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OUTCOMES IN PATIENTS WITH CARDIOGENIC SHOCK FOLLOWING PRIMARY PERCUTANEOUS CORONARY INTERVENTION

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Contribution

SZ conceived, designed and did statistical analysis & manuscript writing. AFO, RBMA, AYH AND KG did data collection and manuscript writing. NYP did review and final approval of manuscript

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ABSTRACT

Objective: To compare the outcome of percutaneous coronary intervention with or without cardiogenic shock in acute myocardial infarction

Methodology: This cross sectional study was conducted from 1st january 2015 to 31st december 2016. All consecutive STEMI patients transferred from Hospital Kualalumpur to IJN via HISNET for Primary percutaneous intervention were included. They were divided into cardiogenic shock (CS) and non-cardiogenic shock (Non-CS) groups. SPSS Version 24.0 was used for study analysis.

Results: A total of 277were included. Of the study population, 247(89%) were in non- cardiogenic shock while 30 (11%) were in cardiogenic shock. Most of baseline characteristics were similar. Diabetes was present in 16 (53.3%) patients in CS and 93 (38%) patients in Non CS group (0.038). Mean first medical contact (FMC) to transfer time was 32 minutes for Non CS and 45 minutes in CS group ($p = 0.023$). Successful PPCI was performed in 98% group as compare to 87% in CS group, ($p = 0.015$). In-hospital mortality was 7(23%) in CS group and 6 (2%) in non CS group ($p < 0.001$). One year mortality was 17 (7%) for non CS as compare to (27%) in CS group ($p < 0.05$). Post procedure haemoglobin, number of inotropes needed at admission, baseline GFR, baseline PH were strong predictors of mortality in cardiogenic shock patients.

Conclusion: Despite of similarities in most of risk factors, mortality rate of acute myocardial infarction with Cardiogenic Shock was higher than non-cardiogenic shock.

Key Words: ST elevation MI, Cardiogenic Shock, Primary Percutaneous Coronary Intervention

INTRODUCTION

Advances in the treatment of acute myocardial infarction, such as the primary percutaneous coronary intervention (PPCI) and use of potent adjunctive medical therapies, reduced the mortality from 18% to 10% in last 2 decades. [1–5] The presence of Cardiogenic shock (CS) in acute myocardial infarction remains the high predictor of mortality. Mortality rates is about 70-80 % with conservative medical management as compare to 40-50% with revascularization for cardiogenic shock.[1–4] Cardiogenic shock is a pathophysiological state because of reduced cardiac output with adequate intravascular volume that results in tissue hypoxia. Cardiogenic shock can also occur in a later phase of STEMI, especially from causes other than acute ventricular dysfunction, such as mechanical complications due to acute mitral valve regurgitation and free wall rupture or interventricular septum rupture.

The aim of this study was to compare the short and long term outcomes and predictors of mortality in patients undergoing PPCI for acute myocardial infarction with and without cardiogenic shock.

METHODOLOGY

This comparative cross sectional study is a sub study of HISNET Registry (Registry of all ST elevation myocardial infarction patients transferred from HKL (Hospital Kuala Lumpur) to IJN (National Heart institute, Malaysia) for PPCI). All the consecutive patients which were transferred from January 2015 to December 2016 via HISNET were included after informed consent. This study was approved by hospital ethical committee. All the patients were divided into cardiogenic shock (CS) and non-cardiogenic shock (Non-CS). The STEMI patients who opted for thrombolytic therapy or late presentation to hospital (more than 24 hours duration of onset of chest) with no signs and symptoms of ongoing ischemia were excluded from the study.

ST elevation myocardial infarction was defined as New ST elevation at the J point in two contiguous leads of >0.1 mV in all leads other than leads V2-V3 or new onset left bundle branch block(LBBB). For leads V2-V3 the following cut points apply: ≥ 0.2 mV in men ≥ 40 years, ≥ 0.25 mV in men <40 years, or ≥ 0.15 mV in women.

