Transradial percutaneous coronary intervention in acute ST elevation myocardial infarction and high-risk patients: experience in a single centre without cardiothoracic surgical backup

Chow J, Tan C H, Ong S H, Goh Y S, Gan H W, Tan V H, Chai S C

ABSTRACT

Introduction: Primary transradial percutaneous coronary intervention (TRI) is shown to be efficacious in stable patients with acute coronary syndrome. We aimed to evaluate the application of primary TRI for acute ST elevation myocardial infarction (STEMI), including among high-risk patients from our registry.

Methods: This was a single-centre case series comprising 138 patients who underwent primary TRI for STEMI between May 2007 and June 2008. TRI was attempted with a 6-Fr guiding catheter in all patients regardless of Killip class status. Outcome measures were success rates of primary TRI, door-to-balloon time, procedure duration and volume of contrast used. All patients were followed up for major adverse cardiac events in-hospital, at 30 days and six months.

Results: A total of 138 patients had primary TRI attempted for STEMI. Four patients failed primary TRI and required a femoral approach. The remaining 134 patients underwent primary TRI. The mean patient age was 56.4 years. Most patients with acute STEMI presented in Killip class I and II (91.8 percent). Only 8.2 percent were in Killip class III or IV on admission. 50 percent of patients presented with anterior STEMI. The median door-to-balloon time for this group was 92 (interquartile range [IQR] 77–121) minutes, with a median procedure time of 39 (IQR 29–51) minutes. The success rate of primary TRI was 97.1 percent.

Conclusion: Success rate, procedural and radiation time for TRI are comparable to those achieved via the femoral approach. Primary TRI is therefore a feasible and effective approach for acute STEMI, even in high-risk patients.

Keywords: acute ST elevation myocardial infarction, feasible approach, high-risk patients, Ikari left catheter, primary transradial percutaneous coronary intervention

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INTRODUCTION

Radial coronary angiography has been performed in numerous centres in both Asia and Europe with increasing operator preference.[1,2] This is partly due to the lower complication rates as well as the feasibility of same-day discharge post procedure for the majority of patients.[3,4] In Changi General Hospital (CGH), Singapore, we have adopted the radial approach for coronary angiography in about 90% of our in- and outpatients since 2005, with an average of 1,300 coronary angiography procedures performed each year.

Percutaneous coronary intervention (PCI) has been considered the optimal strategy to recanalise culprit coronary arteries in acute ST elevation myocardial infarction (STEMI), and this has been endorsed by major international guidelines, stating PCI as a Class I indication for STEMI. Since the introduction of transradial percutaneous coronary intervention (TRI) by Kiemeneij and Laarman,[5] TRI for symptomatic coronary artery disease has become more favourable and feasible over the last ten years, and numerous operators have started reporting their success rates, even in STEMI.[6-8] Although there is a significant learning curve for radial intervention, this approach had been shown to be associated with a lower incidence of vascular access site complications, thus allowing an earlier mobilisation of patients, with reduced hospital stay and hospitalisation costs.[9] Therefore, most authors agree that in the hands

Department of Cardiology, Changi General Hospital, 2 Simei Street 3, Singapore 529889

Chow J, MBBS, MMed, MRCP
Associate Consultant

Tan CH, MBChB, MRCP
Senior Consultant

Ong SH, MBBS, MRCP
Associate Consultant

Goh YS, MBBS, MMed, MRCP
Associate Consultant

Gan HW, MBBS, MRCP
Associate Consultant

Tan VH, MBBS, MRCP
Registrar

Chai SC, MBBS, MRCP
Registrar

Correspondence to:
Dr Tan Chong Hiok
Tel: (65) 6850 3562
Fax: (65) 6260 9173
Email: chong_hiok_tan@cgh.com.sg

of experienced operators, its impact on perfusion time is insignificant compared to the benefits derived from reduced vascular and bleeding complications[10,11] that can significantly affect both morbidity and mortality outcomes.[12-14]

In our institution, we have been performing TRI for STEMI since April 2007. To date, we have performed TRI in more than 300 STEMI patients. In this study, we sought to examine the feasibility of TRI in all STEMI patients as well as the patient success rate.

METHOD

This is a single-centre, real-world registry of consecutive patients who presented with acute STEMI within 12 hours of symptoms between May 2007 and June 2008. The diagnosis of STEMI was made in the presence of a typical chest pain lasting for more than 30 minutes, resistance to nitrates and ST segment elevation > 1 mm in two or more contiguous electrocardiogram leads. All acute PCIs during office hours were performed by a single radial interventionist, as our centre had only one full-time interventionist during the study period. After office hours, acute PCIs for STEMI were performed by either our radial interventionist or visiting consultants who may not be comfortable with TRI. Hence, the approach for after-office-hour cases would be dependent on the interventionist on call.

