ASSOCIATION BETWEEN BODY MASS INDEX AND
OUTCOMES AFTER PERCUTANEOUS CORONARY
INTERVENTION IN MULTI-ETHNIC SOUTH EAST
ASIAN POPULATION: A RETROSPECTIVE ANALYSIS
OF THE MALAYSIAN NATIONAL CARDIOVASCULAR
DISEASE DATABASE - PERCUTANEOUS CORONARY
INTERVENTION (NCVD-PCI) REGISTRY

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Field of Study: Internal Medicine

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ABSTRACT

Objective:

The state of being obese has been generally associated with worse outcomes in many clinical conditions. However, it has been shown in certain settings that obesity might be protective and had better outcomes, and this phenomenon is called "obesity paradox". This study was conducted to examine the relationship between body mass index (BMI) and outcomes after percutaneous coronary intervention (PCI) in a multi-ethnic South East Asian population.

Methods:

This is a retrospective study of anonymized data obtained from the Malaysian National Cardiovascular Disease Database – Percutaneous Coronary Intervention (NCVD–PCI) registry. 28,742 patients from the NCVD-PCI registry who had their first PCI between January 2007 and December 2014 were included. Those without their body mass index (BMI) recorded or BMI less than 11 kg/m^2 or more than 70 kg/m^2 were excluded.

The patients were divided according to their BMI groups, and their baseline characteristics, angiographic profiles and medications upon discharge were compared. In-hospital death, major adverse cardiovascular events (MACE), and vascular complications between different BMI groups were examined. Multivariable-adjusted hazard ratios (HR) for 1-year mortality after PCI among the BMI groups were also calculated.

Results:

The patients were divided into four groups; underweight (BMI <18.5 kg/m^2), normal BMI (BMI 18.5 to <23 kg/m^2), overweight (BMI 23 to <27.5 kg/m^2) and obese (BMI

≥ 27.5 kg/m^2). Comparison of their baseline characteristics showed that the obese group was younger, had lower prevalence of smoking but higher prevalence of diabetes, hypertension, and dyslipidemia. Obese patients were more likely to have multi-vessel disease, but lesser involvement of the Left Anterior Descending (LAD) artery. There was no difference found in terms of in-hospital death, MACE and vascular complications after PCI. Multivariable Cox proportional hazard regression analysis showed that compared to normal BMI group, the underweight group had a non-significant difference (HR: 1.02, p=0.952), while the overweight group had significantly lower risk of 1-year mortality (HR: 0.71, p=0.005).The obese group also showed lower HR but this was non-significant (HR: 0.78, p=0.056).

Conclusion:

Using Asian specific BMI cut-off points, the overweight group in our study population was independently associated with lower risk of 1-year mortality after PCI compared to the normal BMI group.

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LIST OF ABBREVIATIONS

ACE-I   Angiotensin converting enzyme inhibitor

ACS   Acute coronary syndrome

AIDS   Acquired immune deficiency syndrome

ARB   Angiotensin II receptor blocker

BMI   Body mass index

BMS   Bare metal stent

CABG   Coronary artery bypass graft

CI   Confidence interval

COPD   Chronic obstructive pulmonary disease

CVA   Cerebrovascular accident

DES   Drug eluting stent

HIV   Human immunodeficiency virus

HR   Hazard ratio

LAD   Left anterior descending

LCX   Left circumflex

LMS   Left main stem

MACE   Major adverse cardiovascular events

MI   Myocardial infarction

MREC   Medical Research and Ethics Committee

MVD   Multi-vessel disease

NCVD-PCI   National Cardiovascular Disease Database – Percutaneous Coronary

            Intervention

NHMS   National Health and Morbidity Survey

NSTEMI   Non ST-elevation myocardial infarction

PCI   Percutaneous coronary intervention

RCA   Right coronary artery

SD   Standard deviation

STEMI   ST-elevation myocardial infarction

SVD   Single vessel disease

TNF   Tumor necrosis factor

WC   Waist circumference

WHO   World Health Organization

WHR   Waist-to-hip ratio

WSR   Waist-to-stature ratio

CHAPTER 1: INTRODUCTION

Obesity is defined as the state of being grossly fat or overweight. Body mass index (BMI) has been traditionally used to define obesity, in which according to World Health Organization (WHO) classification, a BMI between 25 kg/m^2 to 30 kg/m^2 is considered overweight, while a BMI of 30 kg/m^2 or more is considered obese (WHO, 2000). The prevalence of obesity had been increasing, as shown by Ng et al. (2014) that the proportion of adults with a BMI of 25 or greater had increased between 1980 and 2013 from about 30 to 38% in women and from about 29 to 37% in men. They also estimated that in 2013, more than 2 billion people in the world were overweight or obese and about 671 million of them were obese (Ng et al., 2014).

In Malaysia, the prevalence of overweight and obesity has also been increasing steadily for the past years. According to the National Health and Morbidity Survey (NHMS) 2015, a population based survey involving all the states in Malaysia, the national prevalence of overweight, obesity and abdominal obesity had increased by 0.6%, 2.6% and 2.0% respectively as compared to previous findings in 2011. The prevalence of obesity in Malaysia was reported as 17.7%, which was even higher than the 13% prevalence of obesity globally in 2014 (Institute for Public Health, 2015).

Overweight and obesity are generally associated with higher morbidity and mortality compared to those with normal BMI. It has been reported in large collaborative analyses of multiple prospective studies that BMI above 25 kg/m^2 was a strong predictor of overall mortality, and specifically, each 5 kg/m^2 higher BMI was associated with about 40% higher ischaemic heart disease mortality (Prospective Studies Collaboration, 2009). These prospective studies also shown that those who were

extremely morbid (BMI > 40 kg/m^2) were found to have their median survival reduced by 8 to 10 years, compared to 0 to 1 year for people who had BMI of 25-27.5 kg/m^2 by the time they were 60 years old.

Despite having poorer overall survival and mortality, it has been shown as well in certain conditions that being overweight and obese could be protective. This includes chronic obstructive pulmonary disease (COPD), end-stage renal failure and Human Immunodeficiency Virus (HIV) / Acquired Immune Deficiency Syndrome (AIDS) (McAuley & Blair, 2011). This interesting phenomenon is called 'obesity paradox' and from cardiovascular point of view, it was first reported in 1996 by Ellis et al. that obesity may be protective in patients undergoing percutaneous coronary interventions (PCI).

As obesity has become a major health problem in Malaysia, it would be interesting to see whether obesity paradox also exist in our population. In this study, we examined the prevalence of obesity among patients undergoing PCI and the differences on demographic, clinical and angiographic findings among the different BMI groups. We also examined the association between BMI groups and outcomes after PCI in our multi-ethnic Malaysian population.

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CHAPTER 2: LITERATURE REVIEW

2.1 Classification of BMI

Body mass index (BMI) which has been traditionally used as an indicator of overweight and obesity, is calculated by dividing one's weight in kilograms by the square of one's height in meters. The most widely used BMI classifications are those first proposed by WHO in 2000 and the values are as in the table below:

Table 1: WHO 2000 BMI classifications.

BMI range	Classification
< 18.5	Underweight
18.5 - 24.9	Normal
25.0 - 29.9	Overweight
30.0 and above	Obese
30.0 - 34.9	Class I Obesity
35.0 - 39.9	Class II Obesity
40.0 and above	Class III Obesity

The rationale of dividing into different BMI groups was to identify individuals and groups who are at increased risk of morbidity and mortality. Overweight and obese individuals had been shown to have higher risk of cardiovascular disease and diabetes, and these two major non-communicable disease are major global burden (WHO, 2000).

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However, it has been acknowledged that different populations might have different body proportions, and this resulted in different degree of fatness between different ethnicities despite having the same BMI values. For example, Asian population who have smaller physique compared to their Western counterparts might have higher degrees of fatness at lower BMI values. It has also been demonstrated that Asian people had higher risk of getting cardiovascular disease and type 2 diabetes mellitus at lower BMI values (Decode-Decoda Study Group, 2003).

In 2004, WHO had attempted to identify the BMI cut off points suitable to be used for Asian population. Despite retaining their recommendation to use the original international classification (as per table 1), they however did recommend lower BMI cut off points for Asian people that requires public health action. The suggested categories for Asian population were: below 18.5 kg/m^2 (underweight), 18.6 - 23 kg/m^2 (increasing but acceptable risk), 23-27.5 kg/m^2 (increased risk) and 27.5 kg/m^2 or higher (high risk) (WHO, 2004).

