Primary Percutaneous Coronary Intervention in Acute Myocardial Infarction at Siriraj Hospital: The Improvement over Time

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Objective: *To evaluate the efficacy of the acute ST segment elevation treatment guidelines in reducing the door-to-balloon time at Siriraj Hospital.*
Material and Method: *Retrospective analysis of the data and records obtained from one hundred and twenty eight patients who underwent primary percutaneous intervention for acute ST segment elevation myocardial infarction at Siriraj Hospital between June 2002 and February 2006. Control chart analysis was applied to evaluate the efficacy of the guidelines.*
Results: *The mean door-to-balloon time was consistently reduced from 243.23 minutes before to 137.13 minutes after the guidelines implementation. Control chart analysis showed that this reduction in door-to-balloon time reached statistical significance.*
Conclusion: *The guidelines developed by a multidisciplinary approach could effectively reduce the door-to-balloon time.*

Keywords: *Acute myocardial infarction; Primary percutaneous coronary intervention; Door-to-balloon time*

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Cardiovascular death is the leading cause of death worldwide. The number of patients with acute coronary syndrome is increasing despite improvement in medical technologies[1,2]. Acute ST segment elevation myocardial infarction (AMI) plays an important part of this syndrome. Reperfusion therapy, a time-sensitive procedure, is the treatment of choice for AMI. Early reperfusion within 12 hrs is the key to success. Primary percutaneous coronary intervention (primary PCI) is one of the best treatments and has been proved superior to fibrinolytic therapy in most patients[3]. The authors began performing primary PCI in Siriraj Hospital in 2002. In general, the key performance measurement for successful treatment is door-to-balloon time less than 90 minutes[4]. Previous analysis shown that there was extensive delay in Siriraj's primary PCI process, the average first year door-to-balloon time was 264.26 minutes. Interdisciplinary discussion and clinical practice guidelines were then developed to improve the process and shorten the door-to-balloon time at Siriraj Hospital. This is a retrospective analysis of the data obtained. The objective of the present study was to evaluate the efficacy of our clinical practice guidelines to determine whether it had an impact on door-to-balloon time or not.

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Material and Method

Study population

All patients who came to the emergency department of Siriraj Hospital with chest pain and matched the following criteria were included.

1. The chest pain onset was within 12 hours
2. There were ST-segment elevations > 1 mm in two or more contiguous standard ECG 12 leads
3. Informed consent written

The exclusion criteria were

1. The patients who refused the procedure
2. The patients who had multiple comorbid diseases and were considered by the responsible staff not to be good candidates for revascularization
3. The patients who were proved to have conditions to which primary PCI was inappropriate or could not be performed, the examples were acute pulmonary embolism or acute aortic dissection
4. The patients who were referred from other hospitals
5. The patients who were admitted to the observation ward with other condition and developed acute myocardial infarction in hospital

Study process

All patients fulfilling the above criteria were treated with primary PCI at Her Majesty's Cardiac Center, Siriraj Hospital. The detailed time consuming process was analyzed. The time interval was divided into 5 variables: door-to-ECG time (time period from patients arrived emergency department to ECG recorded), ECG-to-laboratory time (time period from ECG recorded to patients arrived catheterization laboratory), laboratory-to-puncture (time period from patients arrived at catheterization laboratory to vascular assessment), puncture-to-open artery (time period from vascular assessed to TIMI 2 or 3 flow achieved) and door-to-balloon time (time period from patients who arrived at the hospital to TIMI 2 or 3 achieved). The authors collected the data about time taken at each point. If the TIMI 2 or 3 flow could not be achieved, consultation for urgency/emergency bypass surgery was done. The data from this latter group of patients was excluded from this analysis. As documented above, the average first year's door-to-balloon time was 282.45 minutes, which was far more than the ideal 90 minutes. The authors then conducted an interdisciplinary conference to discuss how to improve these variables. The first meeting was held on July 2003, 1 year after the beginning of the project. At that time the guideline for quality improvement was developed. The authors applied the guidelines to clinical practice in December 2003 and present here the results of the procedures. The present study was approved by Siriraj Ethics Committee in November 2006.

Statistical analysis

Statistical analysis was calculated with the SPSS for Windows release 12.0 and Minitab release 14 program. The variables were expressed in mean and standard deviation. The level of statistical difference for all analysis was set at p-value less than 0.05 ($p < 0.05$). Unpaired t-test was used to test for difference of door-to-balloon time before and after implementation of the treatment guidelines.

