Impact of Left Ventricular Systolic Function on Hospital Mortality in Patients Undergoing Percutaneous Coronary Intervention: Results from Thai Percutaneous Coronary Intervention Registry (TPCIR)

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Objective: *To investigate the relationship between left ventricular (LV) systolic function and the clinical outcomes in unselected patients underwent percutaneous coronary intervention (PCI), through analysis of the Thai Percutaneous Coronary Intervention Registry (TPCIR).*

Material and Method: *The association between LV systolic function and in-hospital mortality in 2,427 patients undergoing PCI included in TPCIR between May and October 2006, was studied. Patients were categorized as either left ventricular ejection fraction (LVEF) less than 40% or LVEF 40% or more.*

Results: *In-hospital mortality was 8.0% among patients with LVEF less than 40% and 1.3% in those with LVEF of 40% or more. After adjustment for baseline variables, those associated with increased hospital mortality were, LVEF less than 40% (OR = 2.87, 95% CI = 1.57 to 5.23), p<0.001, history of heart failure (OR = 15.99, 95% CI = 8.10 to 31.56, p<0.001), previous stroke (OR = 66.96, 95% CI = 11.01 to 407.36, p<0.001), and extent of coronary artery disease (OR = 2.12, 95% CI = 1.04 to 4.32, p = 0.038).*

Conclusion: *The results of the present study suggest that LV systolic function, and history of heart failure within two weeks may increase in-hospital mortality following PCI in unselected patients and across all indications for PCI. Assessing LV function before PCI appears warranted.*

Keywords: *PCI, Left ventricular systolic function*

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Left ventricular (LV) function is a strong predictor of an adverse outcome among patients with coronary artery disease (CAD)[1,2]. The prevalence of LV dysfunction in patients with CAD undergoing percutaneous coronary intervention (PCI) ranges between 10% and 30%[3-5]; however, most patients with LV dysfunction are excluded from randomized controlled trials[6,7]. Multi-vessel disease and comorbidities are more common in patients with LV dysfunction than those with preserved LV function[8,9]. Previous research suggested that LV function is the significant predictor of unfavorable outcomes following PCI[9,10]. In patients with multi-vessel diseases and LV dysfunction, PCI was associated with an increased need for further revascularization, a higher incidence of myocardial infarction, and increased risk of combined major cardiac events compared with coronary artery bypass graft (CABG) in a long-term follow-up study[11]. Notwithstanding, PCI has become an increasingly effective modality[12]; as about one-third of patients with LV dysfunction underwent PCI even though the data regarding its safety and benefits have not been rigorously tested.

The objectives of the present study were to: (a) describe the clinical characteristics of patients with LV systolic dysfunction undergoing PCI, and (b) evaluate the association between LV systolic function and hospital outcomes in the Thai Percutaneous Coronary Intervention Registry (TPCIR).

Material and Method

The TPCIR is a clinical database that includes all of the patients who underwent PCI between May and October 2006 at the 27 cardiac centers in Thailand. Data collection was conducted by trained nurses and re-checked by the principal investigators at each site. Web-based, double data entry was used to prevent data entry errors. Data were then sent to the data management

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center at the Thai Heart Association Research Center. The researchers re-examined each electronic submission to confirm its completeness and accuracy.

The TPCIR includes the following prospective data: age, sex, coronary risk factors, chronic kidney disease, history of heart failure, cerebrovascular disease, coronary artery bypass surgery, coronary anatomy, type of stent, left ventricular ejection fraction (LVEF), and in-hospital outcomes.

Measurement of the LVEF was performed using echocardiography or contrast ventriculography and interpreted at each site. LV systolic dysfunction was defined as LVEF less than 40%. Assessment of coronary stenosis was determined at each site by each operator; the presence of a stenosis 50% or more of the left main artery and/or 70% or more of a non-left main coronary artery were considered significant. The physician performing the PCI procedure made all procedural decisions including the type of device, stent selection, and adjunctive pharmacological treatment.

Death was defined as all causes of mortality during hospitalization. In-hospital adverse events included urgent coronary bypass surgery, cardiac arrhythmias, stent thrombosis, myocardial infarction, or access site complications. Each operator recorded lesion characteristics according to the American College of Cardiology/American Heart Association (ACC/AHA) classification[13].