In Malaysia, as obesity had become more prevalent, a local clinical practice guideline (CPG) was jointly published by the Ministry of Health and Malaysian Endocrine and Metabolic Society in 2004 for the management of obesity. In this CPG, the writing committee recommended using lower BMI cut off values to define overweight and obese in Malaysian population (Table 2), and this was similar to the WHO 2004 recommended classification for Asian population as mentioned above.

Table 2: BMI classification based on Malaysian CPG for the Management of Obesity 2004.

BMI range	Classification	Risk of Co-morbidities
< 18.5	Underweight	Low (but increased risk of other clinical problems)
18.5 - 22.9	Normal	Average
23.0 - 27.4	Overweight	Increased
27.5 and above	Obese	
27.5 - 34.9	Class I Obesity	Moderate
35.0 - 39.9	Class II Obesity	Severe
40.0 and above	Class III Obesity	Very Severe

2.2 Obesity paradox in patients who underwent PCI

As mentioned previously, despite the common belief of poorer outcomes in patients who are overweight and obese, the phenomenon termed "obesity paradox" has been demonstrated in many clinical settings, where patients with higher than normal BMI had better outcomes than those within the normal BMI range. In cardiovascular medicine, it was first reported by Ellis et al. in 1996 that in patients who underwent percutaneous coronary intervention (PCI), those who were in the BMI range of 26 to less than 35 kg/m^2 had better outcomes than those with BMI less than 25 kg/m^2. Other than PCI, obesity paradox was also seen in atrial fibrillation, heart failure and after

coronary artery bypass grafting (CABG) (McAuley & Blair, 2011). Many previous studies had been conducted mainly in the Western countries to investigate the relationship between BMI and outcomes after PCI. Table 3 below summarizes some of the previous studies done to investigate the relationship between BMI and outcomes after PCI.

Table 3: Summary of previous studies investigating association between BMI and outcomes after PCI.

Study, country	PCI indications	Sample size (n)	Outcomes	BMI group with best outcomes (kg/m^2)
Ellis et al. (1996), Ohio	ACS, stable angina	3571	In hospital death	25 - 35
Gurm et al. (2002), Ohio and North Carolina	ACS	6271	Complications within 30 days 1-year mortality	30 -39.9
Gruberg et al. (2002), Washington	ACS, stable angina	9633	MACE and 1-year mortality	≥30
Byrne et al. (2009), Canada	ACS, stable angina	38,346	1-year mortality	18.5 - 30
Kang et al., (2009), South Korea	STEMI	3824	In-hospital and overall mortality	≥27.5
Kaneko et al. (2013), Japan	ACS, stable angina	1205	MACE, All cause death, readmission for heart failure	≥30

Kang et al. (2014), New York	ACS, stable angina	780	Target lesion revascularization within 1 year	≥29.3
Numasawa et al. (2015), Japan	ACS, stable angina	10,142	In - hospital complications	25 - 30
Gregory et al. (2016), Canada	ACS, stable angina	6633	Vascular Complications	≥30
Holroyd et al. (2017), United Kingdom	ACS, stable angina	345,192	Mortality at 30 days, 1 year, 3 years, 5 years	25 - 30

- ACS, acute coronary syndrome; BMI, body mass index; MACE, major adverse cardiovascular event; STEMI, ST-elevation myocardial infarction.

As can be seen in Table 3, most of the studies were done in Western countries, while those conducted in Asia were done in Japan and South Korea only. Therefore, more researches are required to examine the relationship between BMI and outcomes after PCI in the Asian population, and whether our local population also exhibit similar better outcomes in the obese group as those demonstrated in the Western countries.

CHAPTER 3: METHODOLOGY

3.1 Research Objectives

1. To examine the prevalence of obesity among patients undergoing PCI.

2. To examine the demographic, clinical and angiographic findings among the different BMI groups.

3. To examine the association between BMI groups and outcomes after PCI. This includes in-hospital outcomes and mortality within 1 year after the index PCI.

3.2 Research Hypothesis

We hypothesize that there was no differences between different BMI groups in terms of outcomes after PCI.

3.3 Research Design and Data Source

This is a retrospective analysis of anonymized prospectively collected data for patients who underwent PCI between January 2007 and December 2014. The data was obtained from the Malaysian NCVD–PCI registry. This registry which was established since 2007 is an ongoing observational prospective registry of patients who underwent PCI initially from eight participating centres and for the last report data was obtained from fifteen participating centres in Malaysia (Ahmad & Liew, 2016). Consecutive patients age above 18 years old undergoing PCI were included in the database. The cases were initially notified using data abstraction form (Appendix A), completed at each site by interventional cardiologists, medical officers, nurses or lab technicians. These were compiled and later transcribed into an online web based centralized

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database which was encrypted with security passwords unique to each user (Liew et al., 2008).

The initial notification comprised of information including: demographics, clinical status, clinical examination and baseline investigations, previous revascularization, cardiac status at the time of PCI, catheterization laboratory visit (including adjunctive pharmacotherapy), PCI procedural details, procedural outcome and clinical status at discharge (Liew et al., 2008) (see Appendix A). Subsequent follow ups were made via phone calls at 30 days, 6 months and 12 months after the index procedure. The status of the patient (dead or alive) at follow up was recorded and any death status reported was cross-checked with the national death registry.

3.4 Inclusion and Exclusion Criteria

All patients from the NCVD-PCI registry with plausible BMI (BMI 11 - 70 kg/m²) who underwent PCI between January 2007 till December 2014 were included in the analysis. Those with BMI less than 11 kg/m² or more than 70 kg/m², or missing BMI data were excluded from the analysis. For those patients who had more than one admission for PCI within the study period, only their first admissions were included in the analysis.

3.5 Data Collection

In our study, 36,010 patients who had their first PCI done between January 2007 and December 2014 were identified. The indications for PCI included both for acute coronary syndrome (ACS) and non-acute coronary syndrome (non-ACS). ACS was

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defined as either unstable angina, Non ST-elevation myocardial infarction (NSTEMI) or ST-elevation myocardial infarction (STEMI). Non-ACS included those who had stable angina, positive functional ischemia test or positive cardiac imaging test.

Those with BMI (derived automatically from height and weight) recorded in the database were included in the study, and for those patients who had repeated PCI done at later date, only their first PCI were included in the analysis. We divided the eligible patient into four different BMI categories; underweight (<18.5 kg/m^2), normal BMI (18.5 to <23kg/m^2), overweight (23 to <27.5kg/m^2) and obese (≥27.5 kg/m^2). The cut off values for these different BMI groups were based on the lower BMI cut off values for public health action suggested by the WHO for Asian population which is also used by our local Malaysian obesity clinical practice guideline (WHO, 2004). From the initial 36,010 patients identified, 7,268 patients were excluded from analysis due to either missing BMI values or having implausible BMI. 28,742 patients then remained and were included for analysis.

3.6 Data Variables

Data were collected for demographic characteristics (age, gender, ethnicity, BMI, smoking status), premorbid conditions, and previous cardiovascular history (previous histories of PCI, coronary artery bypass graft (CABG) surgery, myocardial infarction and heart failure). Premorbid conditions collected included diabetes mellitus, hypertension, dyslipidemia, and renal impairment (serum creatinine > 200 μmol/L).

Indications for PCI and the angiographic findings for all the PCI procedures during the patient's first admission were recorded. Multi-vessel disease was defined as

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having two or more coronary arteries with ≥50% stenosis. The coronary vessels where the intervention was done and the type of stenting employed were recorded as well. The medications upon discharge after the index PCI were also documented.

The outcomes of interest were in-hospital complications and all-cause mortality during admission and within 1 year after the index PCI. In-hospital complications included death, vascular complications or any major adverse cardiovascular events (MACE). Vascular complications included bleeding, access site occlusion, loss of distal pulse, dissection, and pseudoaneurysm, while MACE included periprocedural MI, emergency PCI, emergency CABG, cardiogenic shock, arrhythmia, transient ischemic attack/stroke, cardiac tamponade, and new or worsening heart failure.

3.7 Statistical Analysis

Patients were categorized into four groups according to their calculated BMI. Data for each BMI groups were compared for their differences. Continuous variables were expressed as mean ± standard deviation (SD), and their differences were compared using one-way ANOVA if they were normally distributed. Normality was examined by SPSS skewness and kurtosis. Categorical variables were expressed as frequencies and percentages, and their differences were analysed using Chi-square test.

To evaluate the association between BMI categories and mortality within 1 year, their respective multivariable–adjusted hazard ratios (HR) were calculated using Cox proportional–hazards regression model. The BMI category 18.5 to <23.0 kg/m² (normal BMI) was considered the reference group. Variables included in the model were chosen

by separate univariate analyses; those with p-value of <0.05 were included in the final model, as well as those that were of clinical importance.

