Transferring patients for primary angioplasty in eastern Melbourne (the SHIPEM registry): are we meeting the guidelines?

Michael J Moore, Louise Roberts, Houng-Bang Liew, Esther M Briganti and Gishel New

rimary percutaneous coronary intervention (PCI) is the preferred strategy for reperfusion in patients with ST-elevation myocardial infarction (STEMI).^{1,2} The use of PCI for STEMI has been widely embraced in Australia. Over 23 randomised controlled trials have provided Level I, class A evidence that PCI is superior to fibrinolysis for management of STEMI, and time to reperfusion is directly related to mortality.^{1,2}

Current American and European guidelines recommend a "door-to-balloon" time (see below) of ≤ 90 minutes for patients with STEMI.^{3,4} For patients presenting to a non-PCI-capable unit, the European guidelines also recommend PCI if it can be performed within 120 minutes of first medical contact.⁴

Unlike American and European guidelines, the Cardiac Society of Australia and New Zealand/National Heart Foundation of Australia (CSANZ/NHFA) guidelines for management of patients with STEMI⁵ are centred around "symptom-to-door" time (see below) based on evidence from two multicentre randomised trials.^{6,7} The CSANZ/NHFA guidelines recommend PCI over fibrinolysis,

Abbreviations

ВНН Box Hill Hospital CABG Coronary artery bypass graft CSANZ Cardiac Society of Australia and New Zealand DANAMI- Danish Multicenter Randomized Study of Fibrinolysis versus Primary Angioplasty in Acute Myocardial Infarction-2 **FCG** Electrocardiogram Major adverse cardiac event **MACE** Myocardial infarction **NHFA** National Heart Foundation of Australia PCI Percutaneous coronary intervention SHIPEM Shipping Infarcts for Primary Angioplasty in Eastern Melbourne **STEMI** ST-elevation myocardial

Target vessel revascularisation

ABSTRACT

Objectives: To compare clinical outcomes between patients with ST-elevation myocardial infarction (STEMI) presenting to a hospital with facilities for primary percutaneous coronary intervention (PCI) and patients transferred from a non-PCI-capable unit, and to determine the success rate of meeting clinical guidelines for management of STEMI.

Design, setting and participants: Prospective study of patients with STEMI who underwent PCI at Box Hill Hospital (BHH), Melbourne, between 1 July 2002 and 30 June 2008. We compared two patient groups: "BHH patients", who were admitted directly to BHH (a hospital with PCI capability), and "SHIPEM (Shipping Infarcts for Primary Angioplasty in Eastern Melbourne Registry) patients", who were transferred from other hospitals without PCI capability.

Main outcome measures: Clinical outcomes; symptom-to-first-door time (time between symptom onset and arrival at first hospital); first-door-to-balloon time (time between arrival at the first hospital and inflation of the angioplasty balloon); compliance with Cardiac Society of Australia and New Zealand/National Heart Foundation of Australia (CSANZ/NHFA) guidelines for management of patients with STEMI.

Results: There were 598 patients in the BHH group and 189 in the SHIPEM group. The median first-door-to-balloon time was 89 minutes (interquartile range [IQR], 69–107 minutes) for BHH patients and 128 minutes (IQR, 104–157 minutes) for SHIPEM patients. These figures did not vary significantly over the 6 years of the registry. In the BHH group, 180 patients (30.1%) had a symptom-to-first-door time of \leq 60 minutes, with 32 (17.8%) receiving PCI in \leq 60 minutes. The corresponding figure for the SHIPEM group was 48 patients (25.4%), with 1 (2.1%) receiving PCI within 60 minutes. In the BHH group, 304 patients (50.8%) had a symptom-to-first-door time of 61–180 minutes, with 166 (54.6%) receiving PCI in \leq 90 minutes. In the SHIPEM group, 50 patients (26.5%) had a symptom-to-first-door time of > 180 minutes, with 21 (42.0%) receiving PCI in \leq 120 minutes.

Conclusion: Our study demonstrates that transfer for PCI is feasible and safe in selected patients, with outcomes comparable to those of patients presenting to a PCI-capable unit. However, the CSANZ/NHFA targets, predicated by symptom-to-first-door time, are not being met and have not improved over time, which suggests that strategies to improve symptom-to-first-door, first-door-to-balloon and transfer times need to be addressed.

