Original Article

Three-Year Experience of Primary Percutaneous Coronary Intervention for Acute ST-Segment Elevation Myocardial Infarction in a Hospital without On-site Cardiac Surgery

Sea Hing Ong,[1] *MBBS (Malaya), MRCP (UK)*, Victor YT Lim,[2] *MB ChB (Glas), FRCP (Edin), FESC*, Boon Cheng Chang,[3] *MBBS (Aust), MRCP (UK), FAMS (Cardiol)*, Jayaram Lingamanaicker,[3] *MBBS (Madras), MRCP (UK), FACC (USA)*, Chong Hiok Tan,[3] *MBChb, MRCP (UK), FAMS (Cardiol)*, Yew Seong Goh,[3] *MBBS, MRCP (UK)*, Kok Soon Tan,[3] *MBBCh (Dublin), MRCP (UK), FRCP (Edin)*

Abstract

   Introduction: Primary percutaneous coronary intervention (PCI) for ST-segment elevation myocardial infarction (STEMI) in hospitals without on-site cardiac surgery capability, despite receiving only a class IIb recommendation in the ACC/AHA practice guidelines, can be performed effectively and safely. We reviewed the first 3 years of our experience. Materials and Methods: This is a retrospective single centre review of all patients receiving primary PCI for STEMI between 2003 and 2005. Demographic, procedural and outcome data were analysed. Results: There were 259 patients who underwent primary PCI. The mean age was 55.3 ± 12.3 years. Median door-to-balloon time was 97.5 minutes and 45.2% and 52.9% had anterior and inferior STEMI, respectively. The majority of patients presented with Killip class I (87.6%); however, 5.8% were in Killip class IV. Single vessel disease was found in 47.1%. Angiographic PCI success (defined as residual stenosis <50% with TIMI 3 flow) was achieved in 89.1%. Usage of stents, distal protection and aspiration devices were 97.2%, 27.8% and 34.1 %, respectively; 9.3% required intra-aortic balloon pump insertion. No patients required transfer for emergency coronary bypass surgery as a result of PCI complications. Post-PCI ST resolution >50% was achieved in 80.6%. The mean post-infarct left ventricular ejection fraction was 44.1%. In-hospital, 30-day, 6-month and 1-year mortality rates were 2%, 2.8%, 4.0% and 4.8%, respectively. Clinically driven target lesion revascularisation rate was 2.8% at 1 year. Conclusions: Our results are comparable to those from on-site surgical centres. This supports the feasibility and safety of primary PCI in cardiac centres without on-site cardiac surgery.

                          Ann Acad Med Singapore 2009;38:1085-9

   Key words: Emergency, PCI, STEMI, Transfer

Introduction

   Primary percutaneous coronary intervention (PCI) is now well established as the best re-perfusion strategy for ST-elevation myocardial infarction (STEMI). A meta-analysis comparing primary PCI and fibrinolytic showed a significant reduction in mortality in patients receiving primary PCI (7% vs 9% at 4 to 6 weeks). Furthermore, there is also significantly less re-ischaemia, re-infarction and stroke.[1]

   However, its availability is limited by the requirement for on-site cardiac surgery support. Primary PCI in centres without cardiac surgery had only received a Class IIb recommendation by the American College of Cardiology/ American Heart Association practice guidelines for STEMI.[2]

This is in spite of the inherent risk of transferring an acutely infarcting patient to a tertiary cardiac centre and the resultant delay in re-perfusion therapy.

   The PAMI-No SOS study showed that primary PCI in high-risk STEMI patients in hospitals without on-site cardiac surgery is safe, effective and faster than primary PCI after transfer to a surgical facility.[3] We reviewed our 3-year experience offering a primary PCI service in a hospital without on-site cardiac surgery support.