To avoid biases in the estimates and loss of power, missing data for the included variables (except for BMI) were imputed using multiple imputation by chained equations, with five imputed data sets created. Missing data were assumed to be missing at random. Multivariable Cox proportional hazards regression analysis was then performed with the imputed data sets, and the pooled results were obtained. Multicollinearity between the included variables was examined using standard error of b coefficient. All tests were two sided and a p-value of less than 0.05 was considered to be statistically significant. The assumption of proportional hazards for each covariate was reviewed separately by the means of log-minus-log survival plots. Hazard ratios were reported together with the 95% confidence interval (CI) values. All statistical analyses were performed using SPSS version 23.

3.8 Ethic Statement

The NCVD-PCI has received ethical approval from the Medical Research and Ethics Committee (MREC) under the Ministry of Health Malaysia, and is registered with the National Medical Research Register of Malaysia (ID: NMRR-07-20-250).

CHAPTER 4: RESULTS

4.1 Patient Characteristics

Between January 2007 and December 2014, we identified 28,742 patients with BMI range between 11 to 70 kg/m^2 that underwent their first PCI from our NCVD–PCI database. The patients were divided into 4 groups according to their BMI values as shown in Table 4, and the distribution of patients according to their BMI groups is shown in Figure 1. There were more males than females in all four BMI groups. Overweight and obese groups had significantly higher percentages of males (84.1% and 82.1% respectively) compared to underweight (80%) and normal BMI (81.2%) groups.

Among the three major ethnic groups, Malay showed significantly higher percentages recorded in the higher BMI groups, while Chinese showed the opposite. Comparing the mean age between the four groups, it can be seen that there was a significant trend of decreasing mean age as we move to higher BMI groups. The opposite was true for systolic and diastolic blood pressure, in which the lower BMI groups had significantly lower mean systolic and diastolic blood pressure. The number of current smokers was also significantly higher in the underweight group (32.2%), compared with the obese group (25.7%).
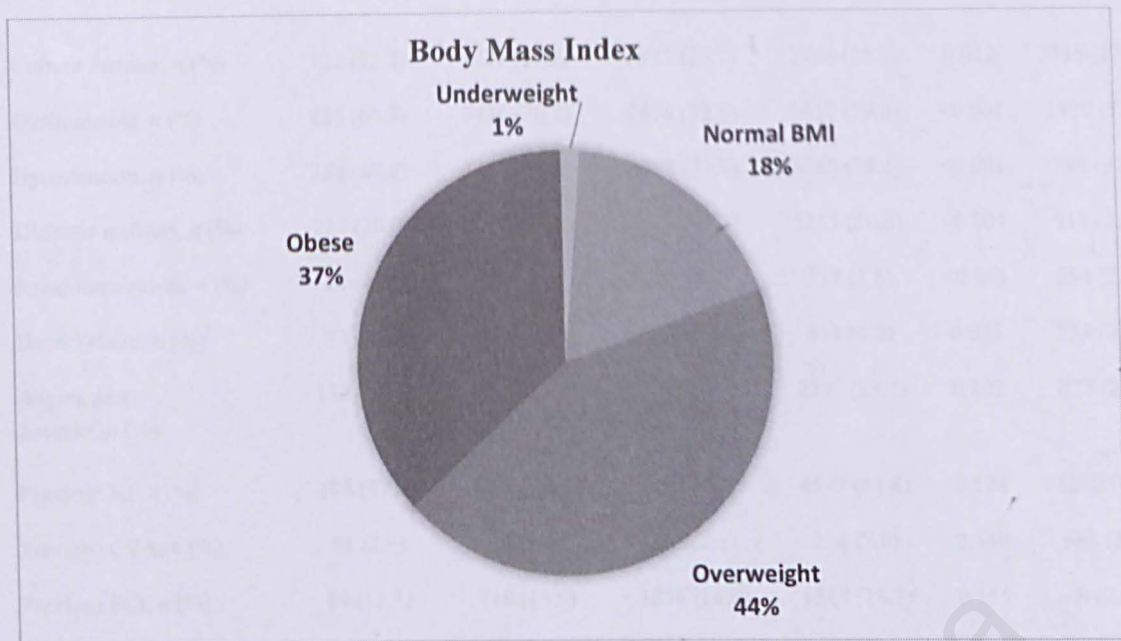
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Figure 1: Distribution of patients according to BMI groups

Table 4: Patient's baseline characteristics and clinical presentation on admission.

	Underweight	Normal Weight	Overweight	Obese	P value	Missing Values, n (%)
	(n = 435)	(n = 5168)	(n = 12605)	(n = 10534)		
Gender, n (%)					<0.001	0 (0)
Male	348 (80.0)	4198 (81.2)	10601 (84.1)	8653 (82.1)		
Female	87 (20.0)	970 (18.8)	2004 (15.9)	1881 (17.9)		
Ethnicity, n (%)					<0.001	24 (0.1)
Malay	199 (45.7)	2183 (42.3)	5967 (47.4)	5977 (56.8)		
Chinese	118 (27.1)	1500 (29.1)	3030 (24.1)	1795 (17.1)		
Indian	78 (17.9)	1077 (20.9)	2649 (21.0)	2029 (19.3)		
Others	40 (9.2)	403 (7.8)	950 (7.5)	723 (6.9)		
Age (mean ± SD)	61.4 ± 11.0	60.2 ± 10.4	57.9 ± 10.0	55.5 ± 10.0	<0.001*	0 (0)
BP on admission (mean ± SD)					<0.001*	1366 (4.8)
Systolic	134.6 ± 28.1	136.6 ± 26.5	136.6 ± 24.8	138.6 ± 24.4		
Diastolic	72.8 ± 13.0	74.6 ± 12.5	76.7 ± 12.2	78.9 ± 12.6		

					*p value	
Current Smoker, n (%)	122 (32.2)	1227 (27.2)	2922 (26.7)	2360 (25.7)	0.012	3715 (12.9)
Dyslipidemia, n (%)	285 (69.9)	3431 (70.3)	8678 (72.6)	7617 (76.0)	<0.001	1479 (5.1)
Hypertension, n (%)	288 (67.9)	3438 (68.7)	8788 (71.7)	8088 (78.4)	<0.001	743 (2.6)
Diabetes mellitus, n (%)	127 (30.0)	2043 (41.1)	5521 (45.3)	5213 (50.8)	<0.001	911 (3.2)
Renal impairment, n (%)	21 (4.9)	332 (6.6)	607 (4.9)	577 (5.6)	<0.001	664 (2.3)
Heart Failure, n (%)	23 (5.5)	218 (4.3)	441 (3.6)	411 (4.0)	0.035	759 (2.6)
Angina past 2 weeks, n (%)	112 (26.5)	1223 (24.4)	2998 (24.5)	2391 (23.3)	0.102	823 (2.9)
Previous MI, n (%)	196 (47.5)	2298 (46.8)	5457 (45.3)	4537 (44.8)	0.104	1250 (4.3)
Previous CVA, n (%)	11 (2.6)	94 (1.9)	262 (2.1)	204 (2.0)	0.549	686 (2.4)
Previous PCI, n (%)	49 (11.3)	719 (13.9)	1836 (14.6)	1544 (14.7)	0.155	8 (0.0)
Previous CABG, n (%)	15 (3.4)	182 (3.5)	485 (3.8)	392 (3.7)	0.755	12 (0.0)
PVD, n (%)	9 (2.1)	56 (1.1)	95 (0.8)	64 (0.6)	<0.001	694 (2.4)
Documented CAD, n (%)	215 (50.9)	2544 (50.9)	6472 (53.0)	5456 (53.1)	0.042	826 (2.9)

- BP, blood pressure; CABG, coronary artery bypass graft; CAD, coronary artery disease; CVA, cerebrovascular accident; MI, myocardial infarction; PCI, percutaneous coronary intervention; PVD, peripheral vascular disease; SD, standard deviation.
- *p value based on One-way ANOVA test.

In terms of previous medical illness and cardiovascular history, obese patients were more likely to have diabetes mellitus, hypertension, and dyslipidaemia, compared with the lower BMI groups. They were however less likely to have heart failure compared with the leaner patients. There was no significant difference noted between the different BMI groups in terms of previous myocardial infarction (MI), cerebrovascular accident (CVA), and previous PCI or CABG.

4.2 Indications and Cardiac Status at PCI

In general, there were more PCIs conducted for non-ACS indication compared to ACS in all four BMI groups (Table 5). The percentages for ACS were higher in the lower BMI groups while the percentages for non-ACS were higher in the overweight and obese groups. Further breakdown of types of ACS showed no significant difference among the BMI groups in terms of diagnosis of unstable angina, NSTEMI or STEMI. However, in those with STEMI, the obese group was more likely to have lower Killip class compared to the lower BMI groups.