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if (i) the time from symptom onset to presentation is ≤ 60 minutes and PCI is available in ≤ 60 minutes; or (ii) the time from symptom onset to presentation is >60 minutes and PCI is available in ≤90 minutes. For patients with STEMI presenting to a non-PCI-capable hospital, the guidelines recommend a firstdoor-to-balloon time of ≤120 minutes (including transfer time), if the time from symptom onset to presentation is between 3 and 12 hours.⁵ The DANAMI-2 (Danish Multicenter Randomized Study of Fibrinolysis versus Primary Angioplasty in Acute Myocardial Infarction-2) trial showed that 30-day clinical outcomes were superior for patients transferred to a PCI site from a peripheral

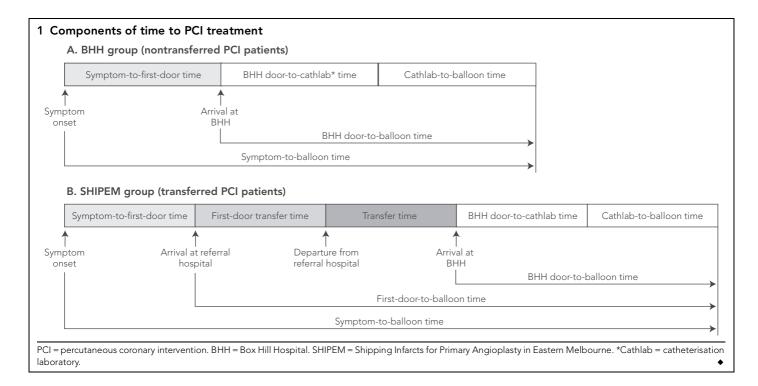
hospital compared with patients who received onsite fibrinolysis, despite the time delay to reperfusion (median door-to-balloon time, 118 minutes). The feasibility and outcomes for such transfer programs have not been formally tested in Australia. We report our 6-year experience of onsite PCI and transfer for PCI. Our aim was to determine whether the current CSANZ/NHFA guidelines could be met effectively in a real hospital situation.

METHODS

Setting

The Eastern Health network in Melbourne, Victoria, serves a population of about

TVR



880 000 people. It includes three acute hospitals, one of which is Box Hill Hospital (BHH). In July 2002, PCI was introduced as the reperfusion therapy of choice at BHH on a 24-hour basis. A formal referral service was established within our network. However, transfer was not mandated for all patients with STEMI, as there remained clinical equipoise as to the superiority of transferring patients for PCI versus administering onsite fibrinolysis treatment. We also accepted referrals for PCI from rural hospitals and other metropolitan Melbourne hospitals within a reasonable distance of BHH. The two main suburban referring hospitals were Maroondah and Angliss hospitals (15 km and 27 km from BHH, respectively).

Definitions

The following definitions were used:

- Symptom-to-first-door time. The time from symptom onset to arrival at the first hospital (Box 1).
- First-door-to-balloon time. The time from arrival at the first hospital to inflation of the angioplasty balloon.
- Symptom-to-balloon time. The time from symptom onset to inflation of angioplasty balloon.
- Procedural success. Less than 30% residual stenosis, with no procedural complications (death, recurrent myocardial infarction [MI] or emergency coronary artery bypass graft [CABG] surgery).

- Major adverse cardiac event (MACE). The composite of mortality, recurrent MI and target vessel revascularisation (TVR).
- Recurrent myocardial infarction. The recurrence of chest pain for ≥ 30 minutes, with new ST elevation, or a rise in creatine phosphokinase (to three or more times the upper limit of normal or to at least 50% higher than the pre-PCI level).
- Target vessel revascularisation. PCI or CABG involving the target vessel.

Other procedural complications included haemorrhage (defined according to TIMI [thrombolysis in myocardial infarction] criteria), 10 stroke, CABG, cardiogenic shock and groin complications.

Patients re-presenting with another STEMI (involving the index lesion or a different lesion or vessel) ≤ 30 days or ≤ 12 months after the initial PCI were recorded as having a 30-day or 12-month MACE. However, a second PCI procedure in the same patient was excluded from the analysis. Likewise, patients re-presenting with another STEMI ≥ 12 months after the initial PCI were excluded from the analysis.