To assess change in mean and standard deviation (SD) of door-to-balloon time over the study period, patients were divided into groups of 5 according to time from Jul 2002 to Feb 2006. In each group, mean and SD of door-to-balloon time were computed and separately plotted against time interval.

The upper and lower control limits were set by convention at $\pm$ 3SD from the mean. Distribution of data points within these 3SD limits was the expected variation, which naturally occurred due to random causes inherent in the process on a regular basis. This is called 'common cause variation' in statistical process control. Special cause variation is defined by the occurrence on the control chart of the patterns listed below:

- 1 point beyond 3 SD from the average;
- 9 points in a row on the same side of the average;
- 6 points in a row, all increasing or all decreasing;
- 2 out of 3 successive values are on the same side of the centerline and more than two standard deviations from the centerline

Table 1. Time intervals from the first year primary PCI project

Time interval	Time (min)		
	Mean (SD)	Median	Min, Max
Door-to-ECG	23.74 (32.56)	10	0, 160
ECG -to-laboratory	209.80 (385.49)	77	20, 2213
Laboratory-to-puncture	14.73 (5.81)	14.5	6, 28
Puncture-to-open artery	21.44 (13.53)	19	2,74
Door-to-balloon	269.94 (389.92)	141	52, 2310

Special cause was used as indication of statistical significance.

Results

The first year primary PCI data is shown in Table 1. There were 49 patients undergoing primary PCI and reached the inclusion criteria during July 2002-June 2003, 33 males and 16 females. The patients' average age was 62.18 years (35-82). There were extensive delays in all 5 variables of interest. The mean door-to-balloon time was 282.45 minutes, which was much higher than expected. The longest time interval was the time period between patients' arrival at the emergency department and the time patients arrived at our catheterization laboratory. After several interdisciplinary discussions, the authors concluded that the two time intervals most feasible to improve were door to ECG and ECG to laboratory time.

The authors also found that 85.7% of the patients had door-to-balloon time more than 90 minutes. This group of patients had a high mortality rate when compared to the patients whose door-to-balloon time was less than 90 minutes (0% VS 13.7%)

After development of the clinical practice guidelines called "fast tract" which include clear indications to obtain the ECG by nurses, the availability of fellow in charge, the pathway to minimize the transportation time and the calling system for all responsible staff. There was a trend of improvement in both door-to-balloon time and in the percentage of patients whose door-to-balloon time was less than 90 minutes, which occurred in every year as shown in Table 2.

The authors divided the patients into two groups, those before and those after implementation of the guidelines, and compared the mean door-to-balloon time between groups. The results are shown in Table 3. The authors found that the mean door-to-balloon time decreased from 243.23 minutes before the guidelines implementation to 137.13 minutes after the guidelines implementation but the difference did not reach statistical significance ($p = 0.364$).

The authors then used process control chart analysis and the results are shown in Fig. 1. The mean door-to-balloon time was still more than 90 minutes but there was trend of improvement over time. The mean DTB time was reduced from 243.23 minutes before the guidelines implementation to 137.13 minutes after. There was persistent reduction in door-to-balloon time after the guidelines implementation. The reduction in door-to-balloon time reached statistical significance through using the control chart concept that was "9 points in a row on the same side of the average".

Table 2. The percentage of patients whose door-to-balloon time were less than 90 minutes, categorized by the year that primary PCI was performed. (DTB = door-to-balloon time as minutes)

Year	N	DTB (min)			%DTB ≤ 90 minutes
		Mean (SD)	Median	Min, Max	
2002	19	305.74 (526.36)	149	73, 2310	15.8
2003	61	223.75 (238.96)	165	57, 1346	19.7
2004	31	136.65, 59.23	128	39, 330	22.6
2005	17	138.00, 79.30	122	68, 409	23.5

Table 3. Mean door-to-balloon time in minutes before and after the implementation of guidelines. (DTB = door-to-balloon time, two-sided p-value = 0.364)

Guidelines status	N	DTB (min)			p-value
		Mean (SD)	Median	Min,Max	
Before	80	243.23 (372.85)	150	12, 2310	
After	48	137.13 (66.19)	124.5	39, 409	
Total	128	203.40 (266.72)	134	39, 2310	0.364

Discussion

Primary percutaneous coronary intervention (primary PCI) has been proved superior to fibrinolysis for treatment of acute ST elevation myocardial infarction in terms of death, recurrent ischemia or length of hospital stay. However, primary PCI needs extensive resources. Availability of cardiologist, interventional cardiologist, and catheterization laboratory personnel is a key for success. Even in the Western world the "ideal" door-to-balloon (DTB) time of 90 minutes was rarely achieved[5-7].

