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Highlights of the first Malaysian National Cardiovascular Disease Database (NCVD): Percutaneous Coronary Intervention (PCI) Registry

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KEYWORDS

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PCI registry;
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Summary

Objective: The Malaysian NCVD-PCI registry attempts to determine the number and to monitor the outcomes of Percutaneous Coronary Intervention (PCI), based on selected performance indicators. It provides a comprehensive view to determine the level of adherence to existing guidelines, to evaluate the cost-effectiveness of treatment and prevention programs and to facilitate quality improvement activities of the participants. It also aims to stimulate research and to act as a reference for future studies.

Methods: It was a voluntary, multi-centered, observational, cohort study and included patients of 18 years or above, with coronary artery disease who underwent PCI at eight participating centers in the year 2007.

Results: A total of 3677 patients underwent 3920 PCI procedures with 6299 stents for 5512 lesions. The mean age of patients was 56.7 ± 10.11 years. The mean BMI was 26.38 ± 4.21 kg/m², while 80% of all subjects had a BMI above 23 kg/m². Males constituted 81.2% of the total population and 98.4% of the total population had at least one cardiovascular risk factor. Regarding PCI status, 90.1% were elective cases and 94% of cases had a low TIMI risk index at the beginning of PCI. Femoral approach accounted for 59%, radial approach for 34% and brachial

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approach for 1% of all cases. The median fluoroscopy time was 15.7 min and the median door-to-balloon time for primary infarct PCI was 93.5 min. The commonest site of lesion was the left anterior descending artery, accounting for 48% of all lesions and 92.8% of all lesions were de novo. The mean lesion length was 24.4 ± 15.18 mm and about 28% of all lesions had high risk characteristics. Drug-eluting stents and bare metal stents were used in 53.6% and 42.5% of cases, respectively. After PCI, 91% of all lesions achieved TIMI grade 3 flow. Regarding pharmacotherapy, 99.5% of all patients received unfractionated heparin, 5% received LMWH prior to intervention, 96% received aspirin and 98% received clopidogrel. Over-all in-hospital mortality and 30 day mortality for the entire cohort was 1.1% and 1.8%, respectively.

Conclusion: A summary of the first nationwide PCI registry has been presented. The subjects were much younger with a high prevalence of cardiovascular risk factors. The majority of cases (90%) were elective procedures with a low TIMI risk index. Mean door-to-balloon time for primary PCI was higher than the recommended guidelines. There was good prescribing of antiplatelets and heparin. Over-all in-hospital and 30 day mortality were comparable to other registries.

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Introduction

Since its introduction in Malaysia in 1983, PCI has been extensively practiced and developed over the years, keeping pace with advanced technologies worldwide. Up-to-date, at least 35 public, private and public hospitals perform approximately 9000 PCI procedures annually [1]. However there had been no national registry to record the data correctly.

The NCVD-PCI registry is the first multicentre interventional cardiology project, involving the main cardiac centers in Malaysia. It provides real-life data that can represent the total population characteristics and help to identify the gap between guideline recommendations and actual clinical practice.

The current study summarizes the over-all design and the results of the first annual NCVD-PCI registry in the year 2007.

Methods

Study design

The NCVD-PCI registry 2007 was a voluntary, multi-centered, observational cohort study designed to evaluate the clinical outcome of patients, 18 years old or above with coronary artery disease who underwent PCI at eight participating centers in the year 2007. The contents of the case report form have been summarized in the appendix [Appendix 1].

Data management

The case report form with details of patient characteristics, clinical and procedural information was completed at each PCI and followed up at 30 days and 6 months intervals with data sheets completed accordingly. The patient's national identification number was used to avoid double-counting. After verification, data were entered into the NCVD website (eNCVD). Edit checking and data cleaning were performed periodically to identify missing or inconsistent data. After all queries were resolved, the dataset was locked and exported to the statistician for analysis. The operation of

NCVD was supported by an extensive ICT infrastructure to ensure operational efficacy and effectiveness.

Statistical analysis

Continuous data were summarized as median, mean \pm SD, minimum and maximum; discrete data were presented as a percentage. Prognostic factors were presented as a Hazard ratio, 95% CI and *P*-value. All analyses were performed using STATA version 9.

Results

In the year 2007, a total of 3677 patients among eight participating sites underwent 3920 PCI procedures with 6299 stents for 5512 lesions.

