Original Article

A comparison of rescue and primary percutaneous coronary interventions for acute ST elevation myocardial infarction

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ABSTRACT

Objective: To perform a comparative analysis of in-hospital results obtained from patients with acute ST elevation myocardial infarction (STEMI), who underwent rescue or primary percutaneous coronary intervention (PCI). The aim is to determine rescue PCI as a practical option for patients with no immediate access to primary PCI.

Methods: From the Cardiology PCI Clinic of the National Hospital of Sri Lanka (NHSL), we selected all consecutive patients presenting with acute STEMI < 24 h door-to-balloon delay for primary PCI and < 72 h door-to-balloon delay, (90 min after failed thrombolysis) for rescue PCI, from March 2013 to April 2015 and their in-hospital results were analyzed, comparing rescue and primary PCI patients.

Results: We evaluated 159 patients; 78 underwent rescue PCI and 81 underwent primary PCI. The culprit left anterior descending (LAD) vessel (76.9% vs. 58.8%; P = 0.015) was more prevalent in rescue than in primary patients. Thrombus aspiration was less frequent in rescue group (19.2% vs. 40.7%; p = 0.004). The degree of moderate-to-severe left ventricular dysfunction reflected by the ejection fraction < 40% (24.3% vs. 23.7%; P = 0.927) and prevalence of multivessel disease (41.0% vs. 43.8%; P = 0.729) revealed no significant difference. Coronary stents were implanted at similar rates in both strategies (96.2% vs. 92.6%; P = 0.331). Procedural success (97.4% vs. 97.5%; P = 0.980) and mortality rates (5.1% vs. 3.8%; P = 0.674), were similar in the rescue and primary groups.

Conclusion: In-hospital major adverse cardiac events (MACE) are similar in both rescue and primary intervention groups, supporting the former as a practical option for patients with no immediate access to PCI facilities.

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1. Introduction

Percutaneous coronary intervention (PCI) and fibrinolytic therapy are two efficient methods used to advocate restoration of myocardial circulation in patients with acute myocardial infarction (AMI). However, in patients undergoing fibrinolytic treatment, the restoration of normal epicardial flow of thrombolysis in myocardial infarction (TIMI) grade 3 is not achieved in a significant number of cases. This promotes rescue PCI strategy, early after failure of fibrinolytic treatment, as a viable treatment option.

Class IA evidence has established that primary PCI is apparently the preferred therapy for acute ST-elevation myocardial infarction (STEMI). In order for PCI to be of maximal benefit to the patient, however, the procedure must be performed within an ideal time interval at a well-equipped facility with skilled staff, that provides 24/7 service; this kind of environment is not readily accessible under different circumstances for all STEMI patients. Furthermore, there is a difference in prevalence of using primary PCI, between countries as well as areas within the same country.

In Sri Lanka, difficulties to reach centers that offer primary PCI in a timely manner makes rescue PCI a crucial therapeutic option for patients who fail reperfusion. The clinical impact and the
selection of the precise strategy is still controversial, however it still yields non inferiority when compared with those of a primary procedure. 5-9

Therefore, depending on available facilities for early PCI, both primary and rescue PCI strategies are proving to be effective for coronary reperfusion. 10 The objective of this study was to perform a comparative analysis of the outcomes of rescue and primary PCI performed at the Cardiology Unit-5, NHSL over a period of 2 years (March 2013–April 2015).

2. Methods

This was a cross-sectional study conducted at Cardiology Unit-5, National Hospital of Sri Lanka (NHSL). Consecutive patients presenting with an acute ST elevation myocardial infarction (STEMI) who underwent primary or rescue PCI with either balloon or coronary stent implantation, performed by a single unit invasive cardiologist members, within the study period from March 2013 to April 2015, were recruited at the time of the procedures. Those who received prior thrombolysis at the first contact point for the current event underwent rescue PCI due to failed thrombolysis while those who did not receive prior thrombolysis at the first contact point underwent primary PCI. Successful or failed thrombolysis is diagnosed based on an ECG done 90 min after administration of thrombolytics. Failed thrombolysis is defined when there is <50% ST segment resolution in a single lead showing maximum ST elevation in the baseline ECG,11-13 persistent ongoing chest pain or cardiogenic shock (i.e. patients who required inotropic support to maintain a minimum systolic blood pressure of 90 mmHg before the PCI intervention). Patients underwent rescue PCI according to the discretion of the clinician, within the first 72 h of the acute event. In our study, streptokinase was the only fibrinolytic agent administered before rescue PCI was performed.