Siriraj Hospital began performing primary PCI in 2002. At that time, there were many obstacles. As shown in Table 1, the average DTB time in the first year was 282.45 minutes, which was unacceptable. This delayed process had grave impact on the patients. The patients whose DTB time was less than 90 minutes had a significant mortality benefit over another group. This finding was also consistently demonstrated worldwide. Time delayed could be divided into two parts, the time from beginning of symptom to patient recognition and the DTB time. The second one was the authors' target to improve. The DTB time consisted of four parts, door-to-ECG time means time period from patients arriving in the emergency department to ECG recognition. This period was dependent on nurses in charge and on the physicians at the emergency department. The ECG-to-laboratory is a time period from ECG recognition of STEMI to transfer to the catheterization laboratory. This period was dependent on the hospital management system. The cath-to-puncture time and puncture-to-open artery time were dependent on both the interventional cardiologist and the catheterization unit personnel. Therefore, the primary PCI procedure involves many personnel involved and showed that the solutions to this complicated problem must be derived from an interdisciplinary approach. Data from the Western world show that to achieve less than 90 minutes door-to-balloon time, the hospital must have an innovative protocol and supportive environment

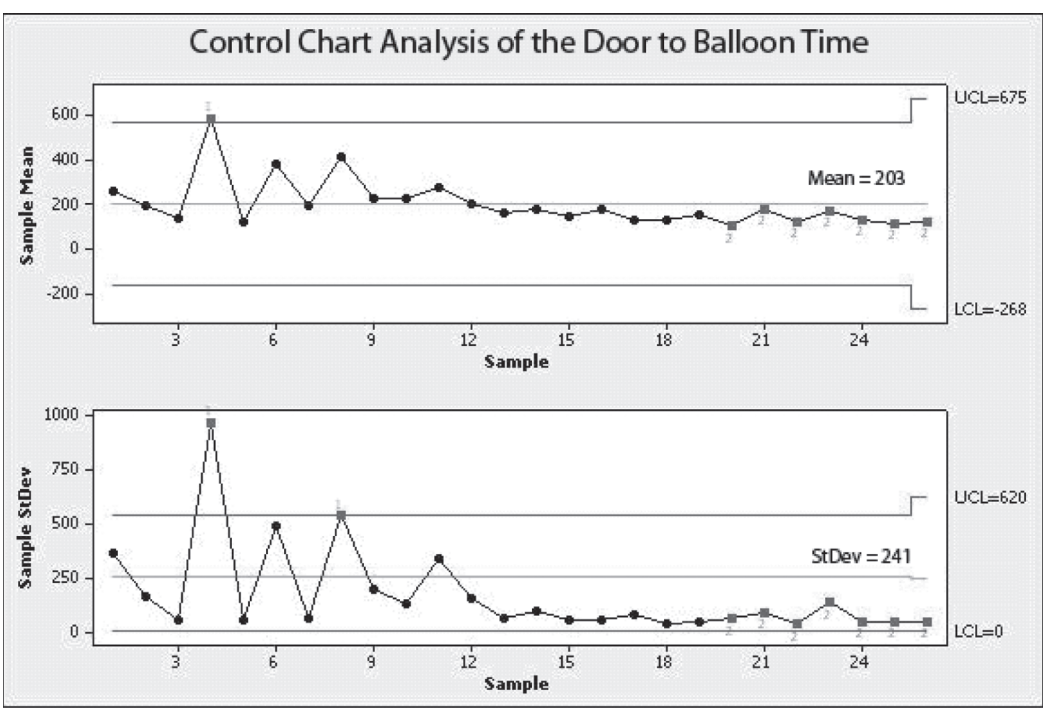

Fig. 1 Process control chart analysis of door-to-balloon time of 128 consecutive patients, the upper panel show the trend of mean door-to-balloon time, the point plotted in the graph was mean door-to-balloon time of each group of patients (5 patients in one group), the guidelines were implemented after the sixteenth group, standard deviation of door-to-balloon time was plotted in the lower panel (Mean = mean door-to-balloon time of each group of patients, StDev = standard deviation of door-to-balloon time of each group of patients, UCL = upper confidence limit, LCL = lower confidence limit)

that includes explicit goals, engaged senior management and clinical leaders, collaborative interdisciplinary teams, detailed data feedback, and a non-blaming patient-focused organizational culture[8].