Cardiogenic shock was defined as a persistent fall in systolic blood pressure below 90 mm Hg for at least 30 min with a cardiac index of less than 1.8 l/min/m2 without inotropic support or 2.0 to 2.2 l/min/m^2 with inotropic support and raised pulmonary capillary wedge pressure i.e. >15 mm Hg in presence of adequate intravascular volume

Non Cardiogenic shock group was defined as a hemodynamically stable patients with systolic blood pressure of more than 90 mm Hg with a cardiac index of more than 2.0 l/min/m2 without inotropic support. Cardiogenic shock (CS) died group included all patients who died in same hospital admission for primary PCI. Cardiogenic shock (CS) survived group included all the cardiogenic shock patients who were discharge from hospital after primary PCI in stable condition. Procedure Success (successful Angioplasty) was defined as the establishment of TIMI III coronary blood flow in the infarct related artery without procedural complication i.e. dissection, perforation or cerebrovascular accident.

The patient demographic data, clinical examination, laboratory investigation, supplementary treatment and Angiographic characteristics are entered through a specially designed proforma. SPSS Version 24.0 was used for study analysis. Categorical variables like gender, diabetes, hypertension, smoking history, use of IABP, ventilator support etc. were expressed as numbers and percentages while continuous variables like age, timing variables, PH, GFR etc. were expressed as mean $\pm$ SD (Standard deviations). The McNemar test was used to analyze the study.

RESULTS

All the 277 HISNET registry patients who underwent PPCI for acute myocardial infarction were included. Among the 277 patients, 247(89%) were with in cardiogenic shock while 30(11%) were in cardiogenic shock. Mean age of Age was 53 ± 10 in CS group and 54 ± 9 in Non-CS group (0.568). Male gender, smoking history, hypertension, old MI) in both groups were similar. Diabetes was present in 16(53.3%) patients in CS and 93 (38%) patients in Non CS group (0.038). The Baseline characteristics are shown in detail in table 1. Most of the time variables were also similar in both groups of patients. Mean First Medical contact(FMC) to transfer time was 32 sec for Non CS and 45 minutes in CS group($p = 0.023$). Timing variables are shown in detail in table 2. Radial route was used in only 9 (30%) of CS group versus 163 (66%) of Non-CS group ($p < 0.001$) as shown in table 3. Successful PPCI was performed in 98% group as compare to 87% in CS group, (p valve 0.015). In-hospital mortality was 7(23%) in CS group and 6 (2%) in non CS group (p valve <0.001). One year mortality was 17 (7%) for non CS as compare to (27%) in CS group (p valve <0.05) as shown in table 4. In subgroup analysis of cardiogenic shock patients, mean age of CS died patients was 56.4 ± 11.02 years while 53.2 ± 7.8 years in CS survived group. Their baseline characteristics are shown in table 5 in detail. Post procedure hemoglobin (Hb), number of inotropes needed at admission, baseline GFR, baseline PH were statistically significant between both groups, the detail is shown in table 5. First medical contact to balloon time was 119.6 ± 34.8min in CS died patients and 109.23 ± 40.8min in CS survived patients group ($p<0.01$). Total ischemic time was 260.0 ± 91.75min in CS died vs.307.23 ± 199.9min in CS survived group($p<0.01$). Multiple vessel disease (MVD)

was present in all CS died patient 7(100%)Vs. 3(13%) in CS survived group(p<0.001).Angiographic success was documented in 4(57.14%) vs.22(95.6%) in CS died Vs. CS survived group respectively(p valve 0.031). The procedural characteristics of both group are shown in detail in table 6.

Table 1: Baseline Demographic and Clinical Characteristics

Characteristics	Frequency(%) Non CS(n=247)	CS(n=30)	p value
Age, Mean ± SD (years)	53 ± 10	54 ± 9	0.568
Age, Median (Inter quartile range; Q1-Q3)	53 (45-60)	56 (48-60)	0.546
Male, (%)	214 (87%)	27 (90%)	0.778
History of smoking,(%)	149 (67%)	17 (68%)	0.881
Hyperlipidemia, (%)	14 (18%)	4 (13%)	0.540
HPT, (%)	109 (44%)	17 (57%)	0.193
DM, (%)	93 (38%)	16(53.3%)	0.038
Past History of MI,(%)	13 (5%)	5 (17%)	0.379