Written informed consent was obtained from each patient before performing the PCI procedure and data collection. The research protocol was reviewed and approved by each local institutional ethics committee and the study was performed in accordance with the Declaration of Helsinki.

Statistical analysis

The frequencies and percentages of the categorical data were presented. The continuous variables were reported as a mean ± SD. For categorical variables, differences between the patient groups were examined using the Chi-square (or Fisher's exact test) or the Z-test. For the continuous variables, differences between groups were assessed using the Student's t-test or the Mann-Whitney U-test. Clinical meaningful predictive variables of in-hospital mortality were selected and tested by univariate and multivariate analysis. Each variable was independently tested in a univariate regression model, then those that achieved a p-value of less than 0.25 (and were clinical meaningful) were selected for testing in a multivariable logistic regression. The odds ratios (ORs) and 95% confidence intervals (CIs) were used to illustrate the association between clinical variables and in-hospital mortality. A p-value of less than 0.05 was required for statistical significance. All of the analyses were done using SPSS version 16 (SPSS Inc., Chicago, Illinois, USA).

Results

Four thousand one hundred fifty six patients underwent PCI between May and October 2006 were enrolled in the TPCIR. Among these, LV function was available in 2,427 (58.4%). Two thousand fifty six (84.7%) patients had LVEF 40% and greater, and 371 (15.3%) had LVEF of less than 40%.

The baseline characteristics of both groups are presented in Table 1. The mean age was 63.0±11.3 years (68% male). Most patients (69.7%) had hypertension and almost 40% had diabetes mellitus. The clinical history of heart failure within two weeks before the PCI procedure was recorded in 14.8%. One-third of patients (35%) had a history of myocardial infarction. Multi-vessel disease presented in 65% of the patients and left main disease was presented in 0.2% of all patients.

Patients with LVEF of less than 40% compared to those with LVEF 40% and greater were older (p = 0.014) and had a higher prevalence of chronic kidney disease (p = 0.011), previous myocardial infarction (p = 0.005), prior coronary artery bypass surgery (p = 0.048), and heart failure within two weeks prior PCI (p = 0.001). The remaining baseline characteristics were not significantly different between the two groups.

Indications for PCI and clinical presentation between the two groups are presented in Table 2. PCI patients with LVEF of less than 40% were more likely to present with ST elevation myocardial infarction (p<0.001). By comparison, PCI patients with LVEF of 40% or more were more likely to present with chronic stable angina albeit not a statistically significant trend (32.0% vs. 18.9%, p = 0.061).

The procedural characteristics of the patients are presented in Table 3. Patients with LVEF of less than 40% compared to those with LVEF of 40% or more were more likely to have complex CAD including AHA type C lesion, chronic total occlusion, and the presence of thrombus in the coronary artery. Drug-eluting stents were more likely to be used in patients with LVEF of 40% or more than those with LVEF of less than 40% (p<0.001).

In-hospital outcomes are presented in Table 4. The total mortality rate was 8% in patients with LVEF

of less than 40% and 1.3% in those with LVEF of 40% or more. Patients with LVEF of less than 40% compared to those with LVEF of 40% or more were more likely to have urgent coronary artery bypass surgery, ventricular arrhythmias, cardiogenic shock, and major bleeding complications. The rate of acute/subacute stent thrombosis was low in both groups.

Univariate analysis are presented in Table 5. Age, previous stroke, chronic kidney disease, history of heart failure within two weeks, LVEF of less than 40%, and extent of CAD were independently related to in-hospital mortality. After adjustment for the variables from Table 5, the factors associated with increased mortality were: LVEF of less than 40%