Transfer protocol

The decision to transfer patients with STEMI was at the discretion of the referring hospital. Clinical details and electrocardiogram (ECG) results were communicated by telephone and facsimile to the on-call cardiology registrar at BHH. Although priority was

requested for transfers, availability of ambulances and waiting times varied. On arrival at BHH, patients were transferred directly to the catheterisation laboratory, by-passing the emergency department. Outside office hours, the on-call team was activated during transfer.

Procedural protocol

Following coronary angiography, PCI was performed. If the patient was unsuitable for PCI, they were referred for CABG or treated medically. All patients received a loading dose of aspirin and clopidogrel before or during PCI. Use of glycoprotein IIb/IIIa inhibitors or a thrombus aspiration device was at the discretion of the interventional cardiologist. Drug-eluting stents were used in patients at high risk of restenosis according to Victorian Department of Human Services criteria. Duration of clopidogrel treatment was at the discretion of the cardiologist.

Ethics approval

Ethics approval for our study was obtained from the Eastern Health Research and Ethics Committee. Informed consent was obtained from all patients.

Data collection and analysis

Data were prospectively collected for all consecutive patients between 1 July 2002

2 Baseline characteristics			
	BHH $(n = 598)$	SHIPEM (n = 189)*	Р
Male	467 (78.1%)	139 (73.5%)	0.20
Mean age in years (SD)	64 (14)	61 (14)	0.01
Age > 80 years	70 (11.7%)	20 (10.6%)	0.67
Current smoker	166 (27.8%)	64 (33.9%)	0.11
Diabetes mellitus	93 (15.6%)	23 (12.2%)	0.25
Hypertension	286 (47.8%)	80 (42.3%)	0.19
Hypercholesterolaemia	261 (43.6%)	64 (33.9%)	0.02
Previous MI	95 (15.9%)	29 (15.3%)	0.89
Family history of coronary artery disease	161 (26.9%)	60 (31.7%)	0.20
Previous PCI	81 (13.5%)	21 (11.1%)	0.39
Previous CABG	17 (2.8%)	4 (2.1%)	0.59
Cardiogenic shock	26 (4.3%)	10 (5.3%)	0.59
Out-of-hospital VF arrest	6 (1.0%)	4 (2.1%)	0.23
Anterior MI	238 (39.1%)	79 (41.8%)	0.63

BHH = Box Hill Hospital. SHIPEM = Shipping Infarcts for Primary Angioplasty in Eastern Melbourne.

MI = myocardial infarction. PCI = percutaneous coronary intervention. CABG = coronary artery bypass graft.

VF = ventricular fibrillation. *Patients transferred to BHH.

and 30 June 2008 and entered into a database (Cardiobase, version 6, Magnus Medical Software, Greensborough, Vic, Australia). Rescue PCI (following failed fibrinolysis) (n=33) and facilitated PCI (planned, immediate PCI following pharmacotherapy) (n=7) cases were excluded from this analysis. Demographics, clinical presentation, symptom-to-door and door-to-balloon times, procedural details and clinical outcomes were recorded. Follow-up at 30 days and 12 months was performed by telephone and review of patient records.

Statistical analysis

All analyses were conducted using Stata software, version 9 (StataCorp, College Station, Tex, USA). We compared the clinical outcomes of patients presenting to BHH, a PCI-capable unit (the "BHH patients"), with those of patients transferred from non-PCI-capable units (the "SHIPEM [Shipping Infarcts for Primary Angioplasty in Eastern Melbourne] patients"). Variables were reported as mean (SD), median (interquartile range) or as number (percentage). Differences between groups were tested by two-tailed unpaired t-test or Kruskal–Wallis rank test for continuous data, and χ^2 test for categorical data.

The primary endpoints were mortality, recurrent MI, TVR and MACE at 30 days and at 12 months. Associations between groups and the primary endpoints, adjusted for age and cardiovascular risk factors, were

determined by odds ratios (95% confidence intervals) using logistic regression. Cardio-vascular risk factors included in the adjusted model were age, sex, diabetes, hypertension, hypercholesterolaemia and current smoking. All Pvalues were two-sided, and a P value of ≤ 0.05 was considered statistically significant.

RESULTS

Patient population and treatment

Of the 838 patients with STEMI who proceeded to emergency coronary angiography, 13 (1.6%) were patients re-presenting with a second STEMI during the study period. They included one with acute stent thrombosis, two with subacute stent thrombosis, four with late stent thrombosis, two with STEMIs involving a different lesion from the index artery and two with STEMIs involving the non-index artery. These 13 events were therefore excluded from being counted as index procedures, but were counted as MACEs.