Materials and Methods

Patient Population

   This is a retrospective single-centre registry of all patients

---

[1] Department of Cardiology, Changi General Hospital, Singapore
[2] Department of Cardiology, National Heart Centre, Singapore
[3] Department of Cardiology, Changi General Hospital, Singapore
Address for Correspondence: Dr Sea Hing Ong, Department of Cardiology, Changi General Hospital, 2 Simei Street 3, Singapore 529889.
Email: seahing@gmail.com

who underwent primary PCI for STEMI in our centre between 2003 and 2005. During this period, due to the small number of available interventional cardiologists in our hospital, we were only able to perform primary PCI during weekdays up to midnight. The inclusion criteria were patients with ST-segment-elevation myocardial infarction, or new onset left bundle branch block diagnostic of an acute myocardial infarction, arriving within 12 hours of symptom onset.

Procedure

All the PCI procedures were performed by 3 experienced interventional cardiologists who collectively performed about 500 elective PCI cases per year at a tertiary hospital. A proven protocol for immediate transfer to a surgical centre was in place: an ambulance was on standby during each primary PCI procedure, and if required, can arrange the transfer of a patient to a tertiary centre within 30 minutes. Our cardiac catheterisation laboratory was fully equipped with the usual interventional equipments such as a wide range of balloons and stents, as well as adjunct devices including distal protection devices, aspiration catheters and intra-aortic balloon pumps.

Follow-up and Statistics

Clinical data were collected from a review of patient case notes and databanks from the cardiac catheterisation laboratory. Follow-up data up to 1-year post PCI were retrieved from the case notes. For patients who were lost to follow-up, phone interviews were carried out to establish the major cardiac adverse events at 30 days, 6 months and 1 year. All statistical analyses were completed using the statistical package SPSS (version 12.0, SPSS, Chicago).

Results

Baseline Characteristics

A total of 259 patients underwent activation for primary PCI in our centre between 2003 and 2005. During this same period, another 427 patients underwent thrombolysis after presenting with STEMI during hours where primary PCI was unavailable. The baseline characteristics are outlined in Table 1. The mean age of the patients was 55.3 ± 12.3 years. The racial distribution of these patients was 53.7% Chinese, 27.4% Malays, 15.1% Indians, 1.2% Caucasians and 2.7% of other races. This was consistent with the racial distribution of the general population in Singapore. The majority of the patients had either inferior (52.9%) or anterior (45.2%) territory myocardial infarctions. Most of the patients in our cohort were in Killip Class I on presentation (87.6%) with only 5.8% presenting with cardiogenic shock (Killip Class IV).

Angiographic data are summarised in Table 2. The most

Table 1. Baseline Clinical Characteristics (n = 259)

Variable	Values (%)
Mean age ± SD (y)	55.3 ± 12.3
Gender (male)	88.0
Hypertension	37.5
Diabetes	30.5
Hyperlipidaemia	69.9
Smoking history (current/previous)	52.1
Previous MI	6.6
Previous PCI	9.3
Previous CABG	0.0
Anterior MI	45.2
Inferior MI	52.9
Lateral MI	1.9
Killip Class I	87.6
Killip Class II	5.4
Killip Class III	1.2
Killip Class IV	5.8

CABG: coronary artery bypass grafting; MI: myocardial infarction; PCI: percutaneous coronary intervention; SD: standard deviation

common infarct-related coronary artery was the left anterior descending artery (45.3%) followed closely by the right coronary artery (44.5%). A small number of patients had the left coronary artery main stem as the infarct-related artery (0.4%).

Procedural Results

The most common coronary occlusion requiring primary PCI were de novo occlusions accounting for 93.1% of the procedures. Primary PCI were also performed for rescue PCI (0.4%) and stent thrombosis (1.2%). PCI was not done in 10 patients (3%). Of these, 2 patients had normal coronaries, 4 patients required coronary artery bypass grafting (CABG) and 4 patients had TIMI 3 flow of the infarct-related artery requiring early PCI instead of primary PCI.

