent (133 cases) of the 146 cases with coronary aneurysm for a duration of 10 to 21 years (mean, 13.6 years). The summary of follow-up data is shown in Fig. 1 and 2. Coronary artery aneurysm occurred in 24.6 per cent of all patients. The authors categorized KD patients into four groups. Group I represented KD with no coronary involvement, Group II was KD with CAA (small-medium size) without stenosis, Group III was KD with persistent moderate size CAA without stenosis and Group IV was KD with persistent giant CAA with and without stenosis. (Table 1)

The data from Kato's study was then modified to represent the clinical course and outcomes for patients with KD who received a standard dose of IVIG (2 g/kg) (IVIG-treated group). It was assumed that reduction in the incidence of CAA to 4 per cent occurred in IVIG-treated KD patients based on the meta-analysis reported by Durongpisitkul, et al[18]. Further assumption was made that for the 4 per cent of patients with CAA, the proportions of different degrees of coronary complications (such as mild ectasia, small size of CAA, moderate size of CAA and large or giant aneurysm with or without stenosis) were similar to the untreated group (control group).

The overall cost for initial treatment during admission was estimated based on the provider cost

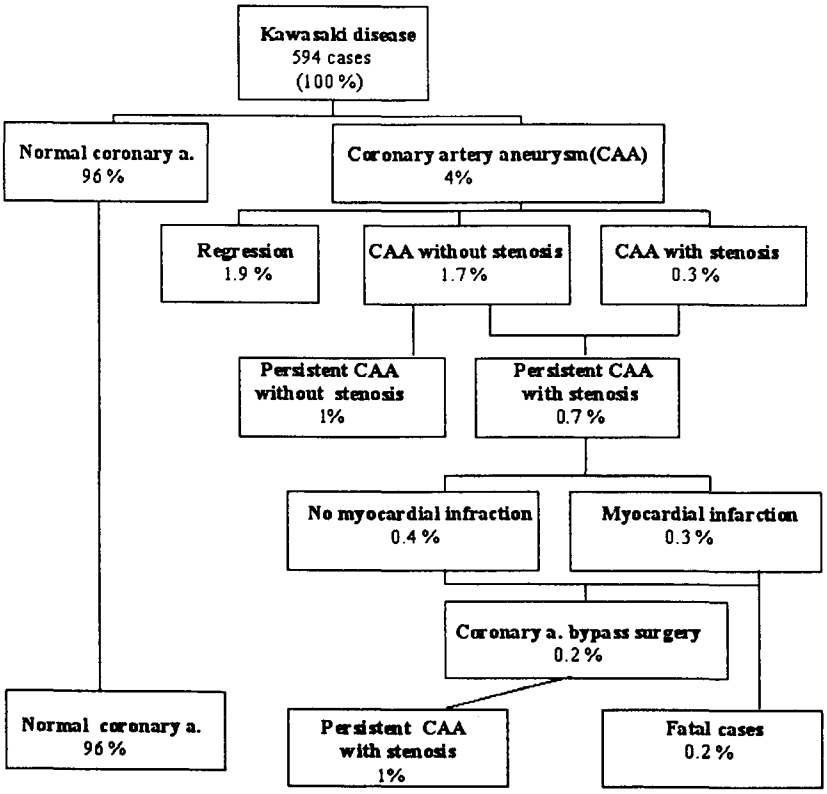

Fig. 2. The simulation model of long-term outcomes of Kawasaki Disease with reduction of CAA after treatment with IVIG policy.

Abbreviations: CAA = Coronary artery aneurysm, MI = Myocardial infarction, Bypass Sx = coronary artery bypass graft surgery.

data from the Division of Pediatric Cardiology, Department of Pediatrics, King Chulalongkorn Memorial Hospital conducted over a 9 year period from 1992 to 2000[21]. The authors used some additional data such as mean age (2.65 ± 2.5 years old), average body weight (12 kg) and average length of admission (5 days) to complete this analysis. The costs of follow-up were estimated based on the American Heart Association's (AHA) guidelines for long-term management of KD patients[22] (Table 2). These follow-up costs including complication-related cost arising from KD were calculated using the cost study conducted at King Chulalongkorn Memorial Hospital October 2000 to March 2001[23,24]. Total medical expense for medications, investigations, and procedures was calculated based on the listed price of each item at Chulalongkorn Hospital (Table 3). The incurred costs were compared between the IVIG-treated group and control group in two follow-up periods: 1) long-term follow-up of 10 to 21 years (based on Kato's model as described above) and 2) the period of average life expectancy for a Thai population (approximately until 60 years old). The cost-benefits analysis were calculated and compared according to the standard analyses that include cost per effectiveness, average cost per case, net cost and incremental cost-effectiveness ratio.