We analyzed case reports where primary PCI was performed within the first 24 h of AMI onset and rescue PCI was performed within the first 72 h of AMI onset i.e. 90 min after failed thrombolysis. The PCI procedure reports were collected from 2 cath labs by conventional means, and recorded on a prespecified database sheet. This report contains the clinical and angiographic baseline data, and procedural results. Occurrence of major in-hospital adverse cardiac events till the time of discharge was documented from patient records.

A diagnosis of STEMI was reached when patients presented with chest pain and ST elevation in two consecutive leads or with new onset LBBB (Left Bundle Branch Block) in electrocardiogram (ECG). 14 We have taken ST elevation in ECG as ST elevation at the J point in at least 2 contiguous leads of >2 mm (0.2 mV) in men or >1.5 mm (0.15 mV) in women in leads V2–V3 and/or of >1 mm (0.1 mV) in other contiguous chest leads or the limb leads.15 The diagnosis of acute STEMI was made either at the NHSL or the peripheral hospitals where patients were transferred from.

In the event of a coronary stent implantation, all the patients were administered aspirin, clopidogrel, statin and heparin. Abciximab (Reopro) was administered at the operator’s discretion, and was the only GP IIb/IIIa blocker recorded in the study.

We classified the AMI location as being anterior or non-anterior in relation to the culprit AMI vessel. The left ventricular ejection fraction and the diameter of stenosis of the vessels were analyzed with a qualitative method (visual), performed in 2 cath labs. Successful PCI was defined as a TIMI flow grade 3.16 Major adverse cardiac events (MACE) were documented until the patient was discharged. Recurrent chest pain associated with ECG changes as criteria for reformation, performance of a new PCI of the culprit vessel as target vessel-revascularization (TVR), in-hospital coronary artery bypass graft (CABG) surgery and all-cause deaths were taken into account.

Statistical analysis was done with SPSS 17.0 and STATA 13. All continuous variables were expressed as mean ± SD, while counts and percentages were used to express discrete variables. Chi-square test for evaluating dichotomous variables and the Student t-test for continuous variables were included in the univariate analysis. To establish the independent influence of each baseline variable in the in-hospital mortality rate, we used the Cox regression model. Characteristics which demonstrated a p value ≤ 0.25 with the log rank test were included into the model. P values ≤ 0.05 were considered significant.

Ethical clearance was obtained from the Ethics Review Committee of NHSL. Permission was taken from Director, NHSL to conduct the study at the Institute of Cardiology. Consent was not sought from the patients as data were extracted from patients’ records and no additional investigations were done.

3. Results

From March 2013 to April 2015, 250 patients underwent primary and rescue PCI in Unit 5 of the Institute of Cardiology, NHSL, out of which 159 patients (63.6% from a total of 250 patients) fulfilled the aforementioned criteria. The data was analyzed in a comparative fashion: 78 (49.05%) patients underwent rescue PCI within 72 h door-to-balloon delay and 81 (50.94%) patients underwent primary PCI within 24 h door-to-balloon delay. Demographics and angiographic variables of the study population were analyzed (Table 1). Additionally, data regarding the use of a common glycoprotein inhibitor as well as the results of the PCI procedure were also recorded (Table 2).

4. Discussion

4.1. Significance of variables between the two strategies

In our study, rescue PCI (49.1%) was adapted as frequently as primary PCI (50.9%) to treat patients presenting with acute STEMI. Rescue and primary PCI procedures showed no significant association with regard to the patient’s age group, sex, diabetes, active smoking or location of the myocardial infarctions. The angiographic variables revealed that, at the time of the rescue procedure, the reduction in ejection fraction was not discernible when compared to primary PCI. There was no notable difference in