A total of 257 patients presented with STEMI for acute PCI during the study period, of which 138 patients had TRI and 116 had PCI performed via the femoral approach. The rest underwent rescue PCI after failed thrombolysis. 138 patients who underwent attempted primary TRI for STEMI were included in this study, but only 134 of these attempts were successful. TRI was performed in patients regardless of their Killip class status, and no patients were excluded as a result of a negative Allen's test. The only exclusion criterion for TRI was a history of previous coronary artery bypass grafting (CABG). In our study, we defined a low-risk group as patients who presented with STEMI in Killip class I or II and a high-risk group as those whose STEMI was in Killip class III or IV. In the analyses of door-to-perfusion time, PCI duration, radiation duration and the total volume of contrast used, patients were excluded from the analysis if they presented within one hour of another preceding STEMI patient and if the acute PCI was already in progress. This was due to logistic limitations, as our institution had only one cardiac catheterisation laboratory.

All patients received standard dual anti-platelet therapy with a loading dose of aspirin 300 mg and clopidogrel 600 mg prior to PCI, while glycoprotein IIb/IIa inhibitors were used at the discretion of the attending interventionist. Before PCI, patients were pre-treated with an intravenous bolus of unfractionated heparin at 100 IU/kg. All patients were subsequently placed on CGH's Joint Commission International (JCI) accredited acute myocardial infarction (AMI) pathway and observed in a coronary care unit for at least 24 hours. An intra-aortic balloon counter pulsation pump (IABP) was inserted via the femoral approach either peri or post PCI, if indicated.

Upon discharge, the patients were given aspirin 100 mg plus clopidogrel 75 mg daily for up to two months if bare metal stents were deployed, and up to one year for drug-eluting stents. This is in accordance with the ACC/AHA/ESC guidelines. Beta-blockers, angiotensin-converting enzyme inhibitors and lipid-lowering drugs, if well tolerated and not contraindicated, were also routinely administered to all patients in accordance to our pathway.

Radial artery cannulation was performed with the right arm positioned beside the patient's body and the wrist hyperextended. Local anaesthesia with 3 ml of 2% lingocaine was administered before the radial artery was punctured with a 21G needle provided in the Cordis Transradial Kit (Cordis Corporation, Miami, FL, USA), and a 0.021" straight tip mini guidewire was inserted through the needle. Upon removal of the cannula, an 11-cm 6 Fr sheath was placed over the guidewire. To reduce radial artery spasm and thrombosis, an intra-arterial drug cocktail containing verapamil 2.5 mg and heparin 2,000 U was delivered through the sheath. Diagnostic angiography was performed using 5 Fr catheters and PCI, using 6 Fr guiding catheters. The radial sheath was removed after the completion of TRI in the cardiac lab. Local haemostasis was obtained by radial compression, followed by the application of Stepty-P (Nichiban Company, Tokyo, Japan). This plaster, originally developed for haemostasis after arterial blood sampling from the radial artery, is composed of an elastic tape and a pile made of sponge, and is prepared as a pre-sterilised set. It was removed 2–3 hours after application.

The outcome measures included success rate of primary TRI, door-to-balloon time, procedure duration and volume of contrast used. Comparisons were also made between the low-risk and high-risk TRI subgroups. All patients were followed up for major adverse cardiac events (MACE) in-hospital, at 30 days and at six months, over a period of 6–12 months. MACE was defined as death, recurrent myocardial infarction and repeat target lesion revascularisation (TLR) or target vascular revascularisation.

Clinical, angiographic and procedural data were

Table I. Baseline demographics and lesion characteristics of patients who underwent TRI (n = 134).

Baseline demographic	No. (%)
Mean age ± SD (yrs)	56.4 ± 11.7
Male	119 (88.8)
Race	
Chinese	70 (52.2)
Malay	45 (33.6)
Indian	15 (11.2)
Others	4 (2.9)
Risk factor	
Diabetes mellitus	42 (31.3)
Dyslipidaemia	58 (43.3)
Hypertension	64 (47.8)
Smoking	90 (67.2)
Previous MI	15 (11.2)
Previous PCI	13 (9.7)
CAD extent	
SVD	48 (35.8)
DVD	53 (39.6)
TVD	28 (20.9)
Any LM	5 (3.7)
STEMI site	
Anterior	67 (50)
Non-anterior	67 (50)
Killip class	
I	98 (73.1)
II	25 (18.7)
III	2 (1.5)
IV	9 (6.7)

TRI: transradial percutaneous coronary intervention; SD: standard deviation; MI; myocardial infarction; PCI: percutaneous coronary intervention; CAD: coronary artery disease; SVD: single-vessel disease; DVD: double-vessel disease; TVD: triple-vessel disease; STEMI: ST elevation myocardial infarction; LM: left main disease

Table II. Results of coronary angioplasty in our patients (n = 134).

