นิพนธ์ต้นฉบับ

การลดลงของระดับ ST–segment และภาวะแทรกซ้อนทางด้านหัวใจในผู้ป่วยโรคกล้ามเนื้อหัวใจตายเฉียบพลันที่ได้รับการขยายหลอดเลือดด้วยบอลลูน

วิวัฒน์ กาญจนรุจวิวัฒน์, พ.บ.*

* กลุ่มงานอายุรกรรม โรงพยาบาลพระปกเกล้า

บทคัดย่อ

วัตถุประสงค์: ในปัจจุบันการรักษาโรคกล้ามเนื้อหัวใจตายเฉียบพลันโดยการขยายหลอดเลือดด้วยบอลลูนเป็นวิธีการรักษาที่มีประสิทธิภาพ แต่เนื่องจากความสัมพันธ์ระหว่างระดับการลดลงของค่าเอสที (ST segment resolution) กับผลการรักษาทางด้านหัวใจนั้นยังไม่มีความชัดเจน จึงได้ทำการศึกษานี้เพื่อติดตามผลสัมฤทธิ์ทางด้านหัวใจเมื่อวัดระดับการลดลงค่าเอสทีที่ระยะเวลา 90 นาที 24 ชั่วโมง และ 48 ชั่วโมง หลังการขยายหลอดเลือดด้วยบอลลูน และศึกษาถึงปัจจัยพื้นฐานที่มีผลให้ ST segment ลดลงมากกว่าร้อยละ 50 และน้อยกว่าร้อยละ 50

วิธีการศึกษา: เป็นการศึกษาแบบ descriptive โดยการเก็บข้อมูลคลื่นไฟฟ้าหัวใจหลังการขยายหลอดเลือดด้วยบอลลูนในผู้ป่วยโรคกล้ามเนื้อหัวใจตายเฉียบพลันที่ได้รับการขยายหลอดเลือดด้วยบอลลูน ระหว่างวันที่ 1 เดือนสิงหาคม ถึง 31 เดือนธันวาคม พ.ศ. 2556 โดยแบ่งระดับการลดลงของระดับเอสทีเป็นสองกลุ่มคือ ลดลงมากกว่าร้อยละ 50 และ น้อยกว่าร้อยละ 50 และเก็บข้อมูลเพื่อประเมินผลการรักษาทางด้านหัวใจเป็นระยะเวลา 1 เดือน

ผลการศึกษา: จากการศึกษาในผู้ป่วย 26 ราย พบระดับการลดลงของค่าเอสทีที่มากกว่าร้อยละ 50 คิดเป็นจำนวน 10 ราย (ร้อยละ 38.4) 12 ราย (ร้อยละ 46.1) และ 14 ราย (ร้อยละ 57.7) ที่ระยะเวลา 90 นาที 24 ชั่วโมง และ 48 ชั่วโมงตามลำดับ ในช่วงระยะเวลา 1 เดือนที่เก็บข้อมูลพบว่ามีผู้ป่วยเสียชีวิตจากโรคหัวใจหลังการรักษา 1 ราย (ร้อยละ 3.8) เกิดภาวะโรคกล้ามเนื้อหัวใจขาดเลือดซ้ำ 3 ราย (ร้อยละ 11.4) และ เกิดภาวะหัวใจล้มเหลวอันเนื่องมาจากหัวใจ 2 ราย (ร้อยละ 7.6) จากการศึกษาพบว่า โอกาสเกิดโรคกล้ามเนื้อหัวใจตายเฉียบพลันซ้ำ เป็นปัจจัยเดียวที่แสดงค่าน้อยกว่าอย่างมีนัยสำคัญในผู้ป่วยที่มีระดับการลดลงของค่าเอสทีมากกว่าร้อยละ 50 เมื่อวัดที่ระยะเวลา 48 ชั่วโมง ระดับ Thrombolysis in myocardial infarction (TIMI) flow 3 หลังการขยายหลอดเลือดด้วยบอลลูนมีจำนวน 19 (ร้อยละ 73.1) คิดเป็นร้อยละ 75 กับ 70, 83 กับ 64 และ 90 กับ 60 ระหว่างกลุ่มที่ค่าเอสทีลดลงน้อยกว่า 50 และมากกว่า 50 ในช่วงระยะเวลาทั้ง 3 ดังกล่าว

