Original Article

Multi-Center, Prospective, Nation-Wide Coronary Angioplasty Registry in Thailand (Thai PCI Registry): Registry Design and Rationale

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Background: Coronary artery disease (CAD) is one of the most common causes of death worldwide. Percutaneous coronary intervention (PCI) is currently the main revascularization modality for these patients. The practice of PCI, outcomes and resource utilization varies in many parts of the world. Therefore, it is important to have local information regarding the patient demographics, pattern of PCI practice, and outcomes.

Objective: To report the study design, protocol and rationale of the Thai PCI registry.

Materials and Methods: Thai PCI Registry is a prospective, multi-center study which is an initiative project of the Cardiac Intervention Association of Thailand (CIAT). The study consisted of phase I for cross-sectional data registry and phase II for follow up study. The project was started in November 2015. All catheterization laboratories in Thailand were invited to participate in this nationwide registry. The details regarding patient characteristics, procedural details, equipment, and outcomes of PCI were prospectively collected using well-constructed case record form. The protocol of the registry has been approved by the Central Research Ethics Committee (CREC). The project received a research grant from the Health System Research Institute, The Ministry of Public Health, in Thailand, March 2017.

Results: There were 39 hospitals from all areas of the country participated in the registration. The hospital type and size were varied and well represented of the PCI centers in Thailand. The registry planned to enroll all consecutive PCI patients at each hospital for approximately one year with the estimated number of PCI at 22,000 procedures. Initially, all patients were followed up for at least 6 and 12 months.

Conclusion: The present study provides rationale, protocol, definition and study design of Thai PCI registry. The results of the Thai PCI registry would yield the essential information regarding the current real-world practice as well as the results and complications of PCI.

Keywords: Coronary angioplasty; Nationwide registry; Percutaneous coronary intervention; Thailand; Real-world

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Coronary artery disease (CAD) is one of the most common causes of death worldwide[1]. Similarly in Thailand, according to the latest World Health Organization (WHO) data published in 2018, CAD deaths in Thailand reached 60,372 or 12.35% of the total deaths[2]. Percutaneous coronary intervention (PCI) is currently the main revascularization modality for these patients[2,3]. The number of PCI has rapidly increased in many countries including Thailand[4,5]. However, the results of PCI can be varied due to many factors including operator experience, hospital

volume, team expertise, availability of equipment, ancillary medication, etc.[6-8]. Furthermore, PCI can be varied from countries to countries in term of practice, cost, and resource consuming[9]. Therefore, it is important to have local information regarding the patient demographics, indications of treatment, pattern of PCI practice, equipment utilization, appropriateness of PCI, as well as its success, complication, and mortality rate.

Worldwide, there has been an increasing emphasis on measuring and improving the quality of medical care. While results from randomized controlled trials provide the highest level of evidence regarding the efficacy of interventions, they have well recognized limitations, as it may not always reflect "real world" medical settings and often underrepresent significant portions of reality. Clinical registries have emerged as a powerful tool to assess healthcare effectiveness and safety and improve quality of care, as well as to inform on the real-world impact of new interventions or medications[10-13]. In the United States, the American College of Cardiology (ACC) had created the National Cardiovascular Date Registry (NCDR) nearly 20 years ago. CathPCI registry has provided the data of adherence to the ACC/American Heart Association (AHA) practice guideline, procedural standards and appropriate use criteria for coronary revascularization since then[13,14]. Unlike western countries, no regular nationwide PCI registry had been established in Thailand. The only Thai Acute Coronary Syndrome (ASC) registries were reported in 2007[14] and in 2012[15].

Since then, the numbers of PCI in Thailand have been rapidly increasing, as the Ministry of Health has supported the increase in accessibility to PCI in all areas across the country. The policy resulted in more scholarship for cardiologists from many rural hospitals to have an interventional cardiology training as well as the increase in the numbers of catheterization laboratories nationwide.