Table 2: Timing of Presentation

Characteristic	Frequency (%) Non-CS (n=247)	CS (n=30)	p value
Onset to FMC, >3hours	88 (40%)	8 (32%)	0.418
Onset to FMC,	148 (80- 245)	120 (80-280)	0.562
Median (Inter quartile range; Q1-Q3)	minutes	minutes	
FMC to transfer, >30minutes	76 (52%)	14(74%)	0.070
FMC to transfer,	32 (25_53)	45(31_71)	0.023
Median (Inter quartile range; Q1_ Q3)	minutes	minutes	
FMC to balloon, >120minutes	49 (22%)	9 (35%)	0.165
FMC to balloon, Median	92 (76_113)	98 (86_130)	0.093
(Inter quartile range; Q1-Q3)	minutes	minutes	
Ischemic time, >180 minutes	183 (77%)	20 (74%)	0.743
Ischemic time, Median	260 (186-345)	232 (182-374)	0.779
(Inter quartile range; Q1-Q3)	minutes	minutes	

Table 3: Procedural Characteristics

Characteristic	Frequency (%) Non CS (n=247)	CS (n=30)	p value
Radial approach, (%)	163 (66%)	9 (30%)	<0.001
Successful procedure, (%)	241 (98%)	26 (87%)	0.015

Table 4: Outcome of Study Population

Characteristic		Frequency (%)		p value
		Killip <2 (n=247)	Killip >2 (n=30)	
In hospital Mortality, (%)		6 (2%)	7 (23%)	<0.001
Length of stay, Median (Inter quartile range; Q1-Q3)		3 (3 -4)	4 (3 -6)	0.276
30 days Mortality,(%)	Total	9(3.6%)	8(29.6%)	<0.05
	New	3 (2%)	1 (4%)	0.314
6 months Mortality, (%)	Total	16(6.4%)	8(29.6%)	<0.05
	New	7 (4%)	0	>0.05
1 year Mortality, (%)	Total	17(6.9%)	8(29.6%)	<0.05
	New	1 (1%)	0	>0.05
Mean Follow up duration (months) Median (Inter quartile range; Q1-Q3)		11 (6 -13)	10 (7 -13)	0.657

Table 5: Clinical and Baseline Characteristics of the Different Groups of CS

Variables	CS DEATH(n=7)	CS Survived(n=23)	P value
AGE(years)	56.4±11.02	53.23±7.8	0.549
HYPERTENSION	4(57%)	13(56.3%)	0.25
DIABETES	4(57%)	14(60.8 %)	0.40
SMOKING	3(43%)	16(70%)	0.10
PAST PCI	2(28.6%)	4(17.4%)	.06
Old CVA	0	1(4.3%)	1.00
ESRD	1(14.3%)	3(13%)	0.35
Insulin dependent DM	2(28.6%)	8(34.8%)	0.10
PH	7.11 ±1.1	7.32±1.3	0.01
Ventilatory support	7(100%)	5(21.7%)	0.01
BASELINE HB	15.5±2.9	15.12±2.02	0.25
Post procedure - HB	10.9±3.5	12.3± 2.54	<0.01
BASELINE GFR	42.5±18	51.56± 14.5	<0.01
No of inotropes	2.1±.7	1.1±0.8	<0.01
FMC to balloon time	119.6±34.8min	109.23 ±40.8min	<0.01
Total ischemic time	260.0±91.75min	307.23 ±199.9min	<0.01

Table 6: Procedural Characteristics Between the Two Groups of CS

Variable		Group A(CS death)n=07	Group B(CS Survived) n= 23	p value
Vessel involved(IRA)	Left main	1(14.3%)	1(4.3%)	0.418
	LAD	4(57.14%)	10(43.5%)	0.392
	Cx/OM	0	4(17.39%)	0.548
	RCA	2(28.6%)	8(34.8%)	1.000
Severe multiple Vessel disease		7(100%)	3(13%)	0.001
Total occlusion of IRA		7(100%)	16(69.5%)	0.037
Post procedure TIMI 0/1		3(43%)	1(4.3%)	0.031
More than one stent used in IRA		3(42.85%)	4(17.39%)	0.306
Angiographic success		4(57.14%)	22(95.6%)	0.031
Bifurcation disease in IRA/L		2(28.6%)	3(13%)	0.565
Use of IABP		5(57.14%)	3(13%)	0.007
REINTERVENTION		1(14.3%)	1(4.3%)	0.418
Temporary pace maker		1(14.3%)	15(65%)	0.03
Major vascular complication		1(14.3%)	3(13%)	1.00
Stroke/TIA		1(14.3%)	3(13%)	1.00