After implementation of the "fast tract" guidelines, the DTB time was consistently reduced but did not reach statistical significance. The reason was the inadequate power of the study due to low patient number. In fact, Siriraj Hospital had more than 100 primary PCI cases per year but more than half of the patients were referred from other hospitals or were in hospital patients, which were excluded from this analysis.

Improvement in management process is time dependent. If there is consistent benefit after any intervention, in this case, shortening of DTB time, it means that the intervention does work. This is the concept of control chart analysis. The authors then applied the control chart analysis to the presented data. By dividing the patients into groups of five, the authors found that there were at least nine consecutive groups of patients in which DTB was below the overall means DTB. This is the significant finding shown by the control chart concept. The variation of DTB time among cases was also reduced as demonstrated by the stability of standard deviation graph in the lower panel of Fig. 1 When only the last 10 patients were analyzed, the mean DTB time was only 129.1 minutes confirmed that there was still improvement over time.

The present study had some limitations. It was a retrospective analysis and was conducted in only one center. The effective guidelines in one center might not be applicable to other centers. The variables used in this analysis were expressed as a mean, which might be, in some situations, not appropriate. This is the limitation of control chart analysis. However, the median door-to-balloon time (not shown in the present paper) was close to the mean and changed in the same way. The superior accessibility to data, which could be used to analyze the quality process, was the main reason for using the control chart concept in the present study.

In conclusion, clinical practice guidelines, which are developed by a multidisciplinary approach, could effectively reduce the door-to-balloon time. The authors are still improving toward the ideal 90 minutes door-to-balloon time.

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พัฒนาการในการรักษาโรคกล้ามเนื้อหัวใจตายเฉียบพลันด้วยวิธีการขยายหลอดเลือดหัวใจที่โรงพยาบาลศิริราช

สัชชนะ พุ่มพฤกษ์, ชุณหเกษม โชตินัยวัตรกุล, เชิดชัย นพมณีจำรัสเลิศ, อัครินทร์ นิมมานนิตย์, พิชชุดา วิรัชพินทุ, สรรเสริญ เจริญไทย

วัตถุประสงค์ : *เพื่อศึกษาประสิทธิผลของแนวทางการรักษาโรคกล้ามเนื้อหัวใจขาดเลือดเฉียบพลัน ซึ่งพัฒนาขึ้นจากความร่วมมือแบบสหสาขา ในการลดระยะเวลาตั้งแต่ผู้ป่วยมาถึงโรงพยาบาลศิริราชจนกระทั่งได้รับการรักษาด้วยวิธีขยายหลอดเลือดหัวใจด้วยบอลลูน*

วัสดุและวิธีการ : *ศึกษาย้อนหลังจากข้อมูลผู้ป่วยที่ได้รับการรักษาด้วยวิธีดังกล่าว ตั้งแต่แรกเริ่มโครงการในปี พ.ศ. 2545 โดยเปรียบเทียบระยะเวลาตั้งแต่ผู้ป่วยมาถึงโรงพยาบาลจนกระทั่งได้รับการขยายหลอดเลือดหัวใจก่อนและหลังการใช้แนวทางการรักษา การวิเคราะห์ใช้หลักการของ control chart analysis*

ผลการศึกษา : *ผู้ป่วยทั้งหมด 128 ราย ระยะเวลาดังกล่าวลดลงจาก 243.23 นาทีเป็น 137.13 นาทีหลังจากมีการใช้แนวทางการรักษาที่ชัดเจน ความเปลี่ยนแปลงนี้มีนัยสำคัญทางสถิติ*

สรุป : *แนวทางการรักษาซึ่งพัฒนาโดยความร่วมมือจากสหสาขาสามารถลดระยะเวลา และพัฒนาคุณภาพการรักษาได้อย่างมีประสิทธิภาพ*