PCI detail	No. (%)	
	Pre-TRI	Post TRI
TIMI flow		
TIMI 0	82 (61.2)	1 (0.7)
TIMI 1	23 (17.2)	1 (0.7)
TIMI 2	13 (9.7)	6 (4.5)
TIMI 3	16 (11.9)	126 (94)

PCI: percutaneous coronary intervention; TRI: transradial percutaneous coronary intervention

retrospectively entered into a computerised database. Absolute numbers and percentages were computed to describe the patient population, including the patient demographic characteristics, medical history and cardiac presentation. TRI procedure timings, including door-to-perfusion time, procedural and fluoroscopy duration and volume of contrast used, were compared between the high-risk and low-risk groups by using unpaired Student's *t*-test or Mann-Whitney U test for continuous variables. All statistical analyses were carried out using the Statistical Package for the Social Sciences version 12 (SPSS Inc, Chicago, IL, USA). A statistically significant value was set as $p < 0.05$ for all analyses.

RESULTS

A total of 257 consecutive patients presented with STEMI during the study period and underwent acute PCI. Primary TRI was attempted in 138 (55%) STEMI patients, and there were four failed attempts. The baseline demographics and risk profiles of the patients are summarised in Table I. The mean age of the patients was 56.4 ± 11.7 years, with a Chinese male predominance. 13 (9.7%) patients had a history of prior PCI. The majority of TRI patients (75.4%) had either single- or double-vessel disease, with 50% of them presenting with anterior STEMI. TRI was performed in 11 (8.2%) patients who were deemed to be in the high-risk group, as defined by Killip class III or IV on presentation.

Only four (2.9%) patients in the TRI group had a failed procedure via the radial approach. Three of these patients had failed radial artery cannulation, of which two were in Killip class I and one was in Killip class III. One patient underwent a successful radial artery cannulation, but the percutaneous transluminal coronary angioplasty (PTCA) wire failed to advance across an anomalous right coronary artery due to poor guider support. The overall success rate was 97.1%. Four patients were referred for early CABG after initial balloon angioplasty to restore blood flow, as they had severe triple vessel disease with left main involvement. No patient was referred for emergency CABG as a result of complications arising from PCI. None of the patients in our registry had any major vascular complications, defined as major bleeding requiring blood transfusion and/or surgical treatment for haematoma, after primary TRI.

77.5% of the patients in the TRI group used only a single Ikari left 6 Fr guider for both diagnostic coronary angiography and PCI, regardless of the STEMI site. The remaining patients underwent diagnostic angiography with a multipurpose Tiger 5 Fr catheter before selection of the appropriate guider. Stents were deployed in 119 (88.8%) patients, with the majority (96.6%) being bare metal stents. Direct stenting was performed only in 19 (14.2%) patients with no thrombus load, while aspiration devices were used in 31 (23.1%) patients with a high thrombus load. The choice of direct stenting or utilisation of aspiration devices was left to the discretion of the interventionist. In our institution, if the thrombus load was deemed by the interventionist to be low after successfully crossing the lesion with the PTCA wire, aspiration devices were usually not used.

IABPs were utilised in six out of the 11 high-risk

Table III. Procedural description for TRI among our patients (n = 134).

PCI details	No. (%)
Stents deployed	119 (88.8)
Bare metal stents	115 (85.8)
Drug eluting stents	4 (3)
Mean no. of stents ± SD	1.16 ± 0.66
Mean stent diameter ± SD (mm)	2.91 ± 0.94
Mean stent length ± SD (mm)	25.28 ± 14.93
Direct stenting	19 (14.2)
Aspiration	31 (23.1)
Inpatient transfer for CABG	4 (3)
Mean length of stay ± SD (days)	4.49 ± 4.89
Mean LVEF post PCI ± SD	46.1 ± 8.98

TRI: transradial percutaneous coronary intervention; PCI: percutaneous coronary intervention; SD: standard deviation; CABG: coronary artery bypass grafting; LVEF: left ventricle ejection fraction

Table IV. Measured outcomes for TRI among our patients (n = 119).