Of the remaining 825 patients, 620 (75.2%) presented to BHH and 205 (24.8%) were transferred from a non-PCI-capable unit

Of the 620 BHH patients, 598 (96.5%) proceeded to PCI. Eight patients not suitable for PCI (1.3%) were referred for CABG, and 14 (2.3%) were managed medically. Of the 205 SHIPEM patients, 189 (92.2%) pro-

ceeded to PCI, seven (3.4%) patients were referred for CABG and nine (4.4%) were managed medically. Of the 598 BHH patients who proceeded to PCI, 542 (90.6%) were successfully followed up at 12 months and 176 of the 189 SHIPEM patients who proceeded to PCI (93.1%) had a 12-month follow-up. Outcomes were known for all these patients except one from BHH who was lost to follow-up after the 30-day contact.

Patient demographics and clinical status

The BHH patients were significantly older than the SHIPEM patients and had a higher prevalence of hypercholesterolaemia (Box 2). There was no difference in procedural details between the groups (Box 3), and no patients required "bail-out" CABG for a procedural complication.

Time from symptoms to treatment

Fewer than a third of patients in either group presented within 60 minutes of symptom onset: 180 of 598 BHH patients (30.1%), and 48 of 189 SHIPEM patients (25.4%) (P=0.214). The majority of patients presented within 3 hours: 484 of 598 (80.9%) BHH patients and 139 of 189 SHIPEM patients (73.5%) (P = 0.029). Patients in the SHIPEM group had significantly longer median symptom-to-first-door, first-door-toballoon and symptom-to-balloon times than the BHH patients (Box 4). Median first-doorto-balloon times did not change significantly over the 6-year study period (data not shown). The median transfer time for the SHIPEM group was 36 minutes (interquartile range 25-48 minutes).

A small minority of patients in the shortest symptom-to-door time category (≤60 minutes) received PCI within the 60-minute time interval recommended by the CSANZ/ NHFA guidelines. Thirty-two of 180 BHH patients (17.8%) and one of 48 SHIPEM patients (2.1%) received PCI within 60 minutes. Of patients with a symptom-to-door time of 61-180 minutes, 166 of 304 BHH patients (54.6%), and 12 of 91 SHIPEM patients (13.2%) received PCI within 90 minutes. Of the patients with a symptom-todoor time of > 180 minutes, 57 of 114 BHH patients (50.0%) received PCI within 90 minutes, and 21 of 50 SHIPEM patients (42.0%) received PCI within 120 minutes.

In the BHH group, 52.1% of patients achieved a door-to-balloon time of ≤ 90 minutes. Only 13.9% of the SHIPEM group achieved a first-door-to-balloon time of

3 Procedural details			
	BHH (n = 598)	SHIPEM (n = 189)*	P
Procedural success	577 (96.5%)	186 (98.4%)	0.18
LAD coronary artery infarct	243 (40.6%)	79 (41.8%)	0.63
Mean LVEF (SD)	56% (13%)	54% (13%)	0.16
LVEF ≤ 35%	27 (4.5%)	15 (7.9%)	0.12
Vein graft intervention	9 (1.5%)	3 (1.6%)	0.94
Stent thrombosis	8 (1.3%)	2 (1.1%)	0.77
TIMI flow grade before PCI			
Grade 0	451 (75.4%)	129 (68.3%)	_
Grade 1	29 (4.8%)	9 (4.8%)	_
Grade 2	53 (8.9%)	27 (14.3%)	_
Grade 3	65 (10.9%)	24 (12.7%)	0.13
TIMI flow grade after PCI			
Grade 0	21 (3.5%)	1 (0.5%)	_
Grade 1	6 (1.0%)	2 (1.1%)	_
Grade 2	29 (4.8%)	12 (6.3%)	_
Grade 3	542 (90.6%)	174 (92.1%)	0.16
Drug-eluting stent	241 (40.3%)	70 (37%)	0.42
GP IIb/IIIa inhibitor usage	473 (79.1%)	149 (78.8%)	0.94
Aspiration device	7 (1.2%)	2 (1.1%)	0.90
Distal protection device	4 (0.7%)	3 (1.6%)	0.24
Intra-aortic balloon pump	62 (10.4%)	12 (6.3%)	0.10

BHH = Box Hill Hospital. SHIPEM = Shipping Infarcts for Primary Angioplasty in Eastern Melbourne.