สรุป: ระดับการลดลงของค่าเอสทีในผู้ป่วยโรคกล้ามเนื้อหัวใจตายเฉียบพลันไม่มีผลต่ออัตราการเสียชีวิตและผลทางด้านหัวใจเมื่อติดตามเป็นระยะเวลา 1 เดือน และระดับ TIMI flow หลังการขยายหลอดเลือดด้วยบอลลูนไม่มีผลต่อการลดลงของค่าเอสที

คำสำคัญ: โรคกล้ามเนื้อหัวใจตายเฉียบพลัน; การขยายหลอดเลือดด้วยบอลลูน; การลดลงของระดับเอสที

Original article

ST–Segment Resolution and Cardiac Outcomes after Primary Percutaneous Coronary Intervention (PPCI) in Patients with Acute ST–Segment Elevation Myocardial Infarction

Wiwat Kanjanarutjawiwat, M.D. [*]

[*]Department of Medicine, Prapokklao Hospital

Abstract

Background: The Primary Percutaneous Coronary Intervention (PPCI) is an effective strategy of choice for ST-elevation myocardial infarction (STEMI), but the association between ST-segment resolution after PPCI and short term cardiac outcome is still not clearly defined. Thus, this study determines whether ST-segment resolution at 90 minutes, 24 hours, and 48 hours after PPCI should predict short term 1-month mortality and cardiac outcomes in patients with STEMI.

Materials and methods: This study included 26 patients with STEMI who were treated with PPCI between August 1st, and December 31st, 2013. ECG were collected at presenting and at 90 minutes, 24 hours, and 48 hours after balloon deflating to assess 1-month mortality and other cardiac outcomes. The appearance ST-segment resolution was divided into 2 categories: complete ST-segment resolution (≥50%) and non-complete ST-segment resolution (<50%) to determine difference in short term prognosis.

Results: Number of patients with complete ST-segment resolution (≥50%) were 10 (38.4%), 12 (46.1%), and 14 (57.7%) at 90 minutes, 24 hours, and 48 hours respectively. During short term 1 month follow up, there were 1 death case developed (3.8%), 3 cases developed (11.4%) recurrent AMI, and 2 cases developed (7.6%) congestive heart failure. Less recurrent acute myocardial infarction (AMI) rate in complete ST-segment resolution group at 48 hours was the only statistical significant (P = 0.032) among all cardiac outcomes. Thrombolysis in myocardial infarction (TIMI) flow 3 after PPCI was observed in 19 (73.1%) patients and divided into 75% vs 70%, 83% vs 64%, and 90% vs 60% respectively in three time points between non-complete and complete group.

Conclusions: The degree of ST-segment resolution did not predict mortality rate at 1-month. There was no statistically significant in TIMI flow after PPCI between complete and non-complete resolution groups.

Introduction

Acute myocardial infarction (AMI) is one of the leading health problems both in Thailand and all around the world. ST-segment elevation myocardial infarction (STEMI), the most severe form of AMI, cause highest risk of death and cardiovascular complications e.g. congestive heart failure, cardiogenic shock etc. In 2010, there were 7.2 million deaths from AMI (12.2% of all cause mortality)[1]. In Thailand, there were about 470 patients admitted from AMI each day which leaded to 12 mortalities per day[2].

Previous studies have demonstrated that ST-segment elevation resolution is an important predictor of decreased risk of death and cardiovascular event in patients with acute ST-segment elevation myocardial infarction (STEMI)[3, 4]. The evidence on the predictive value of ST-segment resolution has come from thrombolytic studies. In Primary Percutaneous Coronary Intervention (PPCI), the relationship between ST-segment elevation resolution and rates of death and cardiovascular event is not clearly understood.

The aim of this study was to assess whether the degree of ST-segment resolution is a predictor of short-term mortality in patients with STEMI treated with PPCI.

Materials and methods

Study populations: This study included patients with STEMI who were presented within the onset of first 24 hours and treated with PPCI between August 2013 at December 2013 in Prapokklao Cardiac Center of Excellence.