We deployed intra-coronary stents in 97.2% of the patients; all of these were bare metal stents. Two patients who had stent thrombosis only underwent balloon angioplasty. Guardwire distal protection device (Medtronic) and aspiration catheters were used in 27.8% and 34.1% of patients, respectively. Only 9.3% of patients required intra-aortic balloon pump insertion; the main indications were cardiogenic shock and left main stem or severe triple vessel disease requiring urgent CABG. The usage of glycoprotein IIb IIIa receptor antibodies was 20.5%, all of which were eptifibatide. In our hospital, the use of this drug is predominantly for rescue purpose hence the low usage. Most of our interventionalists preferred the distal protection or aspiration devices, which

Table 2. Angiographic Data

Variable	Values (%)
IRA - LAD	45.2
IRA - LCX	8.9
IRA - RCA	44.8
IRA - Left main stem	0.4
Single vessel disease	47.1
Double vessel disease	33.2
Triple vessel disease	19.7
Initial TIMI flow grade 3	0 ± 0.9
Final TIMI flow grade 3	3 ± 0.4
Initial percent stenosis	100 ± 6.3
Final percent stenosis	0 ± 10.8

IRA: infarct-related artery; LAD: left anterior descending artery;
LCX: left circumflex artery; RCA: right coronary artery;
TIMI: thrombolysis in myocardial infarction
Data are presented as the number (%) of patients or the median value ± SD

Table 3. Procedural Results and Performance Measures

Variable	Values
Median door-to-balloon time ± SD (min)	98.0 ± 53.9
Angiographic PCI success (%)	89.6
ST resolution >50% 1 hour post PCI (%)	80.6
Mean post-MI LVEF ± SD (%)	44.1 ± 11.1
Median length of stay ± SD (d)	5.0 ± 3.9
Transfer for early CABG (%)	2.7
Median PCI duration ± SD (min)	40.0 ± 21.6

CABG: coronary artery bypass grafting; LVEF: left ventricular ejection
fraction; MI: myocardial infarction; PCI: percutaneous coronary
intervention; SD: standard deviation

are often effective in removing or reducing the thrombus burden in the infarct artery. All patients received pre-treatment with a 300 mg loading dose of clopidogrel in addition to aspirin. Although this was the dose given at that time, our current practice is to load with 600 mg of clopidogrel.

The median door-to-balloon inflation time is currently the only recommended performance measure by the ACC/AHA[4] specifically for primary PCI. It has been established that the duration from symptom onset to re-perfusion is directly related to mortality outcomes.[5,6] We achieved a median door-to-balloon time of 98 ± 53.9 minutes, the recommended goal by the ACC/AHA being 90 minutes. The median PCI procedure duration was 40 ± 21.6 minutes (Table 3).

Angiographic PCI success was defined as post-PCI residual luminal stenosis of <50% with TIMI 3 flow in the infarct-related artery. With this definition, 89.6% of our patients had angiographic PCI success. Although the current definition of reperfusion uses resolution of ST-segment elevation by >70%, at the point of this data collection, a resolution of >50% was acceptable. Of our patients, 80.6% achieved ST resolution of >50% 1 hour post-primary PCI. Univariate analysis of our cohort revealed that this was associated with a lower in-hospital mortality rate (0.5% vs 11.1%; $P = 0.001$).

Of note, none of the patients required emergency transfer for CABG as a direct result of complications from the primary PCI procedure. However, 6 (2.7%) patients required in-patient transfer to a cardiac surgery centre for early CABG due to left coronary artery main stem or severe triple vessel disease. These included 2 patients who required initial primary PCI to restore flow to the infarct-related artery before full re-vascularisation. One had stenting of an occluded left main stem artery in view of haemodynamic instability and the other received balloon angioplasty to the right coronary artery that was the infarct-related artery.