Outcome	TRI
Median door-to-perfusion time; IQR (min)	92; 77–121
Median procedure duration; IQR (min)	39; 29–51
Median fluoroscopy duration; IQR (min)	12; 8.4–17.7
Median volume of contrast; IQR (ml)	130; 110–170

IQR is 25th to 75th percentile.
TRI: transradial percutaneous coronary intervention; IQR: interquartile range

patients during TRI. IABP insertion was performed via the right femoral approach if the patient was in cardiogenic shock, and this procedure could be done concurrently with radial puncture. 82 patients in the TRI group presented with TIMI 0 flow and 94% had post PCI TIMI 3 flow. An average of 1.16 ± 0.66 stents was used in TRI with a mean stent length of 25.28 ± 14.93 mm and a mean stent diameter of 2.91 ± 0.94 mm. Details of the TRI are summarised in Tables II and III.

A total of 119 TRI patients' door-to-perfusion time, procedure duration, radiation duration and volume of contrast used were available for analysis. Currently, our institution has only one cardiac catheterisation laboratory; hence, if a second patient presents with STEMI while another patient is already undergoing PCI, the door-to-perfusion time of the second patient is not analysed. The median door-to-perfusion time for TRI was 92 (interquartile range [IQR] 77–121) minutes. The median procedure duration for TRI was 39 (IQR 29–51) minutes, while fluoroscopy duration was 12 (IQR 8.4–17.7) minutes. The median volume of non-ionic contrast used was 130 (IQR 110–170) ml (Table IV). Between the low-risk and high-risk subgroups, the median door-to-balloon time was comparable (90 vs. 110.5 minutes, p = 0.163). There was, however, a shorter median procedural duration and smaller volume of contrast used for the low-risk group, and this was statistically significant (Table V).

The mean duration of hospitalisation was 4.49 ± 4.89 days in post-TRI patients, as they were all placed on our JCI accredited AMI pathway, which stipulated discharge by Day 5 of AMI if there were no complications. Left ventricle ejection fraction (LVEF) assessment was performed for 129 TRI patients on Day 3 or 4 of STEMI. The mean LVEF was 46.1% ± 8.98% regardless of infarct-related artery. Details of the MACE in post-TRI patients are summarised in Table VI. 123 (91.8%) TRI patients were discharged with no MACE and 116 (89.9%) were still event-free after 30 days. Cardiac deaths occurred in five (3.6%) inpatients and an additional three patients died within 30 days of TRI. Two patients in the TRI group had a re-PCI during the index admission. At six months, the incidence of TLR-PCI was small and insignificant.

A total of 21 patients were lost to follow-up at the end of the study. These were mainly foreign patients who had STEMI while in transit at Singapore Changi International Airport. After the first review at our cardiology clinic, these patients requested to return to their own country for further follow-up. All patients were discharged with dual anti-platelet therapy with beta blockers and statins if there were no compelling contraindications. 96.3% of patients were on both aspirin and clopidogrel, 81.3% were on beta blockers and 95.5% on statins upon discharge. Only 62.7% of patients were taking either ACE-I or angiotensin receptor blockers, and this was often limited by low blood pressure.

DISCUSSION

Currently, our registry data has the largest series of TRI in Singapore. From our experience, TRI is a feasible and effective approach for acute STEMI patients. There is a learning curve for TRI that is similar to diagnostic radial angiography.[2,14] The main challenges are cannulation of the radial artery and manipulation of the catheter. However, the greatest benefit of the approach is the early commencement of ambulation.[15] Other additional benefits include minimal patient discomfort and the reduction of extra manpower during femoral sheath removal in the intensive care unit. Yan et al also echoed this benefit, especially in the elderly population where the effects of bleeding and prolonged immobility led to significant mobility and mortality even after successful PCI.[16]

Our institution's femoral PCI data was published by Ong et al in 2009.[17] Our TRI door-to-perfusion time

Table V. Comparison of door-to-perfusion time, procedure duration and contrast volume according to Killip class.