Table 5: Cardiac status at PCI.

	Underweight	Normal Weight	Overweight	Obese	P value	Missing Values, n (%)
	(n = 435)	(n = 5168)	(n = 12605)	(n = 10534)		
Indication, n (%)					<0.001	50 (0.2)
ACS	164 (37.7)	1851 (35.9)	4418 (35.1)	3366 (32.0)		
Non-ACS*	271 (62.3)	3301 (64.1)	8161 (64.9)	7160 (68.0)		
ACS type, n (%)					0.320	99 (1.0)
STEMI	86 (53.1)	996 (54.4)	2439 (55.7)	1776 (53.4)		
NSTEMI	50 (30.9)	583 (31.8)	1390 (31.7)	1082 (32.5)		
UA	26 (16.0)	253 (13.8)	550 (12.6)	469 (14.1)		
Killip** class, n (%)					0.022	998 (18.8)
I & II	60 (85.7)	720 (88.8)	1822 (91.5)	1312 (92.0)		
III & IV	10 (14.3)	91 (11.2)	170 (8.5)	114 (8.0)		
PCI post STEMI, n (%)					0.071	-
Primary	3 (7.7)	51 (11.7)	131 (13.4)	91 (14.4)		
Rescue	25 (64.1)	313 (72.0)	715 (73.2)	465 (73.3)		
Delayed	11 (28.2)	71 (16.3)	131 (13.4)	78 (12.3)		

- ACS, acute coronary syndrome; NSTEMI, Non ST-elevation myocardial infarction; PCI, Percutaneous coronary intervention; STEMI, ST-elevation myocardial infarction; UA, unstable angina.

- *included stable angina, positive functional ischemia test, and positive cardiac imaging test.

- **Killip class for patients with STEMI only.

4.3 Angiographic Profile

Procedural characteristics were tabulated in Table 6. In terms of number of vessels involvement, the obese group had a tendency towards more multi-vessel involvement, and the underweight group had a tendency towards single vessel involvement.

The characteristics of the lesions however did not differ much among the groups. There was no significant pattern noted in terms of lesion type and lesion length. Left anterior descending (LAD) artery was the most commonly involved vessel compared to the other sites. Among the different BMI groups, the obese and overweight group however showed significantly lesser involvement of the LAD compared to their leaner counterparts. Besides this, the obese group also had a higher proportion of drug eluting stent (DES) used, and was also associated with higher chance of using the radial artery approach for vascular access.

Table 6: Angiographic profile and lesion characteristics.

Angiography findings	Under weight	Normal Weight	Overweight	Obese	P value
Coronary disease, *n* (%)					<0.001
SVD*	140 (50.5)	1669 (51.9)	3945 (49.9)	3124 (47.2)	
MVD**	137 (49.5)	1546 (48.1)	3961 (50.1)	3499 (52.8)	
Lesion type, *n* (%)					0.248
A & B1	181 (37.1)	2252 (39.6)	5298 (38.1)	4459 (38.3)	
B2 & C	307 (62.9)	3442 (60.4)	8606 (61.9)	7191 (61.7)	
Lesion Length, *n* (%)					0.485
< 20 mm	207 (45.1)	2424 (45.3)	5759 (44.1)	4863 (44.3)	
> 20 mm	252 (54.9)	2929 (54.7)	7314 (55.9)	6109 (55.7)	
Target vessel, *n* (%)					
LMS	11 (2.2)	121 (2.1)	278 (2.0)	188 (1.6)	0.480
LAD	256 (51.2)	2564 (44.4)	6222 (44.0)	5226 (44.0)	0.017
LCX	48 (9.6)	689 (11.9)	1731 (12.3)	1454 (12.3)	0.309
RCA	121 (24.2)	1358 (23.5)	3368 (23.8)	2897 (24.4)	0.551
Type of stent used, *n* (%)					<0.001
DES	296 (65.1)	3545 (67.1)	8785 (68.2)	7533 (69.9)	
BMS	97 (21.3)	1100 (20.8)	2675 (20.8)	2174 (20.2)	
Other	62 (13.6)	638 (12.1)	1422 (11.0)	1071 (9.9)	
Vascular access, *n* (%)					<0.001
Radial	185 (44.3)	2520 (50.4)	6492 (53.3)	5520 (54.4)	
Femoral	239 (57.2)	2551 (51.0)	5897 (48.4)	4884 (48.1)	

- BMS, Bare metal stent; DES, Drug eluting stent; LAD, Left anterior descending; LCX, Left circumflex; LMS, Left main stem; MVD, Multi-vessel disease; RCA, Right coronary artery; SVD, Single vessel disease.

- *Single Vessel Disease: Lesion of >50% stenosis in 1 coronary system.

- **Multi Vessel Disease: Lesion of >50% stenosis in ≥2 coronary systems.

4.4 Discharge Medications

Upon discharge from the hospital, the rates of prescribing aspirin, clopidogrel and statin were the same for all groups. Usage of other evidence-based therapies such as beta blocker, angiotensin converting enzyme inhibitor (ACE-I) or angiotensin receptor II blocker (ARB) were higher in the obese and overweight group compared to the lower BMI groups (Table 7).

Table 7: Medications at discharge.

Medication on discharge, n (%)	Under weight (n = 435)	Normal Weight (n = 5168)	Overweight (n = 12605)	Obese (n = 10534)	P value
Aspirin	391 (96.3)	4682 (95.8)	11493 (95.7)	9674 (95.8)	0.898
Clopidogrel	391 (96.3)	4548 (93.4)	11188 (93.3)	9416 (93.5)	0.122
Ticlopidine	5 (1.4)	168 (3.7)	356 (3.1)	286 (3.0)	0.031
Beta blocker	263 (68.0)	3394 (71.8)	8645 (73.6)	7312 (74.0)	0.003
ACE-I/ARB	235 (61.4)	2948 (63.1)	7701 (66.1)	6837 (69.7)	<0.001
Statin	369 (93.4)	4480 (93.4)	11182 (94.3)	9345 (93.6)	0.104

- ACE-I, Angiotensin converting enzyme inhibitor; ARB, Angiotensin II receptor blocker.

4.5 Outcomes

Table 8 shows the in–hospital complications after PCI. There was a trend of lower rate of in-hospital death in the overweight and obese group, almost reaching statistical significance (p=0.057). There was no significant difference seen among the

BMI groups in terms of major adverse cardiovascular events (MACE) and vascular complications.

Table 8: In-hospital complications.

Complications, n (%)	Under weight (n = 435)	Normal Weight (n = 5168)	Overweight (n = 12605)	Obese (n = 10534)	P value
Death	6 (1.4)	50 (1.0)	89 (0.7)	68 (0.7)	0.057
MACE*	5 (1.2)	70 (1.4)	154 (1.2)	128 (1.2)	0.879
Vascular complications**	1 (0.2)	28 (0.5)	71 (0.6)	56 (0.5)	0.823

- *MACE (Major Adverse Cardiovascular Event) included periprocedural MI, emergency PCI, emergency CABG, cardiogenic shock, arrhythmia, transient ischemic attack/stroke, cardiac tamponade, new or worsening heart failure.
- **Vascular complications included bleeding, access site occlusion, loss of distal pulse, dissection, pseudoaneurysm.

We performed multiple imputation with chained equations followed by Cox proportional-hazards regression analysis of the imputed datasets to compare the hazard ratios for 1-year mortality between the four BMI groups. Using the normal BMI group as the reference, the unadjusted hazard ratios (HR) for overweight and obese groups were significantly lower at 0.63 (CI: 0.50-0.80, p<0.001) and 0.69 (CI: 0.54-0.87, p=0.002) respectively (Table 9). The underweight group had a higher HR of 1.06 but this was not statistically significant. After adjustment for the covariates, the overweight group remained to have significantly lower HR of 0.71 (CI: 0.55-0.90, p=0.005) compared to the normal BMI group (Table 10). The obese group also had a lower HR of 0.78 but this failed to reach statistical significance (CI: 0.61-1.01, p=0.056).

From our analysis, we also found that other significant predictors of 1-year mortality after PCI were age more than 60, gender, diabetes, dyslipidemia, heart failure, renal failure, ethnicity and ACS as the indication for PCI (Table 10).

Table 9: Unadjusted hazard ratio for 1-year mortality risk after PCI between different BMI groups.

BMI group*	Hazard ratio	95 % Confidence interval	P value
Underweight	1.06	0.55-2.02	0.868
Overweight	0.63	0.50-0.80	<0.001
Obese	0.69	0.54-0.87	0.002

- BMI, Body mass index; PCI, Percutaneous coronary intervention
- *Normal BMI group was the reference group

Table 10: Multivariate Cox regression analysis for predictors of 1-year mortality after PCI.