The diagnosis of STEMI[5] were as follows:

1) Typical chest pain lasting ≥20 minutes

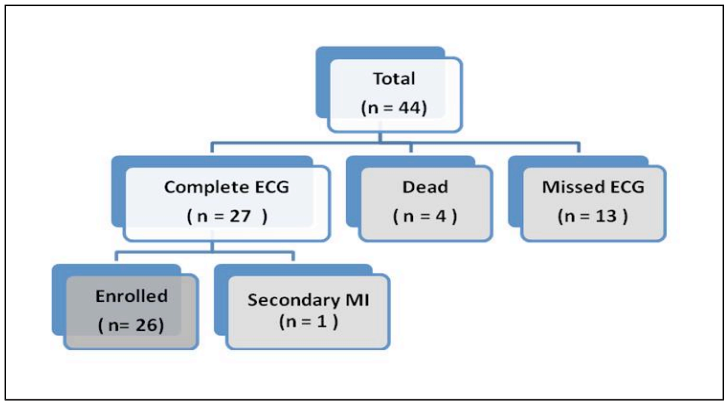
2) ST-segment elevation of ≥1 mm at least two extremities ECG leads or ≥2 mm at least two contiguous precordial ECG leads or new onset of left bundle branch block (LBBB).

The diagnosis was confirmed by coronary angiography at the time of PPCI.

In the study period, there were 44 patients who were treated with PPCI (Figure 1). Patients with missing or inadequate ECG recordings (n=12), with new onset of LBBB (n=1), and secondary MI (n=1) were excluded from the study. Patients with cardiogenic shock and died within 24 hrs after PPCI (n=4) were also excluded. Therefore with 26 patients with STEMI without prior complications and adequate ECG recordings were enrolled in our study.

Electrocardiographic analysis A series of 12-lead ECGs were obtained from all patients included in this study before and 90 mins, 24 hrs, and 48 hrs after the first balloon inflation. The sum of ST-segment elevation was measured at 60 ms after J-point. The sum of "***anterior*** ST-segment elevation" included ECG lead I, aVL, V_1-V_6 and "***Inferior*** ST-segment elevation" included ECG leads II, III, aVF. All measurements were performed using mean interpreted by two cardiologists who were blinded of diagnosis, treatment, and patient outcomes.

Figure 1. Study populations



The degree of ST-segment resolution was calculated by sum of initial ST-segment elevation minus post PPCI ST-segment elevation then divided by initial ST-segment elevation and reported as percentage of ST-segment resolution.

After complete analysis of all ECG recordings, the patients were divided into 2 groups according to the degree of ST-segment resolution: <50% (non-complete resolution) and ≥50% (complete resolution) which rely on the study of thrombolytic therapy.

Study end-points: The primary end-point was 1-month mortality from cardiac cause.

The secondary end-points consisted of:-

1) Congestive heart failure (CHF): defined as Killip classification ≥2

2) Cardiogenic shock: defined as systolic blood pressure (sBP) <90 mmHg at least 1 hr which not responded to fluid resuscitation or rhythm control in case of extreme arrhythmias.

3) Recurrent AMI: defined as recurrent chest pain documented as STEMI, non-STE myocardial infarction, or unstable angina.

The follow up information were collected either by review of medical records and phone call in case of other hospital visits at 30 days after PPCI date or both methods.

Statistical analysis: Categorical data were compared using a x2 test. Continuous data were compared using a Wilcoxon rank-sum test. Univariable and multivariable Cox proportional hazards models were used to assess the association between ST-segment resolution degree and 1-month mortality. A two-sided p <0.05 was considered to indicate statistical significance.

All the statistical analyses were performed using SPSS 19.0 (SPSS, Inc, Chicago, Illinois).

Results: Baseline characteristics according to ST-segment resolution at 90 minutes after PPCI are shown in Table 1. At this early time point, there were 10 patients (38.5%) with complete ST-segment resolution and 16 patients (61.5%) with non-complete ST-segment resolution. The overall patient characteristics were almost similar between two groups except baseline creatinine which was signifi-

cant higher in complete resolution group (p=0.037). Although there was no statistically significant, the complete resolution group were likely to have less hypertension (p=0.070) and more baseline troponin-I level (p=0.097)

In Table 2 showed baseline characteristics according to ST-segment resolution at 24 hours after PPCI. At this later time point, there were 14 patients (53.8%) with complete ST-segment resolution and 12 patients (46.2%) with non-complete ST-segment resolution. The non-complete resolution group had more patients with known hyperlipidemia (p=0.049) and less baseline positive cardiac markers (troponin-I and CK-MB) compare with the complete resolution group, otherwise, there was no significantly different between two groups.