Thus, to provide opportunities to advance in quality of PCI treatment, it is imperative to analyze the contemporary data regarding the current practice of PCI, resource utilization, clinical outcomes and cost effective of PCI in Thailand. The results of these analyses would provide unprecedented information which could be used to improve the healthcare and to reduce mortality in the future. Therefore, the authors conducted a prospective, nation-wide registry of patients receiving PCI in Thailand with following aims: 1) to construct electronic cross-sectional PCI databases across country and form further follow up study, 2) to estimate short-term and long-term clinical outcomes of PCI procedures including failure rate, complications, and mortality of PCI procedure and factors associate with failure of PCI, 3) to perform economic evaluations by cost utility analysis (CUA) of different PCI procedures. The present registry would be the largest and most up-to-date PCI registry in Thailand. In addition, the database framework would hopefully facilitate future registry reports.

Materials and Methods

The Thai PCI Registry was a prospective, multicenter study which was an initiative project of the Cardiac Intervention Association of Thailand (CIAT). The study consisted of phase I for cross-sectional data registry and phase II for follow up study. The project was started in November 2015. All catheterization laboratories in Thailand were invited to participate in this nationwide registry. The estimated number of PCI in the present project was 22,000 procedures. The proposal, protocol, case record form (CRF), and electronic case record form (eCRF) were previously submitted to the Central Research Ethics Committee (CREC), as well as the Local Ethics Committee (EC) in some institutes, for approval. The project received a research grant from the Health System Research Institute, The Ministry of Health, Thailand, in March 2017.

Inclusion and exclusion criteria

All consecutive adult patients aged 18 years or older who received PCIs at the participated hospitals were invited to join in the present study. Patients were informed about the PCI registry and signed the informed consents before enrollments. The process of acquiring inform consents had to be done without the delay in patient's management especially in STEMI and critically ill patients. The patients who were not Thai citizen and those who refused to give the informed consent were not eligible for the registry.

Data collection

The CRFs were constructed consisting of cross-sectional data at admission and follow up data as follows:

Cross-sectional data:

A: Demographic data
B: Episode of care
C: Physical exams and risk factors
D: Cath lab visit
E: Estimation of coronary anatomy
F: PCI procedures

G: Lesions and devices
H: Investigations
J: Discharge

Follow up data follow data at 6 and 12 months:

- Hospitalization
- Cardiovascular events
- Re-vascularization
- Complications
- Health related quality of life (HRQoL)
- Death

Manual of data collections and also definition of each variable were provided in the data collection handbooks which were distributed to all study sites and were available online for retrieval. The data were initially recorded in CRF. Then all data were transferred to electronic eCRF by the trained catheterization laboratory staff.

A workshop for training data collection was organized for research staffs of all study sites at Ramathibodi Computer Training Center in September 2017. Cross-sectional data collection was performed between May 2018 and August 2019. Follow up data at 6 and 12 months would be collected by interview patients at the outpatient clinics (OPD), review medical records, or interview by a phone call with constructed questions.

Data management and quality control

The definition for all variables used in the present study was standardized and provided in the definition handbook. The electronic databases were designed accordingly to CRFs. Data initially recorded in CRFs were then entry in electronic databases by the trained catheterization lab staffs. Data quality control programs were constructed including range values, must enter variable, skip, and cross-link between variables to re-assure data quality. In addition, pop-up warning system was shown, if important data were missing before saving the data of the whole CRFs.

All electronic databases were stored at a central data management unit (DMU), Department of Clinical Epidemiology and Biostatistics, Faculty of Medicine, Ramathibodi Hospital. The authors used storage area network (SAN) with redundant array of independent disks (RAID) for data stored and data backup, which was scheduled every week. Data were monitored in real time by Biostatisticians. Data cleaning and checking were performed monthly.

The practical value of each variable was checked, the value beyond the specified range. In addition, cross-link conditions were developed to ensure the accuracy and consistency of the data. The common input errors were listed, research nurses at study sites were contacted to correct and confirm data.