| Table 1 | Baseline variables according to PCI procedure. |
|----------------|-----------------------------------------------|
| Characteristics | Rescue (n=78) | Primary (n=81) | p value |
| Age | 52.31 [11.90] | 53.14 [12.48] | 0.689 |
| Age >70 | 5 (6.4%) | 7 (8.6%) | 0.594 |
| Females | 12 (15.4%) | 13 (16%) | 0.908 |
| Diabetes Mellitus | 29 (38.2%) | 33 (40.4%) | 0.466 |
| Previous Intervention | 1 (1.4%) | 5 (6.5%) | 0.114 |
| Multivessel CHD | 32 (41.0%) | 35 (43.8%) | 0.729 |
| EF on admission | 45.80 [8.01] | 47.24 [8.10] | 0.275 |
| EF on discharge | 48.88 [8.44] | 51.50 [6.00] | 0.049 |
| Thrombus Aspiration | 15 (19.2%) | 33 (40.4%) | 0.003 |
| Cuirpital Vessel – LAD | 60 (76.9%) | 47 (58.8%) | 0.015 |
| SDT Time (mins.) | 153.46 [258.88] | 265.50 [644.31] | 0.160 |
| Severity of lesion | 0.005 |
| 70%–99% | 51 (65.4%) | 35 (43.2%) | 0.005 |
| 100% (Total occlusion) | 27 (34.6%) | 46 (56.8%) | 0.005 |
| Hospital Stay (days) | 5.48 [1.42] | 5.14 [1.24] | 0.129 |

(MI – Myocardial Infarction, CHD – Coronary heart disease, EF – Ejection Fraction, LAD – Left anterior descending, SDT – Symptom-to-door time).
diagnoses of multivessel coronary disease (Table 1). There was a significant difference in the severity of the vessel lesions between the rescue and primary PCI groups (P = 0.005). The incidence of visible thrombi was less common in rescue than primary PCI strategies; however, the culprit LAD vessel was more prevalent in the former. The lower incidence of thrombus formation and its aspiration could probably be attributed to treatment with fibrinolytic therapy.2

4.2. Age as a factor in atherosclerosis in Sri Lanka

The mean age in our study group being less than 55 years (52.7), is lower than that from high income countries (HIC).17 Age is, in general, a strong prognostic indicator and it is possible that a lower-risk cohort was selected out for the procedure and may not be generalizable. However, this lower age presentation is consistent with other studies on acute MI in broader, more representative populations in Sri Lanka (not necessarily undergoing primary PCI), and probably reflects premature atherosclerosis that is commonly seen in the country.18 To further highlight the relatively younger age population in our study, we compared it with two other similar studies – where the common age groups spanned from the late 50’s to early 60’s.6,10 (Table 3)

4.3. Major adverse cardiac events

Results in our study showed that the incidence of MACE occurred at a similar rate when the two strategies were compared (7.7% vs. 7.4%; p = 0.33). In a comparison study conducted in Brazil, the frequency of MACE was also insignificant between the two groups (6.3% vs. 6.9%; p = 0.89).10 None of the patients required an emergency by-pass. There were 3 patients from the primary group requiring repeat TVR whereas none of the rescue patients underwent TVR. Out of four deaths in the rescue strategy, 3 patients were in cardiogenic shock while all 3 deaths in the primary group, were associated with cardiogenic shock, the obvious reason being, patients in cardiogenic shock will carry a higher mortality rate.19 There was no significant difference in the mortality rates between rescue and primary PCI (5.1% vs. 3.8%; p = 0.67). The mortality rates from our study were reflected in other similar studies as well, that is with no significant difference between rescue and primary PCI.6,10 Data regarding the Major Adverse Cardiac Events (MACE) which occurred in the two PCI strategies were recorded (Table 4).

4.4. What is the reason for similar mortality rates between the two PCI strategies?

In our Sri Lankan set-up, when opting for primary PCI, the patients face various delays (related to administration, decision making and transportation) till the procedure itself. In the rescue strategy, having been administered with thrombolytic therapy, this maintains patency of the affected vessels to some extent, buying time till rescue PCI can be performed, unlike primary PCI where the delay for any form of intervention would probably compromise for the vessel integrity further. Since there is no significant difference in the mortality rates between the two strategies, it shows that rescue PCI is as effective as primary PCI in our set up.