Baseline characteristics of the late 48 hours after PPCI are presented in Table 3. At this time point, higher baseline cardiac enzymes (troponin-I and CK-MB) in the complete resolution group was the only factor that significantly differed between two groups. Although there is no statistically significant, the complete resolution group was likely to have less patients with known coronary artery disease (p=0.082)

Table 1. Baseline characteristics of the patients according to ST-segment resolution at 90 minutes after Primary Percutaneous Coronary Intervention.

Characteristic	ECG 90 min post-PCI		p-value
	Resolution <50% (n=16)	Resolution ≥50% (n=10)	
Gender (male)	75.0%	80.0%	0.768
Age (years)	65.9	61.8	0.447
Onset of chest pain (hr)	5.9	9.9	0.297
Door to balloon time (min)	52.7	46.8	0.619
Systolic blood pressure at arrival (mmHg)	112.6	117.5	0.621
Heart rate at arrival (bpm)	83.4	82.4	0.884
MI location Anterior	56.3%	70.0%	0.483
Inferior	43.7%	30.0%	
Underlying coronary artery disease	12.5%	0%	0.245
Underlying diabetes mellitus	31.3%	40.0%	0.648
Underlying hypertension	43.8%	10.0%	0.070
Underlying hyperlipidemia	37.5%	20.0%	0.237
Hx of smoking at least 10 packs/year	50.0%	80.0%	0.126
Baseline creatinine (mg/dL)	0.8	1.1	0.037
Baseline LDL (mg/dL)	137.0	145.7	0.656
Baseline troponin-I (ng/dL)	13.8	36.7	0.097
Baseline CK-MB (U/L)	68.7	105.2	0.303

Table 2. Baseline characteristics of the patients according to ST-segment resolution at 24 hours after Primary Percutaneous Coronary Intervention.

Characteristic		ECG 24 hrs post-PCI		*P-value*
		Resolution <50% (n=12)	Resolution ≥50% (n=14)	
Gender (male)		75.0%	78.6%	0.829
Age (years)		66.3	62.7	0.506
Onset of chest pain (hr)		5.1	9.4	0.239
Door to balloon time (min)		51.5	49.5	0.863
Systolic blood pressure at arrival (mmHg)		117.6	111.9	0.552
Heart rate at arrival (bpm)		81.9	83.9	0.758
MI location	Anterior	66.7%	57.1%	0.619
	Inferior	33.3%	42.9%	
Underlying coronary artery disease		16.7%	0%	0.112
Underlying diabetes mellitus		50.0%	21.4%	0.127
Underlying hypertension		41.7%	21.4%	0.265
Underlying hyperlipidemia		50.0%	14.3%	0.049
Hx of smoking at least 10 packs/year		50.0%	71.4%	0.263
Baseline creatinine (mg/dL)		0.8	1.0	0.236
Baseline LDL (mg/dL)		125.8	153.4	0.130
Baseline troponin-I (ng/dL)		2.2	40.3	0.002
Baseline CK-MB (U/L)		30.8	129.0	0.002

Table 3. Baseline characteristics of the patients according to ST-segment resolution at 48 hours after Primary Percutaneous Coronary Intervention.

Characteristic		ECG 48hr post-PCI		*P-value*
		Resolution <50% (n=11)	Resolution ≥50% (n=15)	
Gender (male)		72.7%	80.0%	0.664
Age (years)		67.6	61.9	0.285
Onset of chest pain (hr)		5.4	8.9	0.342
Door to balloon time (min)		56.4	46.1	0.374
Systolic blood pressure at arrival (mmHg)		115.5	113.7	0.852
Heart rate at arrival (bpm)		84.6	81.8	0.667
MI location	Anterior	63.6%	60.0%	0.851
	Inferior	37.4%	40.0%	

Table 3. Baseline characteristics of the patients according to ST-segment resolution at 48 hours after Primary Percutaneous Coronary Intervention.

Characteristic	ECG 48hr post-PCI		*P-value*
	Resolution <50% (n=11)	Resolution ≥50% (n=15)	
Underlying coronary artery disease	18.2%	0%	0.086
Underlying diabetes mellitus	36.4%	33.3%	0.873
Underlying hypertension	45.5%	20.0%	0.165
Underlying hyperlipidemia	45.5%	20.0%	0.165
Hx of smoking at least 10 pack/year	45.5%	73.3%	0.149
Baseline creatinine (mg/dL)	0.8	1.0	0.274
Baseline LDL (mg/dL)	134.9	144.2	0.620
Baseline troponin-I (ng/dL)	1.8	37.9	0.004
Baseline CK-MB (U/L)	32.0	121.0	0.005

Table 4. Total 1-month outcome according to ST-segment resolution at 90 minutes, 24 hours, and 48 hours After Primary Percutaneous Coronary Intervention.