The national network meetings considering data collection and management issues were held on August 18, 2018 and on May 11, 2019 to answers the questions and the problems encountered during data collection and computerized entry, and to constantly improve the interface and workflow of eCRF to ensure the effective and accurate data with highest quality. Network communication was initiated through Line® Application. DMU and CIAT staffs provided 24-hour technical support. Site audit was performed as the detailed described below.

Site audit

The authors audited all study sites by randomly selected 10% of the total number of PCI patients of each site. Medical records and hard copy of CRFs were reviewed. Additional audit was performed in whom DMU have questions regarding the correctness of the data. During site visit, all questions regarding the data entry would be answered by the representatives from CIAT.

The participants' confidential data (including ID, name, surname, address, social number, hospital number (HN), telephone number, etc.) were kept separately from the main CRFs in secure environment. Confidential information was only used in ways agreed with those who provided it. Only authorized personnel had restricted access to computers and servers used for data storage

Outcomes of interest

The outcomes of interest included death [all cause of death, cardiovascular (CV) death, and specific cause of death (SCD)], repeated myocardial infarction (MI), repeated revascularization, stroke, heart failure, bleeding, and repeated hospitalization.

The vital status of the patients (death/alive) would be confirmed using data from the National Statistics Office, which was the most accurate information regarding vital status of all Thai Citizen. Verbal autopsy by telephone would be performed to obtain the detail to classify causes of death.

All hospital admission would also be documented, and possible outcomes of interest would be identified. The medical records and the details of each episode would be requested from those hospitals. All information would be presented to outcome adjudication committee who would decide whether the event was classified as the outcome of interest or not. The outcome verification committee

would be blinded of baseline characteristics and other information of the patient.

Statistical analysis

Data would be described using mean and frequency where appropriated. For phase-I, rate of PCI failure, complication, and death would be estimated along with 95% confidence interval (CI). Factors associated with each event would be assessed using a multivariate logistic regression with/without a random-effect model where appropriated. For phase-II, a mixed-effect model or cox regression model would be applied to assess prognostic factors associated with complications and death. Analysis would be performed using Stata Statistical Software, version 16 (StataCorp LLC, College Station, TX, USA).

Patient and public involvement

The study was an observational data registry of PCI details in participating catheterization laboratories. There was no intervention or alteration in patient management. The patients were not involved in the design of the study. No patient was involved in the recruitment to and the conduct of the present study. The results of this Nationwide registry would be presented to all stakeholders, including the Ministry of Public Health, the patients, and the publics and the summary numbers and figures will be available online in the CIAT website.

Ethics and dissemination

The registry was conducted according to the Declaration of Helsinki and the Ethical Guidelines for Human study, which has been approved by the Central Research Ethics Committee (CREC) with the certificate number COA-CREC 006/2018, as well as Local Ethics Committee (EC) in some institutes if required for approval. Patients were invited to participate with the present study. They were provided informed consents either by a written paper or verbal, and could withdraw their consents at any time. Patients who were unable to sign the informed consent (e.g., post-cardiac arrest, unconscious, intubated, or cardiogenic shock patients), the family member who was the legal representative would make the decision for the patients. The present study received grant from the Health System Research Institute, the Ministry of Public Health, Thailand, in March 2017.

The protocol of the registry was submitted to CREC in August 2017 and the first groups of hospitals was approved by CREC in April 2018. After obtaining the CREC approval, some hospitals started to enroll the patients immediately, however, some hospitals also required the approval of the local EC before the registry could be initiated.

The data would be presented as summary data. No data of individual participant would be presented. The results of the registry would be presented to all stakeholders included but not limiting to the Health System Research Institute (grant provider), all catheterization laboratories, administrators of each participating hospital, and the public through multiple channels e.g., oral presentation at the annual scientific meeting of CIAT, peer review publication, Poster and oral presentation to other cardiology meetings. Last but not least the summarization of the results would be available for everyone on the website of CIAT.