The mean age of patients was 56.7 ± 10.11 years and the majority (65%) was in the 50–70 years age group. Males constituted 81.2% of the total population. The distribution of Malays, Chinese, Indians and non-Malay Bumiputeras was 46.7%, 25.1%, 23.8% and 1.8%, respectively.

Of the total population, 98.4% had at least one cardiovascular risk factor (6.5% with one risk factor, 19.3% with two risk factors, 33.3% with three risk factors, 39.4% with four or more risk factors). Of the total population, 75.3% had dyslipidemia, 74.2% had hypertension, 45.6% had diabetes, 21% had a past history of coronary artery disease, 16% were current smokers and 16% had a positive family history. Mean BMI was 26.38 ± 4.21 kg/m², while 80% of all subjects had a BMI above 23 kg/m².

Considering the clinical presentation at the beginning of PCI, 94% of cases had a low TIMI risk index [2,3]. Of the total cohort, 84% was in New York Heart Association (NYHA) class I-II and 4% had congestive cardiac failure. Acute coronary syndrome and cardiogenic shock comprised 20% and 2% of cases, respectively. Of the ACS cases, STEMI, NSTEMI and UA comprised 42%, 30% and 25%, data were unavailable for the remaining 3% of cases.

Of the total 3920 PCIs performed, 90.1% (3533) were elective cases and 9.4% (370) were urgent, rescue or

primary PCI (Table 1). Less than 1% of patients was transferred from another facility for PCI.

About 87% (3397) of PCI were performed during the same laboratory visit as the diagnostic coronary angiogram (ad hoc).

Considering percutaneous approaches for PCI, femoral approach accounted for 59%, radial approach for 34%, brachial approach for 1% of all cases, the remaining 6% comprising multiple site approaches and missing data. The median fluoroscopy time was 15.7 min while minimum and maximum values were 2.2 min and 180 min, respectively. Median door-to-balloon time for primary infarct PCI was 93.5 min.

A total of 5512 lesions were treated with PCI in all patients. On average, 1.5 lesions were treated per patient and 1.4 lesions were treated during each procedure. The commonest site of lesion was the left anterior descending artery, accounting for 48% of all lesions. This was followed by the right coronary artery (29%), left circumflex artery (18%) and grafts (1%). Considering lesion characteristics, 92.8% were de novo, 4.4% were re-stenosis and 0.4% were stent thrombosis. Mean lesion length was 24.4 ± 15.18 mm, mean pre-procedure estimated stenosis was $84.4 \pm 12.14\%$ and about 28% of all lesions had high risk characteristics (ostial, bifurcation, totally occluded and thrombus). According to American College of Cardiology (ACC) classification, most of the lesions (44.4%) were type C (Table 2).

After PCI, 91% of all lesions achieved TIMI grade 3 flow (Table 3).

The commonest post-procedure complications were vessel dissection, which occurred in 3.9% cases, where additional stents were required.

A total of 6299 stents were used, an average of 1.23 stents per lesion. Drug-eluting stents and bare metal stents were used in 53.6% and 42.5%, respectively. Mean stent length was 22.75 ± 7.28 mm. Regarding pharmacotherapy, 99.5% of all patients received unfractionated heparin, 5% received LMWH prior to the procedure, 96% received aspirin and 98% received clopidogrel. Among patients prescribed

Table 1 Distribution of procedures according to PCI status.

PCI status	Total no. of procedures	
	N = 3920	(%)
Elective	3533	90.1
Urgent (NSTEMI/ UA) (Less than 72 h of admission)	190	4.8
Rescue	76	1.9
Primary	104	2.7
Not available	17	0.4

Table 2 Prevalence of lesions according to American College of Cardiology Classification.

Lesion type	N = 5512	Percentage (%)
A	631	11.4
B1	1239	22.5
B2	1038	18.8
C	2436	44.2
Unavailable data	168	0.03

Table 3 Comparison of TIMI flow grade before and after procedure.

Pre-procedure		Post-procedure	
TIMI flow grade	No. (%)	TIMI flow grade	No. (%)
TIMI-0	712 (12.9%)	TIMI-0	114 (2.1%)
TIMI-1	245 (4.4%)	TIMI-1	32 (0.6%)
TIMI-2	755 (13.7%)	TIMI-2	69 (1.3%)
TIMI-3	3528 (64.0%)	TIMI-3	5013 (90.9%)

with clopidogrel, 92% started the medicine prior to the procedure and 47% were given a first loading dose of 300 mg. Only 7.2% received a loading dose of 600 mg. Duration of clopidogrel use depended on the clinical setting and the type of stent implanted. About 34% patients had been already on long term clopidogrel therapy and hence did not receive a loading dose prior to the procedure.