PCI = percutaneous coronary intervention. LAD = left anterior descending. LVEF = left ventricular ejection fraction. TIMI = thrombolysis in myocardial infarction. GP = glycoprotein. * Patients transferred to BHH.

4 Time to treatment			
	Median time in minutes (interquartile range)		
	BHH (n = 598)	SHIPEM (n = 189)*	P
Symptom-to-first-door time	85 (55–150)	100 (60–192)	0.02
First-door-to-balloon time	89 (69–107)	128 (104–157)	< 0.01
Symptom-to-balloon time	179 (143–251)	253 (190–343)	< 0.01

 \leq 90 minutes. In the SHIPEM group, 43.3% achieved a first-door-to-balloon time of \leq 120 minutes.

Clinical outcomes

* Patients transferred to BHH.

There was no significant difference in 30-day mortality, recurrent MI, TVR or MACE between the BHH and SHIPEM groups. There were also no differences in bleeding, stroke or groin complications. There was no significant difference in 12-month mortality, MI, TVR or MACE for BHH and SHIPEM patients. Six patients died of non-cardiac causes within 12 months in the BHH group and none in the SHIPEM group (Box 5).

Effect of transfer on clinical outcomes

No significant difference was found in 30-day and 12-month outcomes (death, recurrent MI, TVR and MACE) between BHH and SHIPEM patients, when adjusted for age and cardiovascular risk factors (Box 6).

DISCUSSION

Our 6-year registry with 12-month followup of PCI in both onsite and transferred patients demonstrates that transfer for PCI is safe and feasible for selected patients, and produces outcomes comparable with those of patients who receive onsite PCI, despite longer door-to-balloon times. These SHI-PEM study results may reflect a selection bias towards better outcomes, which may offset the negative effect of longer door-to-balloon times. Our findings are comparable with those of other large randomised controlled trials.¹

Timely access to PCI for patients presenting to hospitals without PCI facilities remains a challenge in real hospital settings. The DANAMI-2 study demonstrated that, in a coordinated trial with a 30-day combined end point of death, re-infarction and stroke for patients transferred for PCI, with a median door-to-balloon time of 118 minutes, PCI was superior to onsite fibrinolysis.8 Our SHIPEM patient treatment times were comparable to those in the DANAMI-2 trial, with a median first-door-to-balloon time of 128 minutes, despite not having the same dedicated transfer process. A meta-analysis of five randomised controlled trials also reported that transfer for PCI achieved a 42% reduction in death, re-infarction and stroke when compared with onsite fibrinolysis. 12

Major trials have shown a correlation between door-to-balloon times and 30-day outcomes following PCI.1 The American and European guidelines specify a maximum door-to-balloon time of 90 minutes for onsite PCI,3,4 but the CSANZ/NHFA guidelines stratify their recommendations on symptom-to-door times.⁵ Our results demonstrate that the proportion of patients presenting early is low, and that in a real hospital situation, the CSANZ/NHFA guidelines may not be attainable. The guidelines also only include recommendations for door-to-balloon times for transferred patients with symptom-to-door times of 3-12 hours.⁵

The American College of Cardiology Door-to-Balloon Alliance suggests that centres aim for ≥75% of patients achieving a door-to-balloon time of ≤90 minutes, but does not address the issue of transfer. 13 In the BHH group in our study, 52.1% of patients achieved a door-to-balloon time of ≤ 90 minutes. This compares with US registry data demonstrating that 40% of nontransferred and 5% of transferred STEMI patients achieve a door-to-balloon time of ≤ 90 minutes. ¹⁴⁻¹⁶ The median transfer time for SHIPEM patients was 36 minutes, and the DANAMI-2 trial demonstrated that PCI was the preferred reperfusion strategy, provided transfer times were ≤ 120 minutes.8 Only 13.9% of the SHIPEM group achieved a first-door-to-balloon time of ≤90 min-

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5 Clinical outcomes at 30-day and 12-month follow-up			
Outcomes	внн	SHIPEM*	P
30 days	n = 598	n = 189	
Death	30 (5.0%)	11 (5.8%)	0.66
Recurrent MI	9 (1.5%)	2 (1.1%)	0.65
TVR	6 (1.0%)	2 (1.1%)	0.95
MACE	39 (6.5%)	13 (6.9%)	0.73
MACE excluding shock	27 (4.5%)	7 (3.7%)	0.63
12 months	n = 542	n = 176	
Death	37 (6.8%)	14 (8.0%)	0.61
MI	11 (2.0%)	2 (1.1%)	0.44
TVR	10 (1.8%)	3 (1.7%)	0.90
MACE	48 (8.9%)	17 (9.7%)	0.75

BHH = Box Hill Hospital. SHIPEM = Shipping Infarcts for Primary Angioplasty in Eastern Melbourne. MI = myocardial infarction. TVR = target vessel revascularisation. MACE = major adverse cardiac event. * Patients transferred to BHH.