Variables	Hazard ratio	95 % Confidence interval	P value
BMI group*			
Underweight	1.02	0.53 – 1.95	0.952
Overweight	0.71	0.55 – 0.90	0.005
Obese	0.78	0.61 – 1.01	0.056
Male gender	0.74	0.59 – 0.93	0.011
Age more than 60 years	2.08	1.70 – 2.54	<0.001
Diabetes mellitus	1.40	1.13 – 1.73	0.002
Dyslipidemia	0.72	0.58 – 0.89	0.003
ACS	2.04	1.68 – 2.48	<0.001

Heart failure	1.74	1.24 – 2.44	0.002
Chronic renal failure	3.45	2.71 – 4.39	<0.001
Ethnicity**			
Chinese	0.67	0.52-0.87	0.002
Indian	0.71	0.55-0.92	0.009

- ACS, Acute coronary syndrome; BMI, Body mass index; PCI, Percutaneous coronary intervention.

- *Normal BMI group was the reference BMI group.

- **Malay ethnicity was the reference ethnic group.

- The hazard ratios were adjusted for gender, age group, ethnicity, diabetes, hypertension, dyslipidemia, smoking status, previous myocardial infarction, heart failure, cerebrovascular disease, renal impairment, previous CABG and acute coronary syndrome.

CHAPTER 5: DISCUSSION

5.1 Interpretation and findings

In this study, we examined the prevalence of obesity and overweight among patients who underwent PCI over a period of 8 years from 2007 to 2014. Most of the patients were in the overweight group (44%), followed by the obese (37%), normal BMI (18%) and underweight group (1%) (Figure 1). This pattern was similar to the distribution of BMI in the general Malaysian population as reported in the NHMS 2015, in which 33.4% were overweight, 30.6% were obese, 29.3% were having normal BMI, and 6.7% were underweight. In terms of the demographic characteristics, even though the obese group had lesser prevalence of smoking and were younger than their leaner counterparts, in general they had more cardiovascular risk factors such as diabetes, dyslipidemia, and hypertension. The higher prevalence of these co-morbidities in obese people is a well-established observation, and the proposed pathophysiology was obesity is associated with beta cell dysfunction, abnormal lipids metabolism and activation of sympathetic nervous system (Eckel et al., 2011; Klop et al., 2013; De Marco et al., 2014).

Regarding the angiographic profile of the patients, we found that obese patients in our population were more likely to have multi-vessel disease. This can be explained by the fact that obese patients have more cardiovascular risk factors which would predispose to more extensive coronary vessels involvement. We also found that in our study population, the leaner patients had higher rate of involvement of LAD artery compared to the obese group. This might contribute to the poorer outcome in the underweight and normal BMI group patients, as we know that LAD supplies more

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amount of myocardium in majority of patients. However, this is an assumption that we are not able to validate in this study.

Despite having higher prevalence of cardiovascular risk factors, our study showed that overweight and obese patients were 29% and 22% respectively less likely to die within 1 year after PCI compared to the normal BMI group. This survival advantage however was only statistically significant in the overweight group (p=0.005) but less so in the obese group (p=0.056). This means that in our study population, the protective effect of higher-than-normal BMI was only significant in the overweight group but was lost once BMI increased further into the obese range. Our study used a lower cut off values for overweight and obese groups compared to other studies which used the international WHO recommended values, and these findings might suggest that the protective effect of being overweight in Asian population occurs at a lower BMI values compared to their Western counterparts. The standard classification recommended by WHO for non-Asian population defined overweight as BMI of 25 to <30kg/m^2, and obese as BMI ≥30kg/m^2, as opposed to BMI of 23 to <27.5kg/m^2 for overweight and BMI of ≥27.5 kg/m^2 for obese in Asian population (WHO 2004).

The underweight group in our study however did not show any significant difference compared to the normal BMI group in terms of 1-year mortality. The rate of in-hospital complications (MACE and vascular complications) also did not differ significantly among all the BMI groups.

Our findings were similar to those reported by Gruberg et al. (2002) in which overweight patients had lower mortality at one year follow up. In contrast to our findings, their obese population also had significantly better one year outcome, and their

in-hospital complication rates were found to be lower in these two groups. Meanwhile Gregory et al. (2016) found that obese patients had lower vascular complications post PCI, but no differences found in terms of in-hospital major adverse cardiovascular event (MACE) and death. These two studies however were conducted within Western population, and they also used higher cut off BMI values for overweight and obese groups compared to ours.

In general, Asian have smaller physique compared to the Western population, and ethnicity is known to be a confounding factor in determining cardiovascular outcomes (Wild & McKeigue, 1997). Asian population also has been shown to have higher prevalence of cardiovascular risk factors at lower BMI values compared to Western population (Decode-Decoda Study Group, 2003). WHO expert committee therefore suggested using lower cut off points for BMI to trigger public health action in Asian population (WHO 2004). With regards to obesity and outcomes after PCI in Asian people, previously Numasawa et al. (2015) and Kaneko et al. (2013) did show that leaner Japanese patients were associated with higher complications post PCI. Their studies however used BMI definition based on Western population instead of the one proposed for Asian population. Another study involving Asian population was by Kang et al. (2010) from Korea, and they used lower BMI range for obese group, similar to our study. They found that obese patients with STEMI who underwent PCI were also associated with lower rate of 1-year mortality.

Our study is unique compared to these previous studies because: (1) our study population was a multi-ethnic Asian population, comprising three different major ethnic groups (Malay, Chinese and Indian), and (2) we used the lower BMI classification which might be more suitable for Asian population. The findings from our study and all

other studies mentioned above shows that having BMI above the normal range does confer some protective effects in patients undergoing PCI, irrespective of their ethnic origin and the BMI classification used. However, the degree of protection conferred by having higher BMI demonstrated in our study might not be applicable to other Asian populations, mainly because of the differences in their ethnic distribution, and the level of PCI expertise between the countries might differ as well.

From our study findings, we also suspected that the relationship between BMI and mortality may not be linear. Previously, Byrne et al. (2009) and Angeras et al. (2012) in their large registry studies further subdivided the obese groups into smaller subgroups, and they found that the relationship between BMI and mortality was actually U-shaped. Their studies showed that the mortality rates were lowest in the overweight and mildly obese groups, and highest in the underweight and the extremely obese group. As we only used four BMI groups to classify our study population, this bimodal relationship was not very apparent from our result. Despite this, the survival advantage of the overweight group and the non-significant difference in survivals at BMI range above and below the overweight range seen in our study may point towards a U-shaped relationship between BMI and outcomes after PCI. This however needs to be validated from further research using smaller ranges to divide the BMI values.

From a practical perspective, however, we would like to emphasize that we do not promote either overweight or obesity. The current recommendations that every patient should aim to achieve normal BMI and practice healthy lifestyle remained. The results from this study is merely an observation found in this specific cohort and should not be misquoted. The overall health benefits of losing weight are still much more compared to the protective effects of being overweight in certain disease settings. As

mentioned previously, higher BMI had direct effects on other comorbidities and is associated with higher overall morbidity and mortality.

5.2 Mechanism of obesity paradox

The potential underlying mechanism responsible for obesity paradox is still poorly understood. It has been postulated that debilitating chronic disease and older age are usually associated with compromised nutrition, impaired physical function and reduction in lean body mass hence lower BMI (Dixon et al., 2015). Therefore, this group of patients may have lower tolerance towards the stressful state related with PCI and the complications afterward. Overweight and obese patients are also more likely to be adequately treated with intensive pharmacotherapy due to their higher prevalence of comorbidities and younger age, and this would lead to better outcomes compared to their leaner counterparts.

Adipose tissue itself is an endocrine organ which secretes various biological mediators called 'adipokines' and some of these may explain the cardioprotective effects in obese people. For example, lower level of adiponectin which is seen in obese people, has been shown to be associated with better outcomes in patient with pre-existing ischemic heart disease (Beatty et al., 2012). Adipose tissue also produces tumor necrosis factor (TNF) receptor that is thought to neutralize the deleterious effect of TNF alpha on the myocardium (Mohamed-Ali et al., 1999; Ferrari, 1999).

5.3 Limitations

We have identified a few limitations to our study. First, this is a retrospective data analysis which were obtained from NCVD-PCI registry database. There were missing data in most of the parameters studied, and there were patients who were lost to follow up after discharge. As with other observational studies, there is also a possibility of unmeasured or residual confounding. There was also possibility of changes in patients' lifestyles within 1 year after the PCI, and this could affect the outcomes as well.