Results

There were 39 hospitals voluntarily participated in the Thai PCI registry. The distribution of hospital locations covered all areas of the country as depicted in Figure 1. Ten hospitals were located in Bangkok metropolitan area. Another 10 hospitals were from the central part of Thailand. The northern, northeastern, and southern areas had 5 hospitals as their representative, and 3 and 1 hospitals from eastern and western parts of the country also participated in the registry. The details regarding the types of the hospital (e.g., university hospital, tertiary referral center or private hospital), size of the hospital (classified by number of beds) as well as estimated annual numbers of PCI were described in Table 1. Among 39 hospitals, 9 hospitals were university/teaching hospitals, 9 were private hospitals and 21 were government hospitals. The hospital size varied from less than 100-bed hospitals (2/39 hospitals) to over 1,600 beds. There were 11 hospitals with 1,000 or more bed capacity. The number of interventional cardiologists at each center ranged from 1 interventionist (in 4 hospitals) to 10 interventionists at Central Chest Hospital as shown in Table 1. The number of PCI from all 39 hospitals was between 22,000 to over 23,000, therefore, the number of PCI cases in Thai PCI Registry was estimated to be 22,000 cases.

Possible output, outcomes

The present prospective registry would yield the essential information regarding the current practice as well as the results and complications of the real-world practice of coronary angioplasty in Thailand. Patient demographic (e.g., age, sex, indication for PCI, underlying disease) would be obtained. The success