Table 1. Baseline characteristics of all patients

Clinical variables	Overall (n = 2,427) n (%)	LVEF <40 (n = 371) n (%)	LVEF ≥40 (n = 2,056) n (%)	*p*-value
Age (year), mean ± SD	63.0±11.3	64.6±11.8	62.7±11.2	0.014
<55	578 (23.8)	79 (21.3)	499 (24.3)	
55 to 64	697 (28.7)	94 (25.3)	603 (29.3)	
65 to 79	994 (41.0)	162 (43.7)	832 (40.5)	
≥80	158 (6.5)	36 (9.7)	122 (5.9)	
Sex (male)	1,664 (68.6)	264 (71.15)	1,400 (68.1)	0.242
Diabetes	925 (38.1)	144 (38.8)	781 (37.9)	0.763
Smoking	1,015 (41.8)	171 (46.1)	844 (41.0)	0.070
Dyslipidemia	1,854 (76.4)	243 (65.5)	1,611 (78.3)	<0.001
Hypertension	1,693 (69.7)	233 (62.8)	1,460 (71.0)	0.002
Family history of CAD	251 (10.3)	21 (5.6)	230 (11.2)	0.001
Peripheral arterial disease	71 (3.1)	12 (3.9)	59 (3.0)	0.701
Chronic kidney disease	167 (6.8)	37 (9.9)	130 (6.3)	0.011
Previous stroke	7 (0.2)	1 (0.2)	6 (0.3)	0.941
Previous myocardial infarction	814 (35.5)	148 (39.9)	666 (32.4)	0.005
Previous PCI	569 (23.4)	81 (21.8)	488 (23.7)	0.426
Previous CABG	88 (3.6)	20 (5.4)	68 (3.3)	0.048
HF within 2 weeks	417 (17.2)	163 (43.9)	254 (12.3)	<0.001
Extent of coronary disease				0.067
1-vessel	837 (34.5)	113 (30.5)	724 (35.2)	
2-vessel	812 (33.5)	128 (34.5)	684 (33.2)	
3-vessel	771 (31.8)	127 (34.2)	644 (31.3)	
Left main disease	7 (0.2)	3 (0.8)	4 (0.2)	

CAD = coronary artery disease; PCI = percutaneous coronary intervention; CABG = coronary artery bypass graft; HF = heart failure

Table 2. Indications for PCI and clinical presentation

Clinical variables	Overall (n = 2,427) n (%)	LVEF <40 (n = 371) n (%)	LVEF ≥40 (n = 2,056) n (%)	*p*-value
ST elevation MI	268 (11.0)	64 (17.2)	204 (9.9)	<0.001
Primary PCI	130 (5.3)	27 (42.2)	103 (50.5)	0.068
Rescue PCI	17 (0.7)	6 (9.4)	11 (5.4)	0.449
Others PCI	121 (4.9)	31 (48.4)	90 (44.1)	0.375
Non-ST elevation MI	318 (13.1)	53 (14.3)	265 (12.9)	0.596
Unstable angina	607 (25.0)	95 (25.6)	512 (24.9)	0.569
Stable angina	729 (30.0)	70 (18.9)	659 (32.0)	0.061
Asymptomatic CAD	122 (5.0)	15 (4.04)	107 (5.2)	0.612
PCI prior to non-cardiac surgery	16 (0.6)	1 (0.3)	15 (0.7)	0.688
PCI as a staged procedure	138 (5.6)	17 (4.6)	121 (5.9)	0.621
Other indications	229 (9.4)	56 (15.1)	173 (8.4)	<0.001

MI = myocardial infarction

(OR = 2.87, 95% CI 1.57 to 5.23, $p<0.001$), previous stroke (OR = 66.96, 95% CI 11.01 to 407.36, $p<0.001$), history of heart failure within two weeks (OR = 15.99, 95% CI 8.10 to 31.56, $p<0.001$), and the extent of CAD (OR = 2.12, 95% CI 1.04 to 4.32, $p = 0.038$) (Table 6). The adjusted odd ratio and 95% CI are illustrated in Fig. 1. However, the adjusted odd ratio of stroke is likely exaggerated because of the small number of events in each group. Age and chronic kidney disease were not related to increasing mortality according to the multivariate analysis.

Discussion

This large and unselected PCI registry in Thailand made clear that the factors related to in-hospital mortality in patients underwent PCI were LVEF of less than 40%, previous history of stroke, history of heart failure within two weeks prior to PCI, and the extent of CAD. The current study also provided the daily-practice use and characteristics of PCI in patients with LV systolic dysfunction excluded in most clinical trials[14-16].