Second, we did not divide further the obese group into smaller subgroups (mild, moderate, severe obesity) as per classified in obesity guidelines (Table 1 & 2). This may introduce bias when analyzing them as a single group, because as mentioned before, it has been shown in some studies that severe obesity (BMI >40 kg/m^2) had poorer outcomes than the normal and mildly obese groups (Byrne et al., 2009; Angeras et al., 2012)

Third, despite being widely used as a surrogate for obesity, BMI may not be the best proxy for central adiposity. Instead, waist circumference (WC), waist-to-hip ratio (WHR) and waist-to-stature ratio (WSR) have been shown to be a better predictor of abdominal obesity compared to BMI (Song et al, 2013), and our registry did not include any of these measurements. Previous studies have also shown that central obesity measurement such as WHR was an independent predictor for cardiovascular outcomes, and combining such measurement with BMI might be superior than using BMI alone (Kragelund et al, 2005; Coutinho et al., 2013)

Fourth, the BMI calculated in our registry was taken at one point in time only, and this failed to take into consideration any recent weight loss, which could be triggered by declining health status of the patient. Fifth, our study analyzed eight years of collected data, and in the current era of rapidly evolving interventional cardiology field, the tools and technique of PCI have undergone significant changes within this wide timeframe, hence may affect the way that patients were generally treated and their outcomes.

Finally, as our data was collected from up to fifteen different centres, there was some clustering nature of the data, with more data collected from the larger and more well-equipped tertiary centres. This clustering effect was not accounted for in our analysis and might have resulted in bias to the outcomes.

CHAPTER 6: CONCLUSION

Our study showed that except for smoking, the traditional cardiovascular risk factors such as diabetes mellitus, hypertension and dyslipidemia were more prevalent in overweight and obese people undergoing PCI. Despite these findings, overweight patients were found to have lower risk of death within 1 year after PCI compared to patients with normal BMI. The obese group however failed to show any significant survival benefit in this study. This advantage of being overweight needs to be interpreted carefully as we also noted that higher BMI patients in our cohort were younger, had more PCI for non-ACS indication and lesser LAD involvement.

To our knowledge, there was no previous studies that have demonstrated obesity paradox in our Malaysian population. Therefore, it would be interesting to have further researches in the future to determine whether the protective effect of being overweight seen in our study is also present in other cardiovascular and non-cardiovascular settings.

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APPENDIX A - NATIONAL CARDIOVASCULAR DISEASE DATABASE (PCI REGISTRY) NOTIFICATION FORM

NATIONAL CARDIOVASCULAR DISEASE DATABASE (PCI REGISTRY) NOTIFICATION FORM

Instruction: Complete this form to notify all PCI admissions at your centre to NCVD PCI Registry. Where check boxes are provided, please check (√) one or more boxes. Where radio buttons ⊙ are provided, check (√) only one option.

Reporting Centre : _____   B. Date of Admission (dd/mm/yy): ☐☐☐☐☐☐

SECTION 1: DEMOGRAPHICS

1. Patient Name: (as per MyKad / Other Document ID)

2. Hospital RN :

Identification Card Number:

MyKad: ☐☐☐☐☐☐ - ☐☐ - ☐☐☐☐   Old IC No. ☐

Other ID Document No. ☐ → Specify type : (eg. passport, armed force ID) ☐

3. Gender: ⊙ Male ⊙ Female   **5. Nationality:** ⊙ Malaysian ⊙ Non Malaysian

4. Date of Birth: ☐☐☐☐☐ (write DOB as 01/01/yy if age is known)   **6b. Age on admission:** ☐☐ (auto calculate)

7. Ethnic Group:
⊙ Malay ⊙ Punjabi ⊙ Melanau ⊙ Bidayuh
⊙ Chinese ⊙ Orang Asli ⊙ Murut ⊙ Iban
⊙ Indian ⊙ Kadazan Dusun ⊙ Bajau ⊙ Other Malaysian, specify: ....
⊙ Foreigner, specify country of origin: ....

Contact Number: (1):   (2):

SECTION 2 : STATUS BEFORE EVENT

Smoking status: ⊙ Never ⊙ Former (quit >30 days) ⊙ Current (any tobacco use within last 30 days) ⊙ Not Available

Medical history:

Dyslipidaemia	⊙ Yes ⊙ No ⊙ Not known	f) Documented CAD ⊙ Yes ⊙ No ⊙ Not known
Hypertension	⊙ Yes ⊙ No ⊙ Not known	(Presence of >50 % stenosis on CTA, angiogram or ischaemia on functional cardiac imaging such as nuclear, MRI, echo. Positive treadmill test or high calcium score alone are not sufficient)
Diabetes	⊙ Yes ⊙ No ⊙ Not known	

☐ OHA ☐ Insulin ☐ Non pharmacology therapy/diet therapy

		g) New onset angina (<2 weeks) ⊙ Yes ⊙ No ⊙ Not known
Family history of premature cardiovascular disease (1st degree relative with either MI or stroke; <55 y/old if Male & <65 y/old if Female)	⊙ Yes ⊙ No ⊙ Not known	h) History of heart failure ⊙ Yes ⊙ No ⊙ Not known
		i) Cerebrovascular disease ⊙ Yes ⊙ No ⊙ Not known
		j) Peripheral vascular disease ⊙ Yes ⊙ No ⊙ Not known
Myocardial infarction history	⊙ Yes ⊙ No ⊙ Not known	k) Chronic renal failure (>200 μmol/L serum creatinine) ⊙ Yes ⊙ No ⊙ Not known

SECTION 3 : CLINICAL EXAMINATION and BASELINE INVESTIGATION

Anthropometric: a. Height: ☐ (cm) ☐ Not Available   b. Weight: ☐ (kg) ☐ Not Available   c. BMI: ☐ (auto calculate)

Heart rate (at start of PCI): ☐☐☐ beats / min

3. Blood pressure (at start of PCI): a. Systolic: ☐ (mmHg)   b. Diastolic: ☐ (mmHg)

Baseline creatinine: ☐☐☐.☐ micromol/L ☐ Not Available

5. Hb A1c: ☐☐☐.☐ mmol/L ☐ Not Available

Total cholesterol: ☐☐☐.☐ mmol/L ☐ Not Available

6b. LDL Levels: ☐☐☐.☐ mmol/L ☐ Not Available

Baseline ECG: ☐ Sinus rhythm ☐ Atrial Fibrillation ☐ 2nd / 3rd AVB ☐ LBBB ☐ RBBB

Glomerular Filtration Rate (GFR): a. MDRD: ☐☐☐.☐ mL/min/1.73m² (auto calculate)   b. Cockcroft-Gault: ☐☐☐.☐ mL/min (auto calculate)

Formula:
GFR (Modification of Diet in Renal Disease (MDRD) : $186 \times (\text{serum creatinine [micromol/L]} / 88.4)^{-1.154} \times (\text{age})^{-0.203} \times (0.742 \text{ if female})$
GFR (Cockcroft-Gault formula) : Male : $1.23 \times (140 - \text{Age}) \times \text{Weight (kg)} / \text{serum Creatinine (micromol/L)}$
Female : $1.04 \times (140 - \text{Age}) \times \text{Weight (kg)} / \text{serum Creatinine (micromol/L)}$

SECTION 4 : PREVIOUS INTERVENTIONS

Previous PCI: ⊙ Yes ⊙ No
Date of most recent PCI (dd/mm/yy): ☐☐ / ☐☐ / ☐☐
☐ Not Available

2. Previous CABG: ⊙ Yes ⊙ No
Date of most recent CABG (dd/mm/yy): ☐☐ / ☐☐ / ☐☐
☐ Not Available

SECTION 5 : CARDIAC STATUS AT PCI PROCEDURE

1. NYHA:
◉ NYHA I ◉ NYHA II ◉ NYHA III ◉ NYHA IV

2. Killip Class (STEMI & NSTEMI)
◉ I No clinical signs of HF ◉ III Acute Pulmonary Oedema (APO) ◉ Not Applicable / Not Available
◉ II Left Heart Failure (LHF) ◉ IV Cardiogenic Shock

3. Non Invasive Test:
i) ◉ Done → ☑ Stress/ Exercise Test ☑ Nuclear ☑ MRI   ii) Functional Ischaemia
◉ Not Done ☑ Stress Echo ☑ CT Scan ☑ CT FFR   ◉ Positive ◉ Negative ◉ Equivocal