Odds	ratio ((95%	CI)

	Odds Fatio (73 % CI)	
Outcomes	Age-adjusted	CV risk factor-adjusted [†]
30 days		
Death	1.26 (0.61–2.57)	1.17 (0.57–2.42)
Recurrent MI	0.72 (0.15–3.37)	0.66 (0.14–3.12)
TVR	1.09 (0.22–5.49)	1.04 (0.20-5.32)
MACE	1.19 (0.62–2.30)	1.09 (0.56–2.14)
MACE excluding shock	0.83 (0.36–1.95)	0.74 (0.31–1.75)
12 months		
Death	1.31 (0.69–2.51)	1.21 (0.63–2.34)
Myocardial infarction	0.62 (0.14–2.86)	0.60 (0.13–2.81)
TVR	0.65 (0.08–5.64)	0.62 (0.07–5.43)
MACE	1.12 (0.61–2.04)	1.05 (0.57–1.93)

CV = cardiovascular. MI = myocardial infarction. TVR = target vessel revascularisation. MACE = major adverse cardiac event. * SHIPEM (Shipping Infarcts for Primary Angioplasty in Eastern Melbourne) group compared with Box Hill Hospital group. † CV risk factors included: age (per year); sex (male, female); diabetes (yes, no); hypertension (yes, no); hypertension (yes, no); hypercholesterolaemia (yes, no); and current smoking (yes, no).

utes. European guidelines recommend that transferred patients receive PCI in \leq 120 minutes, ⁴ and 43.3% of the SHIPEM patients achieved a first-door-to-balloon time of \leq 120 minutes.

Reasons for delay in transfer of SHIPEM patients included assessment and referral for transfer from the non-PCI-capable hospital, waiting for the ambulance to arrive and travel time. These delays are somewhat offset by the shorter door-to-balloon times at the PCI centre for SHIPEM patients, who bypass the emergency department. Delays are also offset by activating the catheterisa-

tion laboratory team during transfer. Possible strategies to improve door-to-balloon time include a government policy and funding for the ambulance service, ambulance field triage, and "live-in" 24-hour catheterisation laboratory teams. ¹³ Reducing symptom-to-door time also requires increased public awareness and education.

These factors may explain why there was no improvement over time in door-to-balloon times for either the BHH or the SHI-PEM group, despite publication of the CSANZ/NHFA guidelines.⁵ Ambulance field triage (with prehospital ECG) and by-pass-

ing non-PCI-capable centres are strategies currently being implemented in metropolitan Melbourne. These strategies are based on two pilot studies in New South Wales¹⁷ and Victoria. It would not be feasible to establish PCI facilities in all hospitals, because of resource, financial and geographical constraints. There will always remain a need for fibrinolysis in rural and remote areas in Australia. A recent trial has shown the benefits of a strategy of fibrinolysis followed by early (≤ 6 hours) transfer for PCI. 19

There were several limitations to our study. Firstly, it was based on registry data, and secondly, SHIPEM patients were transferred for PCI at the discretion of the referring hospital, which may have led to selection bias. Patients with a good prognosis based on factors such as Killip class, heart rate, blood pressure, renal function, or small inferior MI, may have not been selected for transfer. In addition, elderly patients and those in cardiogenic shock or with comorbidities may have been transferred less frequently. This could potentially have biased the results to better outcomes in the SHIPEM group. However, the results do suggest that the current selection process is at least judicious.

CONCLUSION

Our study represents a local experience, illustrating the feasibility and safety of transferring patients from non-PCI-capable hospitals to a larger centre with PCI facilities. Although our clinical outcomes were acceptable, there remains significant room for improvement in door-to-balloon time and symptom-to-door time. Strategies to improve these require ongoing research, government-driven policy, public health awareness and a geographically tailored approach.²⁰

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COMPETING INTERESTS

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