We clinically and angiographically characterized patients with a relatively large sample of subjects undergoing PCI. However, in the present registry, only 58.4% of the patients undergoing PCI had undergone an LV function assessment before the PCI procedure. This finding is consistent with recent data from the British Cardiovascular Intervention Society, which indicates that only 50%

Table 3. Procedural characteristics of all patients

Lesion characteristic	Overall (n = 3,604) n (%)	LVEF <40 (n = 535) n (%)	LVEF ≥40 (n = 3,069) n (%)	*p*-value
ACC/AHA classification				0.032
A	122 (3.3)	17 (3.2)	105 (3.4)	
B1	912 (25.3)	116 (21.7)	796 (25.9)	
B2	1,062 (29.4)	148 (27.6)	914 (29.7)	
C	1,508 (29.5)	254 (47.5)	1,254 (40.8)	
Bifurcation lesion	679 (18.8)	83 (15.5)	596 (19.4)	0.033
Ostial lesion	402 (11.1)	57 (14.2)	345 (11.2)	0.691
CTO	297 (8.2)	54 (10.1)	243 (7.9)	0.001
Presence of thrombus	345 (9.6)	72 (13.5)	273 (8.8)	0.001
Bypass graft PCI	30 (0.8)	9 (1.6)	21 (0.6)	0.061
Previous treated lesions	231 (6.4)	36 (6.7)	195 (6.3)	0.947
DES	1,905 (52.8)	215 (40.1)	1,690 (55.0)	<0.001
BMS	1,162 (32.2)	213 (39.8)	949 (30.9)	<0.001

n = number of procedure; CTO = chronic total occlusion; DES = drug eluting stent; BMS = bare metal stent

Table 4. In-hospital outcome of all patients

Clinical variables	Overall (n = 2,427) n (%)	LVEF <40 (n = 371) n (%)	LVEF ≥40 (n = 2,056) n (%)	*p*-value
Q wave MI	25 (1.0)	9 (2.4)	16 (0.7)	0.035
Urgent CABG	16 (0.6)	4 (1.0)	12 (0.5)	<0.001
In-stent thrombosis (acute/subacute)	6 (0.2)	0 (0.0)	6 (0.2)	<0.001
Unplanned PCI	6 (0.2)	1 (0.2)	5 (0.2)	<0.001
VT/VF requiring treatment	48 (1.9)	19 (5.1)	29 (1.4)	0.032
Cardiogenic shock	69 (2.8)	25 (6.7)	44 (2.1)	0.001
Heart failure	59 (2.4)	29 (7.8)	30 (1.5)	0.805
Acute kidney injury	53 (2.1)	27 (7.2)	26 (1.2)	0.793
Major bleeding / hematoma	44 (1.81)	8 (2.1)	36 (1.7)	<0.001
Non-entry site bleeding complication	27 (1.1)	10 (2.6)	17 (0.8)	<0.005
All cause of death	57 (2.3)	30 (8.0)	27 (1.3)	0.431
Cardiac death	41 (1.6)	24 (6.4)	17 (0.8)	0.027

VT = ventricular arrhythmias; VF = ventricular fibrillation

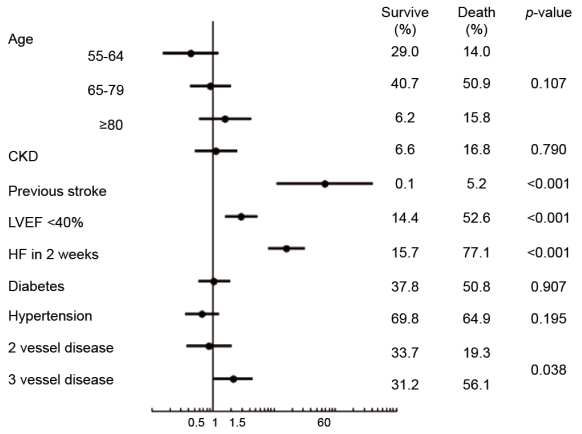

Fig. 1 Adjusted odd ratio and 95% confidence interval for inhospital mortality among patient undergoing percutaneous coronary intervention, CKD = chronic kidney disease; LVEF = left ventricular ejection fraction; HF = heart failure.

of patients undergoing PCI had undergone LVEF evaluation[17].

PCI is recommended for patients with normal LV systolic function with a high-risk profile apparent after non-invasive testing, and in patients whose coronary artery anatomic conditions were associated with a low risk of PCI procedural complications and a high likelihood of good long-term outcomes[18]. Whether the PCI in patients with low LVEF reduces morbidity or mortality over against CABG is unknown. There are limited data comparing the outcomes of patients with LV systolic dysfunction undergoing PCI or CABG[19,20]. Patients with LV systolic dysfunction were mostly excluded from recent clinical trials. For an example, the Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation (COURAGE) did not include patients with LVEF 30% or less[21]. The 2011 AHA guidelines did not recommend