Over-all in-hospital mortality for the entire cohort was 1.1%, of which 80% of deaths were due to cardiac causes and 20% due to non-cardiac causes. The 30 day mortality rate was 1.8%. Poor prognostic factors were Killip class IV, poor TIMI flow post-PCI (grade 0–2), diabetes, advanced age, previous MI and hypertension.

Discussion

The NCVD-PCI registry started with eight main cardiac centers around Malaysia. The mean age of patients undergoing PCI was 56.7 years, much younger compared to the mean age of 65.7 years in Swedish Coronary Angiography and Angioplasty Register (SCAAR) [4]. Eighty percent of all patients had a BMI above 23, the cut-off point for public health action as recommended by WHO [5].

Ninety eight percent of the total cohort had at least one cardiovascular risk factor. In NCVD-PCI registry, diabetes and hypertension were documented in 46% and 72% of patients respectively. In SCAAR, diabetes and hypertension were documented in 20% and 45% of patients, respectively. The high prevalence of cardiovascular risk factors among the Malaysian subjects points towards the importance of primary prevention for coronary artery disease.

The majority (94%) of patients had a low TIMI risk index at the beginning of the procedure, probably co-relating with the fact that the majority (90%) were elective cases. Femoral access was the commonest percutaneous approach (59%), followed by radial approach (34%). Although radial access is associated with fewer vascular complications and the added benefit of easy compressibility and patient comfort, it requires higher technical skills [6], which probably explains the reason for less radial approaches.

While 28% of all cardiac lesions had high risk characteristics, post-procedure TIMI grade-3 flow in 91% of all lesions indicates an over-all good success rate for PCI in the cardiac centers involved. In spite of doing procedures with high risk characteristics and type C lesions, the incidence of stent thrombosis was only 0.4%, which is consistent with other registries. Median door-to-balloon time for primary infarct PCI was 93.5 min, still higher than the recommended door-to-balloon time of less than 90 min [7].

Drug-eluting stents and bare metal stents were used in 53.6% and 42.5% of all procedures respectively, keeping pace with the trend of increasing use of drug-eluting stents. The practice of pharmacotherapy was satisfactory for unfractionated heparin (99.5%), aspirin (96%) and clopidogrel (98%). The duration of dual antiplatelets after PCI depended on the type of stent implanted.

Over-all in-hospital and 30 day mortality was low, reflecting that PCI was safe for most of the patients. Major prognostic factors were Killip class IV and poor TIMI flow post-PCI (grade 0–2).

Conclusion

Analysis of the 1st annual NCVD-PCI report revealed some remarkable features in terms of early age of subjects with a high prevalence of cardiovascular risk factors, low TIMI risk index at intervention and good success rate in spite of a significant percentage of high risk lesions. There was good practice of pharmacotherapy and low in-hospital and 30 day mortality. Median door-to-balloon time was still higher than that of recommended guidelines, an issue that needs attention. NCVD-PCI registry aims to improve the over-all cardiac services in Malaysia through its ongoing journey.

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Appendix A: Summary of case report form

A.1. Notification form

Section 1: Patient demographics (name, identification number, gender, age, contact number, admission status).

Section 2: Status before event (smoking, past medical history and pre-morbidity).

Section 3: Clinical examination and baseline investigation (anthropometrics, heart rate, serum creatinine, cholesterol level, baseline electrocardiogram result).

Section 4: Previous interventions (Percutaneous Coronary Intervention or coronary artery bypass grafting).

Section 5: Cardiac status at PCI procedure (heart failure, Killip classification, New York Heart Association classification, acute coronary syndrome, cardiogenic shock etc.)

Section 6: Cath lab visit (date and time of procedure, PCI status, medications, planned duration of antiplatelets,

percutaneous approach, extent of coronary disease, fluoroscopy time etc.)

Section 7: PCI procedure details (number of lesions treated, lesion type and description, pre-PCI and post-PCI TIMI flow, length of lesion, stent details etc.)

Section 8: In-hospital outcome (if any periprocedural complication).

Section 9: Outcome at discharge (alive/death/transferred to another center).

Follow-up at 30 days (outcome, smoking status, re-admission).

Follow-up at 6 and 12 months (outcome, smoking status, re-admission).

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