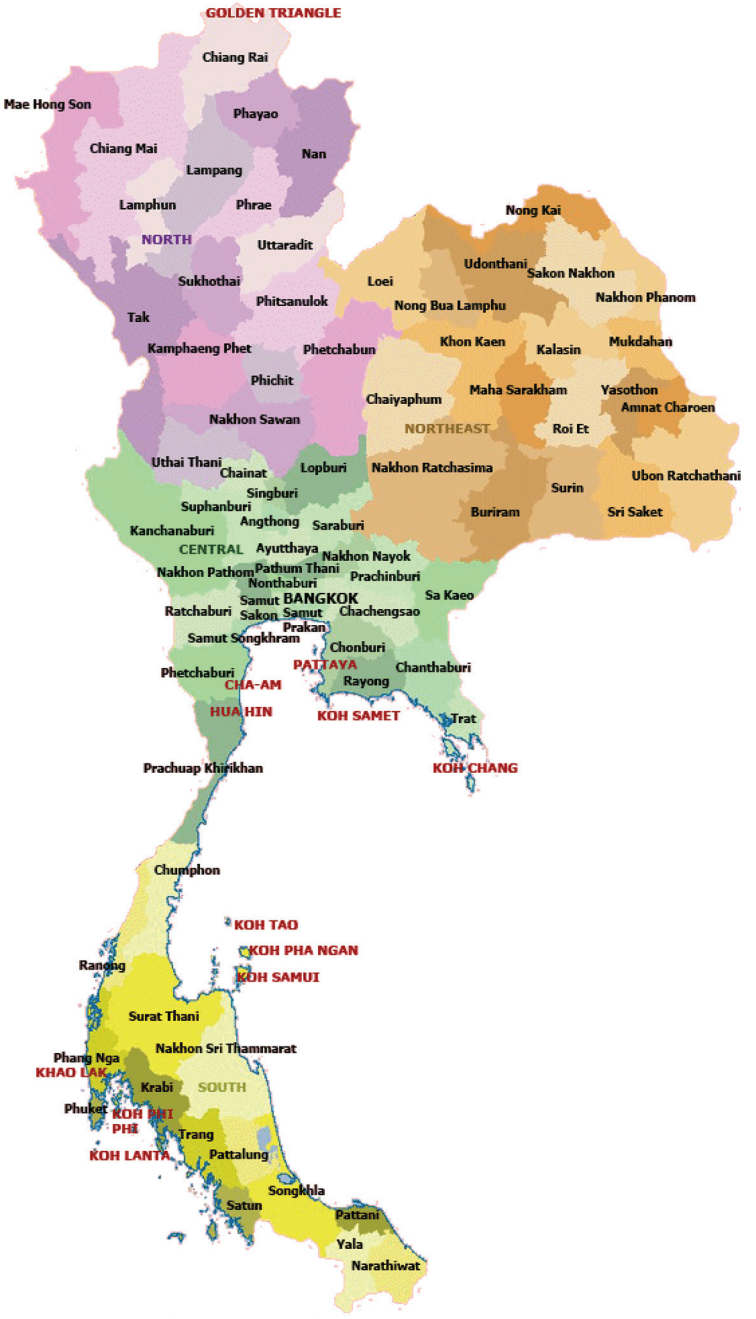

Figure 1. Distribution of the PCI centers participated in Thai PCI registry.

rate, complication rates, type of complications, and mortality would be reported, and multivariate analyses would reveal the independent factors associated with those endpoints.

The quality of PCI procedures could be assessed by benchmarking the results (complications, success rate, mortality) from the present registry to the previous reports from other nation-wide registries. Moreover, the quality assurance of each hospital participating in the present registry could be assessed as well by benchmarking its data with the data from the whole registry.

The present registry would provide the information regarding resource utilization (e.g.,

Table 1. The details of all voluntary PCI centers participated in Thai PCI registry

No.	Hospital name	Type of hospital	Report No. of PCI in 2016*	Report No. of PCI in 2017*	Report No. of PCI in 2018*	No. of intervention cardiologist	No. of hospital bed
1	Maharaj Nakhon Rajchasrima	Government	1,454	1,440	1,513	6	1619
2	Songklanakarin	University	911	1,434	N/A	3	1500
3	Chulalongkorn	University	719	901	815	7	1435
4	Maharaj Nakhon Chiang Mai	University	831	705	615	4	1400
5	Ramathibodi	University	676	790	882	5	1378
6	Sunpasitthiprasong	Government	1,665	1,733	1,888	3	1218
7	Phramongkutklao	University	445	445	484	6	1200
8	Rajavithi	Government	290	423	585	4	1182
9	Buddhachinnarat	Government	1,311	1,856	1,585	6	1063
10	Khon Kaen	Government	694	934	1,017	4	1000
11	Anandamahidol	Government	120	N/A	201	2	1000
12	Udonthani	Government	887	N/A	N/A	4	924
13	Cholburi	Government	644	886	904	3	850
14	Lampang	Government	720	794	720	3	781
15	Suratthani	Government	823	N/A	684	2	780
16	Phrapokklao	Government	689	N/A	939	2	755
17	Maharaj Nakhon Srithammaraj	Government	N/A	N/A	430	2	701
18	Saraburi	Government	593	864	N/A	3	700
19	Hat Yai	Government	412	444	N/A	5	700
20	Bhumibol Adulyadej	Government	387	356	475	4	694
21	Nakhonping	Government	336	N/A	444	5	690
22	Police General	Government	339	N/A	274	3	650
23	Thammasart	University	546	501	570	5	650
24	Nakhonpathom	Government	523	436	332	2	500
25	Naresuan University	University	374	N/A	206	2	471
26	Somdejphrapinklao	Government	198	214	N/A	3	424
27	HRH Maha Chakri Sirindhorn	University	517	309	546	3	360
28	Central Chest Institute of Thailand	Government	2,053	2,028	2,058	10	350
29	Hua Hin	Government	272	263	124	1	340
30	Phyathai 3	Private	263	243	235	4	300
31	Phyathai Sriracha	Private	699	375	555	3	257
32	Chiangmai Ram	Private	52	44	58	3	250
33	Bangkok Hatyai	Private	317	1,277	1,310	3	200
34	Chaophya	Private	112	101	100	3	200
35	Sirikit Heart Center	University	1,629	1,564	1,407	8	200
36	Bangkok Sanamchan	Private	310	798	601	1	198
37	Bangkok Chiang Mai	Private	5	N/A	44	1	180
38	Bangkok Heart	Private	176	391	398	7	97
39	Theptarin	Private	61	N/A	65	1	80
	Total		23,053	22,549	23,064		

	Year 2016	Year 2017	Year 2018
Reported total cases of PCI in Thailand (from all catheterization laboratory including those not participating in Thai PCI registry)*	28,841	36,795	35,557

PCI=percutaneous coronary intervention

* According to national catheterization laboratory survey

average number of guiding catheters, coronary wires, balloons, stents, etc.) which could be beneficial for policy makers such as the Ministry of Health or hospital administrators.