Table 5. Univariate and multivariate regression analysis for in-hospital mortality

Variable	Crude OR (95% CI)	*p*-value	Adjusted OR (95% CI)	*p*-value
Age		<0.001		0.107
<55	1		1	
55 to 64	0.83 (0.44 to 1.54)		0.43 (0.15 to 1.20)	
65 to 79	2.05 (1.23 to 3.40)		0.90 (0.42 to 1.92)	
≥80	2.89 (1.44 to 5.80)		1.56 (0.59 to 4.12)	
Previous stroke		<0.001		<0.001
No	1		1	
Yes	63.02 (18.19 to 218.35)		66.96 (11.01 to 407.36)	
Chronic kidney disease		<0.001		0.790
No	1		1	
Yes	2.61 (1.56 to 4.38)		1.11 (0.50 to 2.46)	
Peripheral artery disease		0.530		
No	1			
Yes	1.34 (0.54 to 3.33)			
LVEF <40%		<0.001		<0.001
No	1		1	
Yes	6.62 (3.88 to 11.26)		2.87(1.57 to 5.23)	
Congestive HF within 2 weeks		<0.001		<0.001
No	1		1	
Yes	9.53 (6.43 to 13.59)		15.99 (8.10 to 31.56)	
Diabetes mellitus		0.018		0.907
No	1		1	
Yes	1.55 (1.08 to 2.24)		1.04 (0.58 to 1.86)	
Hypertension		0.066		0.195
No	1		1	
Yes	0.7 (0.48 to 1.02)		0.66 (0.35 to 1.23)	
Extent of coronary artery disease		<0.001		0.038
1 vessel disease	1		1	
2 vessel disease	1.29 (0.76 to 2.19)		0.86 (0.37 to 2.00)	
3 vessel disease	2.65 (1.65 to 4.26)		2.12 (1.04 to 4.32)	

Variables adjusted in multivariate analysis were; age, previous stroke, chronic kidney disease, peripheral artery disease, LVEF <40%, congestive heart failure within 2 weeks, diabetes mellitus, hypertension, and extent of coronary artery disease

elective PCI in patients with LVEF of less than 50%, and PCI was classified as having an uncertain benefit on revascularization (i.e., for reducing mortality in patients with CAD). Therefore, CABG is the revascularization method of choice in patients with LV systolic dysfunction[18].

The improvement in PCI techniques, including the profile of balloon and stents, the advent of drug-eluting stents, and hemodynamic supports, have improved the outcomes of PCI in modern cardiology practice[22]. Notwithstanding, LV systolic function is still an important predictor of worse outcomes and continues to influence mortality even in the contemporary PCI era. Wallace et al (using the 1998/1999 New York State Angioplasty Registry data) reported that LVEF of 26% or less and 26 to 35% had a respective four-fold and two-fold increased risk of hospital mortality among 55,709 patients undergoing elective PCI[8]. Recently, Masmas et al (using the British Cardiovascular Intervention Society between 2006 and 2011) reported that LV function was a strong predictor of mortality following PCI, with worsening LV function independently predicting short- and long-term outcomes across all indications for PCI[17]. The impact of LV systolic dysfunction on in-hospital mortality may reflect the interaction between LV systolic function and the likelihood of peri-procedural complications[4].

Pre-procedural assessment of LV systolic function is not well addressed in PCI guidelines[18,23]. As a consequence, the LV function assessment before PCI procedure is often neglected. The increasing number of patients directly referred to interventionists, who are more likely to perform PCI on the basis of coronary angiographic findings rather than on the comprehensive cardiac evaluation, may be one explanation. Another possibility is that a PCI procedure is less invasive than CABG and is the preferred mode of treatment chosen by most patients.

Limitation

There were some limitations that had to be taken into consideration when interpreting the results from the present study: (a) only 58.4% of all patients undergoing PCI underwent an LV function assessment and the results of this study may not represent the overall study population, (b) the results of the LV function assessment were reported by each investigator without an independent observer that might lead to a bias, (c) the association between LV systolic function and clinical presentation of CAD (acute coronary syndrome and chronic stable angina) was not well addressed in this present study, and (d) the present study was a registration study and some significant variables influencing patient outcomes might not have been recognized.