Statistical analysis

Four methods were used for weighting between the costs and benefits: average cost per case, cost per effectiveness, net cost and incremental cost-effectiveness ratio for reducing the cases of CAA and decreased mortality rate.

Definition[25,26]

Costs in this study included physician payment, the cost of drug treatment, or individual' out of pocket expenses for transportation and estimates of the value of the individual's time in traveling and receiving a preventive service (that is the individual's indirect cost of prevention).

1) Cost analysis

Average cost per case (baht) = net cost of policy/number of patient in policy

Net cost (baht) = cost of prevention - cost of illness present

2) Cost-benefits analysis: the costs of a policy compared to improvement in health as measured in the money unit.

If benefit is more than cost, it will be determined in terms of "Net benefit" but

If cost is more than benefit, it will be determined in terms of "Net cost", e.g. in KD

Net cost (baht) = cost of prevention - decline in incidence of CAA or death

3) Cost-effective analysis; the cost of policy with effects in a single ratio.

Cost-effectiveness ratio = net cost of policy/health improvement by policy

Health improvement in the present study was reduction in the incidence of CAA. Mortality was not included.

4) Incremental cost-effectiveness ratio; estimated cost per benefit between two policies (Incremental analysis). It will describe the supplementary cost for comparison among different policies.

Incremental cost-effectiveness ratio = cost A- cost B/effectiveness A- effectiveness B

Table 1. The incidence of coronary involvement between the non-IVIG treatment and IVIG treatment group divided to types and severity of coronary artery complications in 10-21 years of follow-up.

Groups	Non-IVIG group Case	%	IVIG group Case	%
Group 1	448	75	570	96
Group 2	72	12	11	1.9
Group 3	60	10	10	1.7
Group 4	28	4.7	4	0.7
Fatal cases	5	0.8	1	0.1

Abbreviations:
Group 1: KD patients with no coronary involvement.
Group 2: KD patients with small to moderate size of CAA without stenosis (Dajani risk group III)(22).
Group 3: KD patients with persistent CAA without stenosis (Dajani risk group III-IV)(22).
Group 4: KD patients with persistent of CAA with stenosis (Dajani risk group IV-V)(22).

Table 2. The investigation-listed which should be done for long-term follow-up in KD patients related with types and severity of coronary artery complications.

Type of complication *	Investigations**
Group 1	1, 2, 3
Group 2	1, 2, 3
Group 3	1, 2, 3, 4, ± 6
Group 4	1, 2, 3, 4, 5, 6

Abbreviations:
* = Groups 1, 2, 3, 4 (same as table 1)
** = 1 = CXR, 2 = EKG, 3 = Echocardiography, 4 = Stress test, 5 = Holter test, 6 = Coronary angiogram.

RESULTS

The cost analyses of the non-IVIG-treated group (control group) and IVIG treated group of KD patients are summarized in long-term follow-up of 10 to 21 years (based on Kato's model) and the period of average life expectancy for a Thai population (approximately until 60 years old) for comparisons of benefits between different long-term follow-up periods (Table 4, Fig. 3).

For the 10-21 years follow-up period, the cost of treatment in the non-IVIG group was lower than the IVIG-treated group in acute illness and short duration of follow-up (10-21 years) (6,343,827 baht *vs* 30,754,089 baht in group I and 1,446,424 baht *vs* 198,883 baht in group II respectively). In contrast, the authors used more money in the non-IVIG treatment group during long-term follow-up when the coronary artery complications appeared (3,112,777 baht *vs* 573,775 baht in group III and 22,548,102 baht *vs* 3,474,448 baht in group IV). The sum of the overall costs for investigations, treatments and follow-up until 10-21 years in the non-IVIG treatment and IVIG treatment group were 33,451,129 baht and 35,001,195 baht respectively. The average cost per case in the IVIG treated group was slightly higher than the non-IVIG treated group, which resulted from the expensive cost of IVIG (58,925 baht/case *vs* 56,315 baht/case respectively) (Table 4).