Outcome	Killip class		p-value
	I/II (n = 109)*	III/IV (n = 10)†	
Median door-to-perfusion time; IQR (min)	90; 77–121.5	110.5; 97.8–139.8	0.163
Median procedure duration; IQR (min)	38; 29–46.5	66; 56–73	< 0.0001
Median fluoroscopy duration; IQR (min)	11.9; 8.2–17.4	16.3; 11.5–22.7	0.095
Median volume of contrast; IQR (ml)	130; 110–160	180; 161.3–202.5	0.05
IABP post TRI	1	6	< 0.0001

IQR is 25th–75th percentile.
* Low-risk group † High-risk group
IABP: intra-aortic balloon counter pulsation pump; TRI: transradial percutaneous coronary intervention

and procedural duration are comparable to those of the conventional femoral approach. Similar results have also been reproduced by many studies that compared TRI with conventional femoral PCI for STEMI.[18-21] Although we did not directly compare the two cohorts in this study, as this was intended to be a descriptive paper looking at the feasibility of TRI in STEMI, our results show that these time intervals were not unduly prolonged compared to the femoral approach. This finding was echoed by Kim at el, who also found that the PCI duration for TRI was not compromised in the setting of acute STEMI in experienced centres.[6] Further evaluation is warranted to determine whether this could potentially translate to shorter door-to-perfusion time. In many centres in Singapore, including CGH, patients present directly to the emergency department instead of a cardiac unit, unlike in Europe; hence, significant confounders exist in the interpretation of door-to-perfusion time.

Many authors tend to exclude high-risk patients, defined as Killip class III or IV STEMI, in their TRI analysis.[22,23] These patients are generally hypotensive, and thus, cannulation of the weak radial pulse may be a challenge. We have, however, included these high-risk patients in our report; from our experience, only one patient had a failed radial artery cannulation from this group. Ranjan et al reported that the incidence of radial artery spasm was more common in Indian female patients;[24] however, interestingly, in our registry, the two patients who had failed radial artery cannulation were both Chinese males. In other case series, patients with a negative Allen's test were excluded. Ours is the only series where patients were not excluded on this basis. None of these patients had failed radial artery cannulation. Furthermore, none developed any vascular complications after the procedure, although it was not a routine practice to check for absent radial pulse post PCI. Therefore, Allen's test may not be a necessity prior to TRI.

In our study, although not statistically significant, there was a trend toward longer door-to-perfusion time for the high-risk group. However, as expected, there was a slight increase in the median procedural duration and volume of contrast used among these patients, as they may require IABP insertion, resuscitation and emergency intubation for acute pulmonary oedema. Nonetheless, our data did suggest that TRI is also feasible in high-risk patients (Killip class III or IV). In conventional femoral PCI, patients in Killip class IV may require IABP support. This is usually inserted in the left groin before PCI, as the PCI is done via the right groin, which may delay door-to-perfusion time and lengthen the total procedure time. In contrast, in the TRI approach, although an additional femoral puncture may still be required, this could be done on the right groin concurrently by the second operator while the interventionist is cannulating the radial artery, thereby minimising the total PCI duration.

Table VI. Major adverse cardiac events (MACE) among radial patients (n = 134).

MACE	No. of patients
In-hospital	134
Death	5
Re-PCI	2
CABG	4
CVA	0
None	123
30-day follow-up	129
Death	3
TLR-PCI	1
Lost to follow-up	9
None	116
6-month follow-up	120
Death	0
Re-MI	1
TLR-PCI	2
TVR-PCI	1
Lost to follow-up	21
None	95

PCI: percutaneous coronary intervention; CABG: coronary artery bypass grafting; CVA: cerebrovascular accident; TLR: target lesion revascularisation; TVR: target vessel revascularisation; MI: myocardial infaction

As this was a purely descriptive study, some inherent limitations exist. Firstly, our study was a retrospective analysis of data from a registry for TRI, and thus, the results may not be applicable to the real world. Prospective data collection for TRI vs. femoral PCI for STEMI has already started since August 2007; randomised trial of TRI vs. TFI would better reflect the wider applicability of this technique. Currently, our institution has only one cardiac catheterisation laboratory, and logistic limitation thus restricts the inclusion of all patients for analysis. This was especially so for the door-to-perfusion time, as consecutive patients who presented within an hour of the preceding STEMI patient were excluded. During the study period, we had only one full time interventionist at our institution who performed all the PCI for STEMI during office hours. This provided ample workload and experience to perfect the technique of TRI. However, in centres with a lower workload per interventionist, the reluctance to adopt TRI for STEMI can be appreciated, and our results may not be as applicable across centres. Finally, the authors acknowledged the significant number of patients who were lost to follow-up at the end of the study period; 21 out of 134 patients were foreigners in transit at the airport. The majority of these patients were well at the 30-day review at the clinic, and their subsequent care was transferred to their primary physicians in their own countries.

In conclusion, although there is a steep initial learning curve for TRI, in experienced hands, it can be performed as proficiently as the transfemoral approach. In STEMI, TRI can be the routine choice, even in high-risk patients, without prolonging the door-to-perfusion time.

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