Conclusion

The Thai PCI Registry (comprising of more than 2,000 patients) confirmed that LV systolic function is related to in-hospital mortality among patients undergoing PCI. PCI in patients with LVEF of less than 40% and history of heart failure within two weeks may increase hospital mortality. The results of the present study suggested that an LV function assessment should be performed on all patients in order to guide therapy and stratify risk.

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What is already known on this topic?

LV systolic function was associated with short and long-term prognosis in patients with CAD. LV function assessment has been recommended in all patients with CAD to guide therapy and risk assessment. However, LV function is not well recommended in PCI guidelines for patients undergoing PCI.

What this study adds?

The present study demonstrated that LV systolic function is related with unfavorable outcomes and warrants the important of LV function assessment in patients undergoing PCI.

Potential conflicts of interest

None.

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ผลของการบีบตัวของหัวใจห้องล่างซ้ายต่ออัตราการเสียชีวิตในโรงพยาบาลของผู้ป่วยที่ได้รับการรักษาโรคหลอดเลือดหัวใจผ่านสายสวน: ข้อมูลจากการลงทะเบียนผู้ป่วยไทยที่ได้รับการรักษาโรคหลอดเลือดหัวใจผ่านสายสวน

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วัตถุประสงค์: *เพื่อศึกษาความสัมพันธ์ระหว่างของการทำงานของหัวใจห้องล่างซ้ายและอัตราการเสียชีวิต ในโรงพยาบาลของผู้ป่วยที่ได้รับการรักษาโรคหลอดเลือดหัวใจผ่านสายสวน ในโครงการลงทะเบียนผู้ป่วยที่ได้รับการรักษาโรคหลอดเลือดหัวใจผ่านสายสวนแห่งประเทศไทย*

วัสดุและวิธีการ: *ทำการศึกษาข้อมูลของผู้ป่วยจำนวน 2,427 ราย ที่ได้รับการตรวจการทำงานของหัวใจห้องล่างซ้าย ในโครงการลงทะเบียนผู้ป่วยที่ได้รับการรักษาโรคหลอดเลือดหัวใจผ่านสายสวนแห่งประเทศไทย (Thai Percutaneous Coronary Intervention Registry) โดยแบ่งผู้ป่วยออกเป็นกลุ่มที่มีค่าการบีบตัวของกล้ามเนื้อหัวใจห้องล่างซ้ายน้อยกว่าร้อยละ 40 และกลุ่มที่มีค่าการบีบตัวของกล้ามเนื้อหัวใจห้องล่างซ้ายมากกว่าหรือเท่ากับร้อยละ 40*

ผลการศึกษา: *พบว่าในผู้ป่วยที่มีค่าการบีบตัวของกล้ามเนื้อหัวใจห้องล่างซ้ายน้อยกว่าร้อยละ 40 มีอัตราการเสียชีวิตในโรงพยาบาลร้อยละ 8 ในขณะที่ผู้ป่วยที่มีการบีบตัวของหัวใจห้องล่างซ้ายมากกว่าหรือเท่ากับร้อยละ 40 มีอัตราการเสียชีวิตในโรงพยาบาลร้อยละ 1.3 ปัจจัยที่มีผลต่ออัตราการเสียชีวิต ได้แก่ การบีบตัวของกล้ามเนื้อหัวใจห้องล่างซ้ายน้อยกว่าร้อยละ 40 (adjusted OR = 2.87, 95% CI 1.57-5.23, p<0.001) ประวัติหัวใจล้มเหลวภายใน 2 สัปดาห์ (adjusted OR = 15.99, 95% CI 8.10-31.56, p<0.001) โรคหลอดเลือดสมอง (adjusted OR = 63.02, 95% CI 18.19-218.35, p<0.001) และความรุนแรงของโรคหลอดเลือดหัวใจ (adjusted OR = 2.12, 95% CI 1.04-4.32, p<0.038)*

สรุป: *การศึกษานี้พบว่าการรักษาโรคหลอดเลือดหัวใจผ่านสายสวนอาจเพิ่มโอกาสการเสียชีวิตในโรงพยาบาล ในผู้ป่วยที่มีประวัติหัวใจล้มเหลวภายใน 2 สัปดาห์ หรือ มีการบีบตัวของกล้ามเนื้อหัวใจห้องล่างซ้ายน้อยกว่าร้อยละ 40 การประเมินการทำงานของหัวใจห้องซ้ายก่อนทำการรักษาอาจจะช่วยในการวางแผนการรักษา และการพยากรณ์โรค*