Clinical Outcomes and Follow-up

Outcome data were analysed for the 249 patients who received primary PCI after activation. The in-hospital and 30-day mortality rates were low at 2.0% and 2.8%, respectively (Table 4). At 1 year, the mortality rate remained low at 4.8%. The in-hospital stroke rate was 1.2%. Clinically driven target lesion revascularisation (TLR) for in-stent re-stenosis at 1 year was 2.8%, despite only bare metal stents being used. All of these patients underwent further PCI as the re-vascularisation strategy. The re-infarction rate at 1 year was 1.2%.

Univariate analysis showed that Killip class IV carried an in-hospital mortality rate of 21.4% compared with 0.9% in patients with Killip class I ($P <0.001$). This relationship was maintained at 30 days, 6 months and 1 year.

Discussion

This review of our experience demonstrated that a hospital without on-site cardiac surgery, and with a team of experienced interventional cardiologists, could provide primary PCI service for STEMI patients safely and effectively. We achieved a low rate of in-hospital major cardiac adverse event (4.4%) and mortality (2.0%). These low outcome numbers were sustained 1 year after the index myocardial infarction. Our mortality data is not only comparable to that of other centres without on-site cardiac surgery (2.7% to 11.3%),[7-14] but also with the outcomes of large, high volume surgical centres as reported in the literature. Although only 5.8% of our patients presented with cardiogenic shock, the in-hospital mortality for this group of patients was relatively low at 21.4%. Other non-cardiac

Table 4. Major Adverse Cardiac Events (MACE) in Patients who underwent PCI

	All cause mortality (%)	Target lesion revascularisation (%)	Re-infarction (%)	Disabling stroke (%)
In-hospital	2.0	1.2	–	1.2
30 days	2.8	1.2	0.4	–
6 months	4.0	2.4	0.8	–
1 year	4.8	2.8	1.2	–

PCI: percutaneous coronary intervention
All data at 30 days, 6 months and 1 year are presented as accumulative rates.

surgery centres have reported mortality rates ranging from 25% to 32% in this sub-group of patients with cardiogenic shock.[8,14] Our high rates of angiographically successful PCI (89.6%) and preservation of cardiac function post-PCI (mean post PCI LVEF of 44.1%) strongly suggest that primary PCI in this setting can be very effective.

Our median door-to-balloon time of 98 minutes was close to, but did not meet the 90 minute target set by the ACC/AHA.[4] This was attributed to a systems learning curve as these were the initial years of our primary PCI programme. In fact, a survey by Bradley et al[15] of 365 hospitals in the US providing primary PCI service showed that only 35.1% of hospitals met the median door-to-balloon target of 90 minutes; 47.8% had timings between 91 to 120 minutes. We have since put in place a primary PCI protocol streamlining the door-to-balloon process in 2007. This has successfully reduced the monthly median door-to-balloon time to between 70 and 90 minutes despite extending the service to 24 hours a day, 7 days a week since September 2006.

In Singapore, a regular primary PCI service for STEMI patients had previously been only offered at tertiary hospitals with on-site cardiac surgery departments. This is also true in many other countries. This is generally regarded as standard and accepted practice, propagated from the early days of PCI when there was a fairly high risk of acute vessel closure after balloon angioplasty that sometimes necessitated emergent coronary bypass surgery; hence, the need for on-site cardiac surgeons. Furthermore, the numbers of trained interventional cardiologists were not high and they were usually employed in tertiary centres.

However, interventional cardiology techniques, equipment and pharmacology had advanced significantly since then. PCI can now be performed at low risk and it is rare that we would require a cardiac surgeon to bail us out of a PCI-related complication. It is our belief that primary PCI for STEMI can be routinely offered even at a smaller hospital without on-site cardiac surgery, and the recent literature have added support to this. Carlsson et al[16] compared the outcome of PCI between centres with on-site and without on-site back up from the Swedish Coronary Angiography and Angioplasty Registry (SCAAR). They found that there was no significant difference in the 30-day mortality of patients receiving PCI for acute STEMI in centres with on-site and without on-site surgical back up (6.7% vs 7.0%, respectively). A similar registry in the US, the National Cardiovascular Data Registry (NCDR) compared 9029 patients who had PCIs performed in 61 centres without on-site cardiac surgery and 299,132 patients at 404 centres with on-site cardiac surgery.[17] It revealed that PCI in both off-site and on-site centres had similar rates of procedural success, emergency surgery, morbidity and risk-adjusted mortality. Although these registries were not randomised studies, they come closest to evidence that on-site surgical back up may not ultimately influence patient outcome.