The present registry collected the information regarding both direct and indirect costs of coronary angioplasty as well as quality of life of the patients which could be used in cost-effectiveness and cost-utility analysis. The results of those analyses would provide unprecedented, and useful information which has not been available before.

The present registry provided training to catheterization laboratory staff of all participating centers. This resulted in increase in research knowledge and experience of nurses and research assistants across the country. These personnel would be valuable assets for each hospital in terms of conducting local research in the future.

Last but not least, the Thai PCI registry has set up the strong network of catheterization centers around the country. The network increases level of communication and understanding among catheterization laboratories in Thailand. Sharing of experience and interesting cases had been done via the network. The network generated by the registry served as a solid platform for future collaboration and research.

Discussion

There were some strengths in Thai PCI Registry. First, it was the latest and the largest of PCI in Thailand. Second, the 39 participated sites were distributed in all area of the country and consisted of all types of hospital (e.g., private hospital, provincial hospital, referral tertiary hospital, and university hospital). Nearly all PCI centers with significant volume of procedures participated. This would be well representative of PCI in the country. Third, data accuracy, consistency and quality were excellent. As mentioned above, the CRF, eCRF were well constructed, the definition of all variables were standardized and all research personnel from all participated sites received intensive training regarding the data input and received continuing 24-hours technical support from the DMU to ensure the highest quality and accuracy of the data. The site auditing was completed in all 39 participating sites.

There were also few limitations in the present registry. Participation was voluntary; therefore, some hospitals were not participated in the registry. The results of angiography (e.g., percent stenosis of the lesion, SYNTAX score, lesion type, etc.) were reported by each site (using the same standardized criteria) and no core-lab analysis was available.

Conclusion

The Thai PCI registry is the initiative project of nation-wide collaboration among catheterization laboratories in Thailand. There were 39 sites voluntarily participating in the present registry. The estimated number of procedures included in the present study was 22,000 procedures. The data from the present registry would provide useful information in many aspects, including patient demographics, details of procedures, equipment utilization, success rate, complication rates, mortality, as well as cost of treatment and quality of life of PCI patients. The information acquired by the present registry would be useful for all stakeholders involving in coronary angioplasty in Thailand, and would lead to increase in patient's accessibility to PCI, better resource allocation and improvement in PCI standard and outcomes of the Thai patients.

What is already known on this topic?

- PCI is an important treatment for patient with CAD.
- Many countries, including Thailand, have encourage the patients to access to PCI, resulting in rapid increase in number of PCI centers and procedures across the nation.
- Although PCI has been proven to be cost-effective in many settings, it is an expensive procedure which could be very resource-consuming particularly in low to middle income countries.
- The PCI procedure and results could be varied significantly in many areas of the world.
- The local information regarding current practice and outcomes is essential but up-to-date data for PCI in Thailand is lacking.

What this study adds?

- This publication describes the rationale and methodology as well as the details of CRF, statistical analytic plan and definition used in Thai PCI Registry.
- It is useful for those who would like to know more about the conduction of the registry and for those who would like to cite the reference.
- Thai PCI registry will provide contemporary data of patient demographics, pattern of practice, outcomes, and resource utilization of PCI in real world practice.
- The registry would be beneficial to policy makers, health care providers, and interventional

cardiologists and leads to increase in standard of care for CAD patients.

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Conflicts of interest

The authors declare no conflict of interest.

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