4. Acute Coronary Syndrome:
◉ Yes → ◉ STEMI → ◉ Anterior ◉ Non anterior   ◉ NSTEMI ◉ UA
◉ No

5. Angina type:
◉ None ◉ Atypical ◉ Chronic stable angina ◉ Unstable angina

6. Canadian Cardiovascular Score (CCS):
◉ Asymptomatic ◉ CCS 1 ◉ CCS 2 ◉ CCS 3 ◉ CCS 4

7. STEMI Event: (Please complete if <24 hrs since onset of STEMI symptoms)

a) STEMI onset:	i. Date: ☐☐ / ☐☐ / ☐☐ (dd/mm/yy) ☑ Not Applicable	ii. Time: ☐☐ : ☐☐ (in 24hr clock)
b) Arrival at first hospital:	i. Date: ☐☐ / ☐☐ / ☐☐ (dd/mm/yy) ☑ Not Applicable	ii. Time: ☐☐ : ☐☐ (in 24hr clock)
c) Arrival at PCI hospital:	i. Date: ☐☐ / ☐☐ / ☐☐ (dd/mm/yy) ☑ Not Applicable	ii. Time: ☐☐ : ☐☐ (in 24hr clock)
d) First balloon inflation/ stent/ aspiration:	i. Date: ☐☐ / ☐☐ / ☐☐ (dd/mm/yy) ☑ Not Applicable	ii. Time: ☐☐ : ☐☐ (in 24hr clock)

8. EF Status (at time of PCI procedure):
☐ % (Do not use '>' or '<' symbol) ☑ Not Available

SECTION 6 : CATH LAB VISIT

1. Date of procedure:
☐☐ / ☐☐ / ☐☐ (dd/mm/yy)

2. PCI status
◉ Elective → ◉ Staged PCI ◉ Ad hoc   ◉ STEMI →
◉ Primary ◉ Pharmacoinvasive
◉ NSTEMI/UA → ◉ Urgent (within 24hrs) ◉ Non urgent   ◉ Facilitated ◉ Delayed Routine PCI
◉ Rescue ◉ Delayed Selective PCI

3. Medication:

a) Thrombolytics	◉ Yes → ◉ <3hrs ◉ 3-6hrs ◉ 6-12hrs ◉ 12-24hrs ◉ >24hrs ◉ No
b) IIb / IIIa Blockade	◉ Yes → ◉ Prior ◉ During ◉ After ◉ No
c) Heparin	◉ Yes → ◉ Prior ◉ During ◉ After ◉ No
d) LMWH	◉ Yes → ◉ Prior ◉ During ◉ After ◉ No
e) Ticlopidine	◉ Yes → ◉ Prior ◉ During ◉ After ◉ No
f) Fondaparinux	◉ Yes → ◉ Prior ◉ During ◉ After ◉ No
g) Bivalirudin	◉ Yes → ◉ Prior ◉ During ◉ After ◉ No
h) Aspirin	◉ Yes → ◉ Prior ◉ During ◉ After ◉ No
i) Clopidogrel	◉ Yes → ◉ Prior ◉ During ◉ After → ◉ <6hrs ◉ 6-24hrs ◉ >24-72hrs ◉ >72hrs ◉ No First / load dose: ◉ 75mg ◉ 300mg ◉ 600mg ◉ ≥1200mg
j) Prasugrel	◉ Yes → ◉ Prior ◉ During ◉ After ◉ No
k) Ticagrelor	◉ Yes → ◉ Prior ◉ During ◉ After ◉ No
l) Others, specify:	◉ Yes → ◉ Prior ◉ During ◉ After ◉ No

4. Planned duration of DAPT:
◉ 1 month ◉ 6 months ◉ >12 months
◉ 3 months ◉ 12 months ◉ Not Available

5. Percutaneous entry: ☑ Brachial ☑ Femoral ☑ Radial

6. Closure device:
◉ No ◉ Suture ◉ Exoseal
◉ Seal ◉ Other, specify: _____

7. Coronary disease >50% stenosis: ☑ LAD ☑ LCx ☑ RCA ☑ Graft ☑ LMS

8. Fluoroscopy time: ☐☐☐ . ☐ minutes ☑ Not Available

9. Total dose: ☐☐☐☐ mGy ☑ Not Available

10. Contrast volume: ☐☐☐ ml ☑ Not Available

a. Patient Name:		b. Centre Code:	
c. Identification Card No.		d. Hospital RN:	

Instructions: 1. For skip lesion, please document as different lesions. Please check one lesion code per page (i.e. : for 2 lesions, please use 2 separate Section 7).
2. Documented Ramus Intermediate Lesions as lesion code 15.
3. For long lesion, please document as one single lesion.
4. Please document intervention involves side branch as a second lesion.

SECTION 7 : PCI PROCEDURE DETAILS   (Complete for ALL intervention. Attach additional form if necessary)

NATIVE
Coronary segment number, lesion codes 1-17

1 RCA prox
6 Left MAIN
7 LAD prox
10 D1
13 LCX prox
8 LAD mid
14 LCX distal
15 OM1
11 D2
2 RCA mid
5 PLV
16 OM2
4 PDA
9 LAD distal
12 D3
3 RCA distal
17 OM3
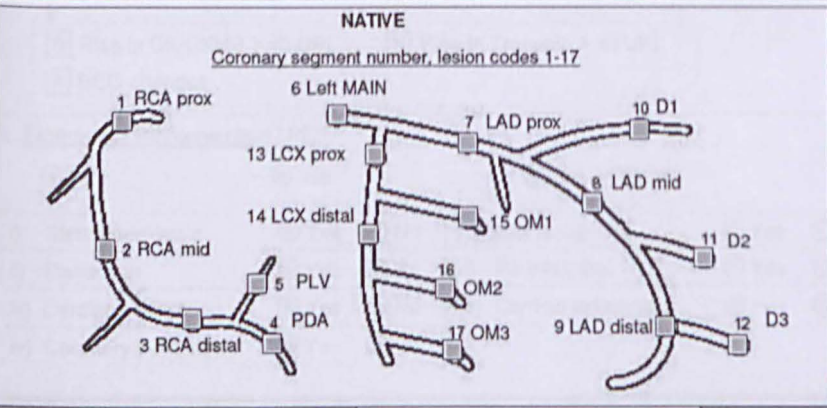
GRAFT
Graft PCI lesion codes 18-25. Also record grafted native coronary vessel

Graft	Target vessel	Graft	Target vessel
▣ 18 LIMA		▣ 22 SVG 3	
▣ 19 RIMA		▣ 23 RAD 1	
▣ 20 SVG 1		▣ 24 RAD 2	
▣ 21 SVG 2		▣ 25 RAD 3	

1. Total no. of lesion treated : _____

2. Lesion code (1-25): ____ to ____ (if applicable)

3. Coronary lesion:
- ◉ De novo
- ◉ Stent thrombosis
  - a. Type: ◉ Acute ◉ Late ◉ Sub acute ◉ Very late
- ◉ Restenosis (no prior stent)
- ◉ In stent restenosis
  - b. Prior stent type: ◉ DES ◉ BMS ◉ Others, specify: ....

4. Lesion type: ◉ A ◉ B1 ◉ B2 ◉ C

5. Location in graft: (complete for graft PCI only) ◉ Ostial ◉ Mid ◉ Native ◉ Proximal ◉ Distal ◉ Anastomosis

6. Lesion description: (if intervention involved sidebranch, please record as second lesion)
- ▣ Ostial ▣ Total Occlusion (≤3 mo) ▣ CTO (> 3 mo) ▣ Thrombus ▣ Calcified lesion ▣ Not Applicable
- ▣ LMS ▣ Bifurcation → a) Medina Classification: i) MB prox. ◉ 0 ◉ 1 ii) MB dist. : ◉ 0 ◉ 1 iii) SB: ◉ 0 ◉ 1

7. Pre-stenosis %: _____ %   TIMI Flow (pre): → ◉ TIMI-0 ◉ TIMI-1 ◉ TIMI-2 ◉ TIMI-3

8. Post-stenosis %: _____ %   TIMI Flow (post): → ◉ TIMI-0 ◉ TIMI-1 ◉ TIMI-2 ◉ TIMI-3

9. Estimated lesion length: ____ mm

12. Lesion result: ◉ Successful ◉ Unsuccessful

10. Perforation: ◉ Yes ◉ No

13. Dissection: (Post Procedure) ◉ Yes → ◉ Flow limiting ◉ Non Flow limiting ◉ No

11. French size:
(i) ◉ Guiding catheter ◉ Guiding sheath → (ii) ◉ 4 ◉ 5 ◉ 6 ◉ 7 ◉ 8 ◉ Other, specify: .....

14. No reflow: ◉ Yes → ◉ Transient ◉ Persistent ◉ No

15. Stent / DEB details for lesion: (please refer instruction sheet for stent codes)

a. Stent code	b. Diameter (mm)	c. Length (mm)	a. Stent code	b. Diameter (mm)	c. Length (mm)
#1 ___	__ . __	___	#4 ___	__ . __	___
Others, specify: _____			Others, specify: _____		
#2 ___	__ . __	___	#5 ___	__ . __	___
Others, specify: _____			Others, specify: _____		
#3 ___	__ . __	___	#6 ___	__ . __	___
Others, specify: _____			Others, specify: _____		