Total 1-month outcome	ECG 90 mins post-PCI				P-value
	Resolution <50%		Resolution ≥50%		
Dead	1	6.2%	0	0%	0.420
Cardiogenic shock	0	0%	0	0%	-
Recurrent AMI	3	18.8%	0	0%	0.145
Congestive heart failure	1	6.2%	1	10.0%	0.727
No complication	11	68.8%	9	90.0%	0.211
Total	16	100%	10	100%	

Total 1-month outcome	ECG 24 hrs post-PCI				P-value
	Resolution <50%		Resolution ≥50%		
Dead	0	0%	1	7.1%	0.345
Cardiogenic shock	0	0%	0	0%	-
Recurrent AMI	2	16.7%	1	7.1%	0.449
Congestive heart failure	1	8.3%	1	7.1%	0.910
No complication	9	75.0%	11	78.6%	0.829
Total	12	100%	14	100%	

Total 1-month outcome	ECG 48hr post-PCI				*P-value*
	Resolution <50%		Resolution ≥50 %		
Dead	0	0%	1	6.7%	0.382
Cardiogenic shock	0	0%	0	0%	-
Recurrent AMI	3	27.3%	0	0%	0.032
Congestive heart failure	1	9.1%	1	6.7%	0.819
No complication	7	63.6%	13	86.7%	0.169
Total	11	100%	15	100%	

Table 5. TIMI flow-after primary PCI

		TIMI Flow grade post-PCI				*P-value*
		2		3		
		n=7 (26.9%)		n=19 (73.1%)		
ECG 90min post-PCI	Resolution <50%	4	25.0%	12	75.0%	0.780
	Resolution ≥50 %	3	30.0%	7	70.0%	
ECG 24hr post-PCI	Resolution <50%	2	16.7%	10	83.3%	0.275
	Resolution ≥50 %	5	35.7%	9	64.3%	
ECG 48hr post-PCI	Resolution <50%	1	9.1%	10	90.9%	0.079
	Resolution ≥50 %	6	40.0%	9	60.0%	

TIMI : Thrombolysis in myocardial infarction, PPCI : Primary Percutaneous Coronary Intervention

The total outcome at 1 month after PPCI according to ST segment resolution at 90 minutes, 24 hours, and 48 hours are shown respectively in Table 4. At 90 minutes time point, there were lower percentage of deaths and recurrent AMI, and higher percentage of congestive heart failure in the complete resolution group, however all of the outcome was not statistically significant including total outcome. There were similar result at 24 hours time point which shows no statistically significant in both groups. The only statistically significant between two groups was shown at 48 hours time point. The rate of recurrent acute myocardial infarction was significant lower in the complete resolution group (p=0.049). Otherwise, there was no statistically different in total outcome between two groups.

TIMI flow has been observed after successful primary PCI. The study showed that all of the enrolled patients achieved at least TIMI flow 2 with 73.1% achieved TIMI flow 3 (Table 5 and Figure 2). In all three time points, there were higher percentage of TIMI flow 3 in non-complete ST segment resolution group with gradual increase in percentage respectively (75% vs 70%, 83% vs 64%, and 90% vs 60%) but data showed no statistical significance.