The overall estimated costs from first diagnosis until the average life expectancy of 60 years, with the need for long-term follow-up for possible development of coronary complications, was more expensive in the non-IVIG treatment compared to the IVIG treatment group (75,482,803 baht *vs* 29,883,883 baht). The average cost per case was 127,075 baht *vs* 66,448 baht for follow-up and management of KD patients with and without IVIG treatment until 60 years old. (Table 4)

DISCUSSION

Although KD is usually an acute and self-limited disease, its coronary artery complications may be serious and progressive. From previous studies, approximately 25 per cent of patients with KD who did not receive IVIG developed a coronary aneurysm (8,10-11). The risk was lowered to about 4 per cent when IVIG was given in the first 10 days of the acute

Table 3. General and specific costs of investigation and treatment in King Chulalongkorn Memorial Hospital.

Costs	Prices
1. Investigations	
Chest X-ray	120.00 baht/time
Electrocardiogram (EKG)	200.00 baht/time
Echocardiogram	1,000.00 baht/time
Exercise stress test	2,000.00 baht/time
Holter test	2,000.00 baht/time
Coronary angiogram	20,000.00 baht/time
2. Medications	
IVIG (Intraglobin-F)	1,591.00 baht/1 gram
Aspirin (60 mg/tab)	0.20 baht/tablet
Aspirin (300 mg/tab)	0.30 baht/tablet
Warfarin (3 mg/tab)	4.70 baht/tablet
Streptokinase	4,865.00 baht/1 vial
3. The other costs	
Transportation cost	113.19 baht/time
Cost of workday loss of a parent	236.00 baht/day
Productivity cost in a Thai population	165.00 baht/day
Cost of out-patient service	1,6471.78 baht/time
Cost of stay in a cardiologic ward	344.00 baht/times
Cost of stay in the PICU	12,983.00 baht/case/day
Cost of CABG in complicated cases	1,221,928.00 baht/case
Average length of stay in the PICU	2 days/case

Abbreviations:
PICU = Pediatric intensive care unit, CABG = Coronary artery bypass graft surgery.

Table 4. The estimation of the total costs of KD patients in the non-IVIG treatment and IVIG treatment group divided to types and severity of coronary artery complications in 10-21 years follow-up.

Groups	Non-IVIG group (Baht)	IVIG group (Baht)
Group 1	6,343,827	30,754,089
Group 2	1,446,424	198,883
Group 3	3,112,777	573,775
Group 4	22,548,102	3,474,448
Total Costs	33,451,129	35,001,195
Cost-benefit analyses for 10- 21 years follow-up (Kato's model)		
Average cost per case	56,315	58,925
Cost effectiveness	383,614	359,576
Net cost	33,451,129	25,365,215
ICE ratio for reduce 1 case of CAA	13,663 baht/case	
ICE ratio for reduce 1 case of Death	387,517 baht/case	
Cost-benefit analyses after beginning CAA until average life expectancy (60 years old)		
Average cost/case	127,075	66,448
Cost effectiveness	865,629	405,484
Net cost	75,482,803	29,883,833
ICE ratio to reduce 1 case of CAA	-590,377 baht/case	
ICE ratio to reduce 1 case of Death	-9,003,243 baht/case	

Abbreviations: CAA = coronary artery aneurysm, ICE = incremental cost-effectiveness ratio.

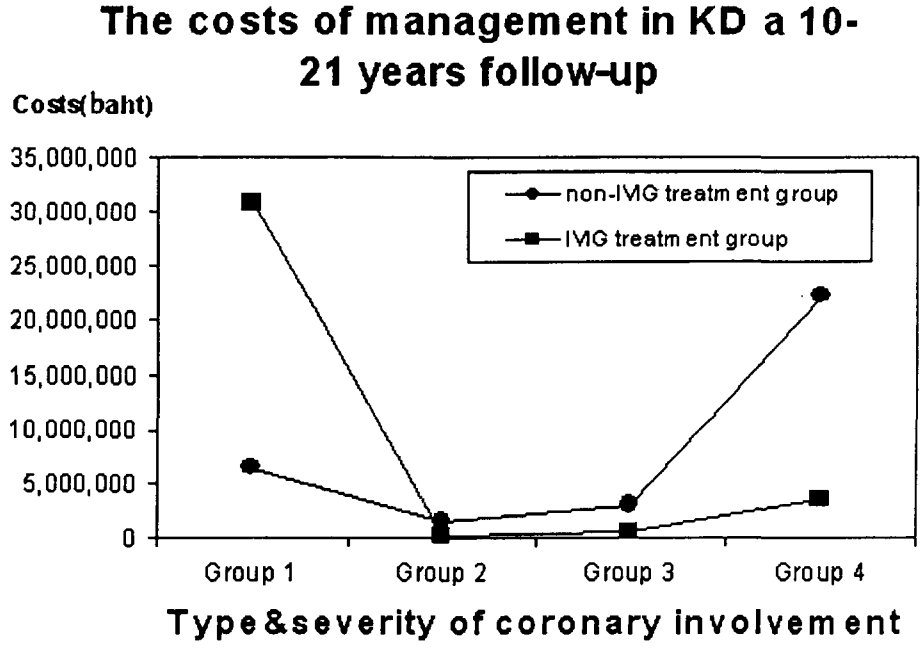

Fig. 3. The calculated total costs of management in KD a 10 -21 years follow-up (Kato's model).