The re-perfusion options for a patient with acute STEMI presenting to a hospital without on-site cardiac surgery are fibrinolytic therapy, transfer to a cardiac surgery centre or on-site PCI. It is well established that transfer for primary PCI is superior to on-site fibrinolytics.[18-20] In fact, the DANAMI-2 trial was prematurely terminated because of the clear benefit of transfer for PCI over on-site fibrinolytic. The composite endpoint of death, re-infarction and stroke was decreased by 41% ($P = 0.0003$) in the transfer group.[20] However, the evidence so far has also shown that primary PCI in centres without on-site cardiac surgery is as safe and efficacious as primary PCI in on-site centres.[3-11] In addition, the advantage of not transferring patients is the faster time to re-perfusion. In our centre, if patients were to be transferred to the nearest surgical centre, an average transfer time of 40 minutes would be expected, gauging from previous experience. This would certainly delay the door to re-perfusion time and may affect patient outcome. Hence, it appears that the preferred re-perfusion strategy for acute STEMI in a non-surgical but PCI-capable centre should be on-site PCI compared to fibrinolysis or transfer to a surgical centre for primary PCI because of the benefit of a shorter door to re-perfusion time despite similar outcomes.

Limitations

This is a retrospective observational study. In addition, the procedures were mostly done during weekdays up until midnight. Hence, there may have been an unintended bias with regard to patient selection. However, as of September

2006, with a larger pool of available interventional cardiologists, we have started to provide a 24-hour primary PCI service. This has also increased our yearly primary PCI numbers to 159 cases in 2006 and 286 cases in 2007. This may in turn translate to better procedural outcome due to increased volume.

Conclusions

Despite being a centre without cardiac surgery back up, we have shown that we can provide primary PCI in a timely, efficient and safe manner with good short-term and medium-term outcomes comparable to surgical centres. In addition, we gain the benefit of avoiding the inherent risks and delays in transferring high-risk patients. Nevertheless, we must make every effort to meet rigorous standards, having experienced interventionalists, a well equipped catheterisation laboratory, efficient coronary care unit staff, proven transfer protocols to a cardiac surgery centre and strict selection criteria for PCI.

REFERENCES

1. Keeley EC, Boura JA, Grines CL. Primary angioplasty versus intravenous thrombolytic therapy for acute myocardial infarction : a quantitative review of 23 randomised trials. Lancet 2003;361:13-20.

2. Antman EM, Anbe DT, Armstrong PW, Bates ER, Green LA, Hand MM, et al. ACC/AHA guidelines for the management of patients with ST-segment elevation myocardial infarction-executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation 2004;110:588-636.

3. Wharton TP Jr, Grines LL, Turco MA, Johnston JD, Souther J, Lew DC, et al. Primary angioplasty in acute myocardial infarction at hospitals with no surgery on-site (the PAMI-No SOS Study) versus transfer to surgical centers for primary angioplasty. J Am Coll Cardiol 2004;43:1943-50.

4. Krumholz HM, Anderson JL, Brooks NH, Fesmire FM, Lambrew CT, Landrum MB, et al. ACC/AHA Clinical Performance measure for adults with ST-elevation and Non-ST-elevation myocardial infarction (A report of the American College of Cardiology/American Heart Association task force on performance measures (writing committee to develop performance measures on ST-elevation and non-ST-elevation myocardial infarction). J Am Coll Cardiol 2006;47:236-65.

5. ZWOLLE myocardial infarction study group. Symptom onset to balloon time and mortality in patients with acute myocardial infarction treated by primary angioplasty. J Am Coll Cardiol 2003;42:991-7.