16. Maximum balloon size / pressure:
a) Maximum balloon size used: __ . __ mm
b) Maximum stent / balloon deploy pressure: __ atm

17. Intracoronary devices used:
- ▣ IVUS ▣ Aspiration catheter ▣ Micro catheter
- ▣ POBA ▣ Cutting / scoring balloon ▣ Rotablator
- ▣ Coil ▣ Mother and Child ▣ Angiojet
- ▣ OCT ▣ FFR ▣ Other, specify: _____
- ▣ Embolic Protection → ◉ Filter ◉ Distal ◉ Proximal

18. Direct stenting: ◉ Yes ◉ No

19. Other Adjunctive Procedure: ◉ Yes → ▣ IABP ▣ Ventilator ▣ Temporary Cardiac Pacing Wire   ◉ No

a. Patient Name:		b. Centre Code:	
c. Identification Card No.		d. Hospital RN:	

SECTION 8 : POST PROCEDURAL COMPLICATION

1. Outcome:

a. Significant Periprocedural MI

◉ Yes ◉ No ◉ Not Available

- ■ Rise in CK/CKMB > x3 URL
- ■ Rise in Troponin > x5 URL
- ■ ECG changes

b. Emergency Reintervention / PCI

◉ Yes ◉ No ◉ Not Available

i)	Stent thrombosis	◉ Yes ◉ No	v)	New ischaemia	◉ Yes ◉ No
ii)	Dissection	◉ Yes ◉ No	vi)	Re-infarction	◉ Yes ◉ No
iii)	Cardiac perforation	◉ Yes ◉ No	vii)	Cardiac tamponade	◉ Yes ◉ No
iv)	Coronary perforation	◉ Yes ◉ No			

c. Bail-out CABG	◉ Yes	◉ No
d. Cardiogenic shock	◉ Yes	◉ No
e. Arrhythmia (VT/VF/Brady)	◉ Yes	◉ No
f. TIA / Stroke	◉ Yes	◉ No
g. Tamponade	◉ Yes	◉ No
h. Contrast reaction	◉ Yes	◉ No
i. New onset / worsened heart failure	◉ Yes	◉ No
j. Worsening renal impairment (rise of post procedural creatinine >25% from baseline)	◉ Yes ◉ No ◉ Not Available	

2. Vascular complications:

a. Bleeding	◉ Yes ◉ No
	◉ Major (any intracranial bleed or other bleeding ≥ 5g/dL Hb drop)
	◉ Minor (non-CNS bleeding with 3-5g/dL Hb drop)
	◉ Minimal (non-CNS bleeding, non-overt bleeding, < 3g/dL Hb drop)
	Bleeding site: ◉ Retroperineal ◉ Percutaneous entry site ◉ Others, specify: ....
b. Access site occlusion	◉ Yes ◉ No
c. Loss of radial pulse	◉ Yes ◉ No
d. Dissection	◉ Yes ◉ No
e. Pseudoaneurysm	◉ Yes ◉ No
	◉ Ultrasound compression ◉ Surgery ◉ Others, specify: ....
f. Perforation	◉ Yes ◉ No

SECTION 9 : IN-HOSPITAL OUTCOME

1. Outcome:

◉ Alive → a) Date of Discharge (dd/mm/yy): ☐☐ / ☐☐ / ☐☐

b) Medication:

	Yes	No		Yes	No
Aspirin	◉	◉	ARB	◉	◉
Clopidogrel	◉	◉	Warfarin	◉	◉
Ticlopidine	◉	◉	Prasugrel	◉	◉
Statin	◉	◉	Ticagrelor	◉	◉
Beta blocker	◉	◉	Others, specify:	◉	◉
ACE inhibitor	◉	◉			

◉ Death → a) Date of Death (dd/mm/yy): ☐☐ / ☐☐ / ☐☐

b) Primary cause of death: ◉ Cardiac ◉ Renal ◉ Others, specify:
◉ Infection ◉ Neurological ....
◉ Vascular ◉ Pulmonary

c) Location of death: ◉ In Lab ◉ Out of Lab

◉ Transferred to other hospital → a) Date of Transfer (dd/mm/yy): ☐☐ / ☐☐ / ☐☐

b) Name of hospital: ....

NATIONAL CARDIOVASCULAR DISEASE DATABASE (PCI REGISTRY) FOLLOW UP FORM

For NCVD Use only:

Centre: [ ]

ID: [ ]

Instruction: This form is to be completed at patient follow up after 30 days, 6 months or 12 months of 1st admission. Where check boxes ☐ are provided, please check (√) one or more boxes. Where radio buttons ◉ are provided, check (√) only one option.

A. Reporting Centre	
B. Patient Name:	

C. Identification Card Number:

MyKad: [ ][ ][ ][ ][ ][ ] - [ ][ ] - [ ][ ][ ][ ]   Old IC No. [ ]

Other ID Document No. [ ] ➤ Specify type : (eg. passport, armed force ID) [ ]

D. Type of Follow Up: ◉ 30 days ◉ 6 months ◉ 12 months   **E.** Date of Follow Up: (dd/mm/yy) [ ] / [ ] / [ ]

SECTION 1: OUTCOME

1. Outcome:

◉ **Alive** ➤ a) Medication:

	Yes	No		Yes	No		Yes	No
Aspirin	◉	◉	ACE inhibitor	◉	◉	Others, specify	◉	◉
Clopidogrel	◉	◉	ARB	◉	◉	....		
Ticlopidine	◉	◉	Warfarin	◉	◉			
Statin	◉	◉	Prasugrel	◉	◉			
Beta blocker	◉	◉	Ticagrelor	◉	◉			

◉ **Death** ➤ a) Date of Death (dd/mm/yy): [ ] / [ ] / [ ]   b) Cause of death: ◉ Cardiac ◉ Non cardiac
◉ Others, specify: ....

◉ **Transferred to other hospital** ➤ a) Date of Transfer (dd/mm/yy): [ ] / [ ] / [ ]   b) Name of hospital: ....

◉ **Lost to follow up** ➤ a) Date of last follow up (dd/mm/yy): [ ] / [ ] / [ ]

2. Has patient stopped smoking?   ◉ Yes (quit >30 days)   ◉ No   ◉ Not Applicable

SECTION 2: READMISSION (within the follow up duration)

1. Has patient been readmitted to hospital?   ◉ Yes   ◉ No

---

1. Date of readmission:
[ ] / [ ] / [ ]
(dd/mm/yy)

Readmission location:
[ ]

Readmission reason:
◉ Non cardiac
◉ CHF
◉ Recurrent angina
◉ Arrhythmia

◉ ACS ➤ ◉ STEMI ◉ NSTEMI ◉ UA
◉ Staged revascularization ➤ ◉ PCI ◉ CABG

CCS:
◉ Asymptomatic
◉ CCS 1
◉ CCS 2
◉ CCS 3
◉ CCS 4
◉ Not Available

Angiography:
◉ Yes
◉ No
◉ Not Applicable

---

2. Date of readmission:
[ ] / [ ] / [ ]
(dd/mm/yy)

Readmission location:
[ ]

Readmission reason:
◉ Non cardiac
◉ CHF
◉ Recurrent angina
◉ Arrhythmia

◉ ACS ➤ ◉ STEMI ◉ NSTEMI ◉ UA
◉ Staged revascularization ➤ ◉ PCI ◉ CABG

CCS:
◉ Asymptomatic
◉ CCS 1
◉ CCS 2
◉ CCS 3
◉ CCS 4
◉ Not Available

Angiography:
◉ Yes
◉ No
◉ Not Applicable

---

3. Date of readmission:
[ ] / [ ] / [ ]
(dd/mm/yy)

Readmission location:
[ ]

Readmission reason:
◉ Non cardiac
◉ CHF
◉ Recurrent angina
◉ Arrhythmia

◉ ACS ➤ ◉ STEMI ◉ NSTEMI ◉ UA
◉ Staged revascularization ➤ ◉ PCI ◉ CABG

CCS:
◉ Asymptomatic
◉ CCS 1
◉ CCS 2
◉ CCS 3
◉ CCS 4
◉ Not Available

Angiography:
◉ Yes
◉ No
◉ Not Applicable