Group 1 : KD patients with no coronary involvement.
Group 2 : KD patients with small to moderate size of CAA without stenosis (Dajani risk group III)[22].
Group 3 : KD patients with persistent CAA without stenosis (Dajani risk group III-IV)[22].
Group 4 : KD patients with persistent of CAA with stenosis (Dajani risk group IV-V)[22].

illness. Although CAA generally regressed, residual abnormalities persisted such as abnormal vascular wall morphology (intimal thickening) and abnormal response to vasodilator drugs[11]. Only high dose IVIG (2 g/kg) has shown to reduce the incidence of CAA but its cost is high[12-20].

In the present study, cost estimations were compared between KD patients with and without IVIG treatment. The authors found that the cost of treatment in the non-IVIG group was lower than IVIG group during the acute phase and with a short period of follow-up, during which time serious complications had not occurred. In contrast, the authors found incremental cost with longer time of follow-up when coronary complications began to develop. These expenses added up in the group not treated with IVIG and exceeded that of the group treated with IVIG during long-term follow-up, either at 10-21 years or until the patients reached the age of 60. In a sense, it can be said that IVIG is a preventive measure that seems to be expensive in the earlier period but cost-effective in the long run.

For obvious demonstrations, analyses of cost *versus* benefit were used to demonstrate the difference of costs and benefits in the IVIG-treated and the untreated groups. First, costs per effectiveness were 383,614 baht *vs* 359,576 baht for non-IVIG-treated (control) and the IVIG-treated group, respectively. These figures show the reduction of coronary involvement by the equivalent of the costs that was more beneficial in the IVIG treatment group than the other group. (Table 4)

Second, net cost; beneficially with the policy, which intends to save life or prevent CAA. When a policy has negative net cost (the cost off illness prevented is greater than cost of prevention), it is said to be a cost-saving policy (net benefit). This designation refers to net cost savings; it does not mean that

the policy simply averts some of the cost of treating the illness. The results demonstrated that the IVIG treatment group had a lower net cost in long-term follow-up. (33,451,129 baht *vs* 25,365,215 baht for the non-IVIG and IVIG treatment groups respectively) (Table 4).

Third, the interest of cost effective indicator is incremental cost-effectiveness ratio. This means that an additional 13,663 baht will be used for supplementary costs to reduce one case of coronary involvement and 387,517 baht to save one life in KD treatment with IVIG. According to the evidence, the authors consider that it is valuable to use IVIG in KD to the decrease morbidity and mortality rate over 10-21 years as in the period of Kato's study (Table 1, Fig. 1). In another way, it is known that the 9.9 per cent of patients with KD with CAA will survive with persistent coronary involvement and need long-term follow-up. These patients will require more health care expenses for treatment, and investigations during long-term follow-up, especially to maintain a healthy life (until 60 years old). After the period of 21 to 60 years, the comparison represented higher costs in the non-IVIG treatment group as the average cost per case analysis was (127,075 baht *vs* 66,448 baht). More money is also spent for medical expenses in the reduction of CAA over a longer period (865,629 baht *vs* 405,484 baht). Approximately 2 times the net cost was spent in the non-IVIG treatment group (75,482,803 baht *vs* 29,883,883 baht) (Table 4, Fig. 3). Incremental cost-effective ratio showed lower cost with time for reduction of one CAA case or one life saved. These finding was similar to the analysis using a short term period, which indicates that the usage of IVIG for treatment KD in Thailand can be consider an effective policy for prevention of long term complications of KD. This does not count the costs of workday losses resulting from the absence from work for follow-up visits, investigations and treatments of complications arising from CAA. If we also consider the productivity loss from death (4 cases), an additional 9,636,000 baht of costs will be lost in the non-IVIG-treated policy.

The authors concluded that the use of IVIG for treatment of all patients with KD in Thailand is cost effective and results in a better clinical outcome compared with no treatment with IVIG over a long-term period. The cost-benefit and outcome of selective treatment with IVIG in a high-risk population of KD is unknown at this time and awaits further study.