DISCUSSION

This study is done in our local Malaysian population using the HKL IJN network for primary PCI. All the patients were transferred from the HKL to IJN who were presented with acute ST elevation myocardial infarction for Primary PCI. Cardiogenic shock patients undergoing PPCI in the contemporary era with adjuvant medical therapy still showed high mortality. Despite an apparent low mortality compared with historical data, 30 days mortality of 30% in CS patients suggests there still remains substantial room for improvement in management of cardiogenic shock secondary to acute myocardial infarction. Our study demonstrated that old age, history of renal disease, diabetes mellitus, more inotropic support at the outset, low PH, need for artificial ventilation, left main coronary artery angioplasty and need for IABP were associated with high mortality rates in cardiogenic shock. An interesting finding from our study is the relatively low subsequent mortality rate for cardiogenic shock patients who survive the first 30 days. So in other words more intense measures in term of revascularization should be taken to manage cardiogenic shock in STEMI.Our study describes the mortality for both non cardiogenic shock and cardiogenic shock patients both for 30 days and 1 year following primary PCI.

Compare to the early studies with use thrombolytic only, the outcome of patient with cardiogenic shock in STEMI improved with the primary PCI. But still less than 20 % of Malaysian population having access to primary PCI in STEMI.[6] The in hospital mortality was just 2% in primary PCI with no cardiogenic shock as compare to 23% with cardiogenic shock but there was a more increasing trend in mortality in non CS patients over the next 12 months as compare to CS patients which may be pertaining to small number of cardiogenic shock patients in our study. Diabetes were more common in cardiogenic shock patients i.e. 53% as compare to non-cardiogenic shock patients in our study population, supported by other similar studies.[6-9] But on analyzing the patients with cardiogenic shock who survived and those who were expired there was no statistically significant difference in the diabetes. This finding may be attributable to relatively small sample size of the cardiogenic patients who expired i.e.07 patients expired of the total 30 CS patients.10 Some of previous studies showed that diabetic patients presented with STEMI complicated by CS is associated with very high mortality as compared to non-diabetics e.g. observations from the PL-ACS (Polish Registry of Acute Coronary Syndromes).[11] However, our finding of no difference in mortality of the cardiogenic shock patients is supported by the SHOCK (Should We Emergently Revascularize Occluded Coronary Arteries for CGS Trial and Registry) registry which shows no difference in mortality of CS patients with or without diabetes.[12] The reason for these difference in the diabetic mortality from shock trail is not clear, may be difference in study population. Sometime the extent and severity of disease in diabetic patient is not suitable/feasible, which may play an important role in the overall outcomes in such patients. The overall 1-year mortality still remains high in our non CS study population i.e. 07% and it appears to be less influenced than may have been expected by contemporary adjunctive treatments.[13] Our mortality rate in cardiogenic shock is comparable to or better than in a recent analysis done in UK population by kunadian et.al. Wherethe short term i.e. 30-day mortality was 37 % as copares to ours where the 30 day mortality is 30% and the 1-year mortality was 44.3% From the BCIS Database analysis. the increase in mortality in the BCIS data base may be because of the large sample size which comprise of study population of 4689 subject.[14] Our mortality rates are comparable to a recent analysis of STEMI patients with Cardiogenic shock where the in-hospital mortality was 39% by Kolte D et.al.[15] We also documented that TIMI flow grade I/0 was more frequent in cardiogenic shock patients as compare to non CS patients. PPCI which was performed through radial route showed less mortalityi.e. predictor of good survival at 1 year. But usually radial route is used in less sick patients. As cardiogenic shock is associated with poor peripheral perfusion, so in most of the cardiogenic shock patients the operator use transfemooral as standard approach. So the less mortality associated with radial approach may be explained partly by this reason in cardiogenic shock. Most of the cardiogenic shock patient underwent primary PCI through transfemoral route as compare to transradial route in the non CS patients which is also supported by the international data. We also found in this study that first medical contact to transfer time from HKL to IJN was more i.e.45 minutes in cardiogenic shock patients as compare to non-cardiogenic shock patients i.e. 32 minutes. But strangely the FMC to balloon time was non-significant in CS and non CS patients. The more transfer time for Cs patient may be because of stabilization first means the stat of inotropic support, oxygen needs etc. first medical contact to balloon time was more than 120 minutes in about 35 % in CS group Vs. 22% in Non-CS group which needs improvement Interesting findings were noted when we further analyze the cardiogenic shock data into those who expired i.e. 7(23%) and those who survived the index hospitalization, i.e. 23(77%) patients.We then look into the different risk factors and procedural characteristics of both the survived and the expired cohort. This allows us to describe the important predictors of poor outcome in cardiogenic shock. It is observed that low PH, low GFR, and number of inotropes needed at the time of admission, post PCI hemoglobin, first medical contact to balloon time and total ischemic time were independent risk factor for mortality. Thus, for example, mean age was 56 years in expired person vs. 53 years in survived group. This is consistent with the GRACE (Global Registry of Acute Coronary Events).[16] In a small study by Tomassini F et.al. In patients with Cardiogenic shock, age more than 75 years (hazard ratio: 1.81, p= 0.04) was a major predictor of mortality. [17] Optimal treatment strategies for older patients presenting with cardiogenic shock in STEMI is still not known which warrant further study. It is further observed that all the patients CS died group have total occlusion of the infarct related artery and severe three vessel disease while only 13% have 3 vessel disease in CS survived cohort. We observed in our study that the need for artificial mechanical ventilation was an independent predictor of higher mortality. The risk in these patients is increased by the presence of more essential features, such as the degree of recoverable neurological injury and other metabolic disturbance, which in most of the time is not clear at time of PPCI. Strategies that improve the outcome among the ventilated patients are not so developed, including in particular therapeutic hypothermia in this part of the world.[18] How much the therapeutic hypothermia influence the outcome cardiogenic shock in patients with or without neurological insult needs further study to explore? In the landmark SHOCK trial, about 60% of patients in the PCI arm and more than 80 % of patients in the CABG arm had severe three vessel disease.[19]