Discussions

The resulsts of this study can be summarized as follows:-

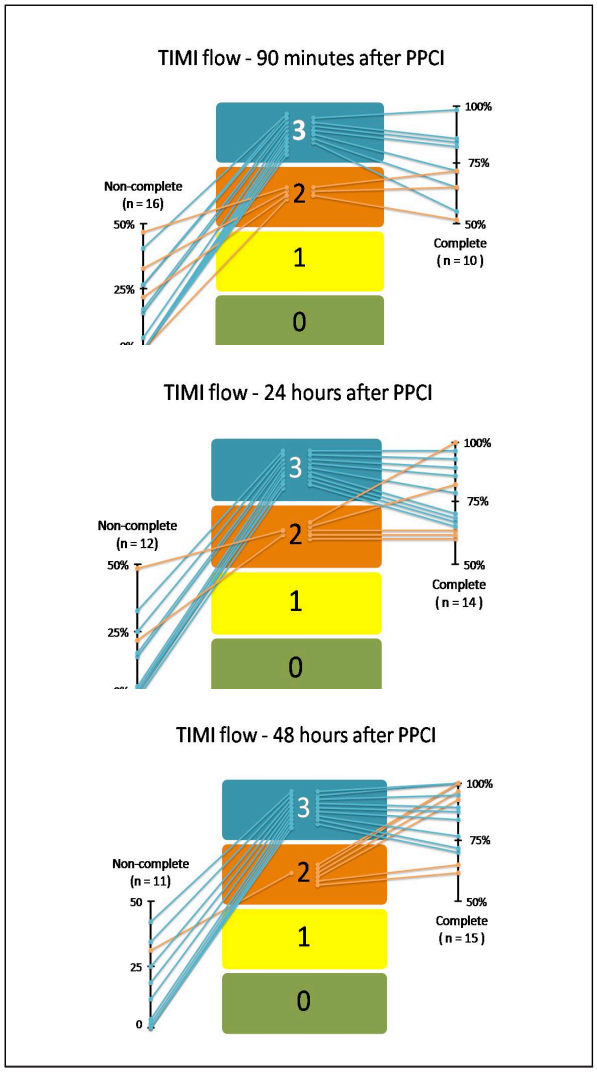
1) The degree of ST-segment resolution on standard 12-leads ECG at 90 minutes, 24 hours, and 48 hours after primary PCI did not predict short term 30-day mortality.

2) Patients with ST-segment resolution ≥50% at 48 hours had significant lower rate of recurrent acute myocardial infarction

3) TIMI flow grade after primary PCI had no association with the degree of ST-segment resolution in all time point.

Number of previous studies have demonstrated vary associations between the degree of ST-segment resolution after primary PCI and clinical outcome in different methods and durations[6]. A meta-analysis in the Assessment of Pexelizumab in Acute Myocardial Infarction (APEX-AMI) trial[7] enrolled 4,866 patients with STEMI treated with PPCI and performed 12-leads ECG at average 32 minutes after PPCI and 4.5 hours after symptoms onset. The results showed that degree of ST-segment resolution is a good predictor of 90 days mortality and composite death/CHF/shock outcome.

Figure 2. TIMI flow grade



In contrast to APEX-AMI, a report from the DANish Acute Myocardial Infarction-2 (DANAMI-2)[8] showed the opposite results. The DANAMI-2 enrolled 1,421 STEMI patients who received either fibrinolysis or PPCI and assessed the degree of ST-segment resolution at 90 minutes and 4 hours. The result showed that the degree of ST-segment resolution were associated with 30-day and 4.2-year mortality in the fibrinolytic group but not in the PPCI group. A recent study from Ndrepepa et. al[9] supported the results of DANAMI-2 study. The study enrolled 900 patients who were treated with PPCI and assessed the degree of ST-segment resolution at 90-120 minutes after PPCI. They concluded that degree of ST-segment resolution did not predict both short and long term mortality, and it had no impact on LVEF at 6 months after PPCI

The result of this study has confirmed that the degree of ST-segment resolution did not predicted the mortality rate of STEMI patients who were treated with PPCI. Timing of ECG after PPCI may be the main reason to explain the different results between APEX-AMI and other three, including this study. APEX-AMI assessed ECG at 30 minutes after PPCI while the other assessed at 90 minutes. The further study with difference in timing of ECG assessment may provide the information to support this hypothesis.

This study has some notable limitations:-

1) It is a single-center study which may not represent the entire population of Thai patients.

2) Limitation of time, small sample size and short duration of the study may not provide the significant result of the study. More sample size and long term follow up period are needed for further useful information.

3) Data collection are limited due to loss of full 12-lead ECG collections in the excluded patients.

4) Techniques of 12-lead ECG interpretation for ST-segment elevation and resolution may need to be more standardized, e.g. computerized technique, to provided more accuracy and precision of the end-result. In this study, we used the means of two cardiologists. We found that the coefficient of variation was about 23% but when corrected to 10%, the result of the analyses were not change.

In STEMI patients who were treated with PPCI, the degree of ST-segment resolution did not predict mortality rate at 1 month. Further studies are needed to assess with optimal number of patients and timing of follow up to gain more information about the association between ST-segment resolution and overall cardiac outcomes after PPCI in STEMI patients.

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