6. McNamara RL, Wang Y, Herrin J, Curtis JP, Bradley EH, Magid DJ, et al. Effect of door-to-balloon time on mortality in patients with ST-segment elevation myocardial infarction. J Am Coll Cardiol 2006;47:2180-6.

7. Weaver WD, Litwin PE, Martin JS. Use of direct angioplasty for treatment of patients with acute myocardial infarction in hospitals with and without on-site cardiac surgery. Circulation 1993;88:2067-75.

8. Ribichini F, Steffenino G, Dellavalle A. Primary angioplasty without surgical back-up at all: results of a five years experience in a community hospital in Europe. J Am Coll Cardiol 2000;35:364A.

9. Politi A, Zerboni S, Galli M, Mameli S, Botto GL, Lombardi R, et al. Primary angioplasty in acute myocardial infarction: experience and results in the first 1,000 consecutive patients. Ital Heart J Suppl 2003;4:755-63.

10. Aversano T. Primary angioplasty at hospitals without cardiac surgery: C-PORT Registry outcomes. Circulation 2003;108 (suppl IV): IV-613.

11. Sanborn TA, Jacobs AK, Frederick PD, Every NR, French WJ. National Registry of Myocardial Infarction 3 and 4 Investigators. Comparability of the quality-of-care indicators for emergency coronary angioplasty in patients with acute myocardial infarction regardless of on-site cardiac surgery (report from the National Registry of Myocardial Infarction). Am J Cardiol 2004;93:1335-9.

12. Kutcher MA, Klein LW, Wharton TP, Applegate RJ, Brindis RG, Shaw RE, et al. Clinical outcomes in coronary angioplasty centers with off-site versus on-site cardiac surgery capabilities: a preliminary report from the American College of Cardiology-National cardiovascular Data registry. J Am Coll Cardiol 2004;43:96a.

13. Wennberg DE, Lucas FL, Siewers AE, Kellet MA, Malenka DJ. Outcomes of percutaneous coronary interventions performed at centers without and with onsite coronary artery bypass graft surgery. JAMA 2004;292:1961-8.

14. Wharton TP, McNamara NS, Fedele FA, Jacobs MI, Gladstone AR, Funk EJ. Primary angioplasty for the treatment of acute myocardial infarction: experience at two community hospitals without cardiac surgery. J Am Coll Cardiol 1999;33:1257-65.

15. Bradley EH, Herrin J, Wang YF, Barton BA, Webster TR, Mattera JA, et al. Strategies for reducing the door-to-balloon time in acute myocardial infarction. N Engl J Med 2006;355:2308-20.

16. Carlsson J, James SN, Stahle E, Hofer S, Lagerqvist B. Outcome of percutaneous coronary intervention in hospitals with and without on-site cardiac surgery standby. Heart 2007;93:335-8.

17. Findings from the National Cardiovascular Data Registry (NCDR) presented at the American College of Cardiology 2008 Scientific Session, 2 April 2008. http://www.theheart.org/article/850757.do. *Accessed date?*

18. Grines CL, Westerhausen DR, Grines LL, Hanlon JT, Logemann TL, Niemela M, et al. A randomized trial of transfer for primary angioplasty vs on-site thrombolysis in patients with high-risk myocardial infarction. J Am Coll Cardiol 2002;39:1713-9.

19. Widimsky P, Budesinsky T, Vorac D, Groch L, Zelizko M, Aschermann M, et al. Long distance transport for primary angioplasty vs immediate thrombolysis in acute myocardial infarction. Final results of the randomized national multicenter trial – PRAGUE-2. Eur Heart J 2003;24:94-104.

20. Anderson HR, Nielson TT, Rasmussen K, Thuesen L, Kelbaek H, Thayssen P, et al. DANAMI-2 Investigators. A comparison of coronary angioplasty with fibrinolytic therapy in acute myocardial infarction. N Engl J Med 2003;349:733-42.