Similarly in SHOCK registry, about 54% of patients had more than one vessel coronary artery disease.[20] It is also obvious from our study that the majority of cardiogenic shock patients have got severe multi vessel coronary artery disease, but which modality of treatment is the best, i.e. CABG VS PCI is still to be answered and needs further randomized control trials. In cardiogenic shock patients, 3 vessel coronary artery disease with and without a chronic total occlusion were strong predictors for short-term mortality.[21] IABP use was an independent predictor for in hospital mortality in cardiogenic shock patient in our study. This finding is supported by the majority of international data. Our study demonstrated that IABP use was an independent predictor of mortality. The benefits from use of IABP have also recently been questioned. Both IABP-SHOCK II&ALKK-PCI registry investigators demonstrated no overall benefit of the use of IABP in CS.[22,23] A meta-analysis which evaluated the use of IABP in primary PCI demonstrated its benefit in patients who were treated by thrombolytic therapy while no benefits in patients treated by primary PCI.[24] But all the observational data is confounded by the fact that, usually in sicker patients the operator opt for IABP. It is also clear from our study that baseline renal function derangement is also a predictor of worst outcome in cardiogenic shock patients so strategies should be consider to limit the contrast induce nephropathy and further decline in renal function. Our study identified the various predictor of mortality in cardiogenic shock patient, so a protocol driven intervention is needed in these sick patient with focus care.

LIMITATIONS

This is a single center nonrandomized study observational study. The sample size is relatively small. The cardiogenic shock was defined by clinical methods, not by the invasive method. The cardiogenic shock patients was also small number to apply to general population.

CONCLUSION

Despite of similarities in most of risk factors and high proportion of successful angioplasties, mortality rate of acute myocardial infarction with Cardiogenic Shock was higher than non-cardiogenic shock. The cardiogenic shock patients who have survived the acute event have overall good survival rate.

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