Limitations of the study

The present study was based on the database of Chulalongkorn Hospital[21,23-24]; some of the costs may not universally represent the expense for management of KD patients elsewhere in Thailand. The costs might be higher if the intangible cost and discount rate were included which was difficult to estimate[25,26]. The incidence of CAA in KD patients with and without IVIG in Thailand may be different from Kato's study.

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การศึกษาความคุ้มทุนของการใช้อิมมูโนโกบูลินรักษาผู้ป่วยเด็กที่ป่วยเป็นโรคคาวาซากิ

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เพื่อหาความคุ้มทุนในระยะยาวของการรักษาผู้ป่วยเด็กที่ป่วยเป็นโรคคาวาซากิด้วยการให้อิมมูโนโกบูลินทางหลอดเลือดดำ โดยจำลองแบบจากการศึกษาผู้ป่วยคาวาซากิจำนวน 594 ราย ที่ Kato และคณะ ได้ศึกษาไว้ถึงภาวะแทรกซ้อนต่อหลอดเลือดแดงโคโรนารีก่อนมีการใช้อิมมูโนโกบูลินรักษาโรคคาวาซากิ เปรียบเทียบกับกลุ่มที่ให้อิมมูโนโกบูลินทางหลอดเลือดดำในการรักษา โดยตั้งสมมติฐานจากการศึกษาที่ผ่านมาว่าการให้อิมมูโนโกบูลินสามารถลดอัตราการเกิดหลอดเลือดแดงโคโรนารีโป่งพองลงได้จากร้อยละ 25 เหลือร้อยละ 4 ในการคำนวณต้นทุนการติดตามการรักษาเป็นระยะเวลา 10 ถึง 21 ปี เช่นเดียวกับที่ Kato ศึกษาไว้ พบว่ากลุ่มที่ไม่ได้อิมมูโนโกบูลินจะมีต้นทุนรวมต่ำกว่ากลุ่มที่ให้อิมมูโนโกบูลินในการรักษาเล็กน้อย (33,451,129 บาท ต่อ 35,001,195 บาท) แต่ในการคำนวณต้นทุนต่อประสิทธิผลของการลดอัตราการเกิดหลอดเลือดแดงโคโรนารีโป่งพองและอัตราการตาย พบว่าการรักษาด้วยอิมมูโนโกบูลินให้ประสิทธิผลที่ดีกว่า (359,576 บาท ต่อ 383,614 บาท) เมื่อคำนวณต้นทุนผลลัพธ์รวมพบว่าได้ผลไปในทางเดียวกันคือ กลุ่มที่ให้อิมมูโนโกบูลินรักษามีต้นทุนของผลลัพธ์รวมต่ำกว่า (25,365,215 บาท ต่อ 33,451,129 บาท) เมื่อคำนวณความแตกต่างของต้นทุนต่อความแตกต่างของผลดีระหว่างการรักษาทั้ง 2 วิธี พบว่าถ้าต้องการลดการเกิดภาวะแทรกซ้อนต่อหลอดเลือดหัวใจโคโรนารี 1 ราย จะต้องเพิ่มต้นทุนขึ้นอีก 13,663 บาท และต้องเพิ่มต้นทุนการรักษาอีกเท่ากับ 387,517 บาท เพื่อให้ผู้ป่วยรอดชีวิต 1 รายเมื่อเลือกการรักษาด้วยอิมมูโนโกบูลิน เมื่อประเมินต้นทุนรวมทั้งหมดเพื่อดูแลรักษาผู้ป่วยในกลุ่มนี้จนถึงอายุ 60 ปี จะพบว่ามีการเพิ่มขึ้นของต้นทุนรวมอย่างมากในกลุ่มที่ไม่ได้รับอิมมูโนโกบูลินในการรักษา (75,482,803 บาท ต่อ 29,883,883 บาท) สรุปได้ว่า การให้อิมมูโนโกบูลินในการรักษาผู้ป่วยโรคคาวาซากิ ในประเทศไทย นอกจากจะมีต้นทุนรวมที่ต่ำกว่าแล้วยังให้ผลลัพธ์ที่ดีกว่ากลุ่มที่ไม่ได้ให้อิมมูโนโกบูลิน

คำสำคัญ : โรคคาวาซากิ, การให้อิมมูโนโกบูลินทางหลอดเลือดดำ, ภาวะหลอดเลือดแดงโคโรนารีโป่งพอง

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