4.5. Univariate analysis

Independent predictors for in-hospital mortality in patients from a Brazil registry had already been determined by univariate analysis, of which the rescue PCI procedure itself was identified as a predictor of in-hospital death, along with an affiliation to female patients, age >70, diabetes, multivessel disease and moderate-to-severe global left ventricular ejection fraction (<40%) to name a few.20 In our study, although high hazard ratios were observed for

### Table 2
Procedural Results according to PCI procedure:

| Characteristics       | Rescue (n=78) | Primary (n=81) | p value |
|-----------------------|--------------|---------------|---------|
| Reopro                | 47 (60.3%)   | 59 (72.8%)    | 0.092   |
| Stented Patients      | 75 (96.2%)   | 75 (92.6%)    | 0.331   |
| DES                   | 60 (76.9%)   | 54 (66.7%)    | 0.251   |
| BMS                   | 15 (19.2%)   | 21 (25.9%)    | 0.251   |
| Stent Length          | 21.92 [7.26] | 22.49 [7.50]  | 0.638   |
| Stent Diameter        | 3.69 [1.01]  | 3.83 [1.12]   | 0.426   |
| Direct Stenting       | 11 (14.1%)   | 14 (17.3%)    | 0.582   |
| Pre Dilatation        | 67 (85.9%)   | 67 (82.7%)    | 0.582   |
| Post Dilatation       | 25 (32.1%)   | 26 (32.1%)    | 0.995   |
| TIMI Flow 3           | 3 (79.4%)    | 79 (97.5%)    | 0.970   |
| Final Diameter Stenosis | 3.04 [0.27] | 3.05 [0.26]  | 0.825   |
| Haematoma             | 1            | 1             | 0.978   |

### Table 3
Comparison of our study with Baer et al. and Ganassin et al.:

| Characteristics       | Baer et al.6 | Ganassin et al.10 | Our Study |
|-----------------------|--------------|-------------------|----------|
| Number of patients    | 317          | 442               | 202      | 78       | 91       |
| Age                   | 59.6 [12.0]  | 61.1 [11.6]       | 57.9 [11.8], 61.3 [13.1] <0.001 | 52.31 [11.90], 53.14 [12.48] 0.67 |
| Diabetes              | 25 (7.9%)    | 46 (10.4%)        | 44 (21.8%) | 43 (23.9%) 0.60 | 29 (38.2%) | 33 (44.0%) 0.46 |
| Hypertension          | 102 (32.2%)  | 124 (28.1%)       | 143 (70.8%), 41 (68.6%) 0.62 | 22 (30.6%) | 28 (37.3) 0.39 |
| Smoking               | 158 (49.8%)  | 219 (49.5%)       | 67 (33.2%), 174 (29%) 0.31 | 28 (35.9%) | 21 (25.9) 0.08 |
| Anterior Infarct      | 151 (47.6%)  | 216 (48.9%)       | 83 (49.4%), 224 (39%) 0.07 | 53 (67.9%) | 45 (55.6%) 0.11 |
| SVD                   | 163 (51.4%)  | 236 (53.6%)       | 171 (84.7%), 496 (82.8%) 0.49 | 46 (59%) | 45 (55.6%) 0.73 |
| Culprit LAD           | 144 (45.4%)  | 216 (48.9%)       | 123 (56.4%), 314 (47.3%) 0.03 | 60 (76.9%) | 47 (58.8%) 0.02 |
| Reinfarction          | 16 (5.1%)    | 29 (6.6%)         | 06 (3.0%), 16 (2.7%) >0.99 | 01 (1.3%) | 01 (1.2%) 0.33 |
| In hospital Mortality | 15 (4.7%)    | 29 (6.6%)         | 14 (6.9%), 38 (6.3%) 0.89 | 04 (5.1%) | 03 (3.8%) 0.67 |

(SVD – Single vessel disease, LAD – Left anterior descending).
age, SD time (symptom-to-door time), diabetes mellitus, hypertension, multivessel disease and thrombus aspiration, these were not significant.

4.6. Comparison with international studies

The analysis of primary PCI results is simulated in other international studies, either regarding procedural success (>90%) or in-hospital deaths (<7%). Notably, these results were also transferred to patients who underwent rescue PCI. These findings were supported by randomized trials that assessed the performance of PCI after thrombolysis treatment which included a similar trend in mortality in these patients. Table 3 compares variables from two different studies along with ours.

4.7. Ejection fraction on discharge

Even though our study revealed that the ejection fraction on discharge was marginally significant i.e. lower in rescue than primary PCI patients (48.88% [8.44] vs. 51.50% [6.00]; p = 0.049), the mortality rates between the two groups were similar and below 6%. In a small observational study with 63 patients who underwent rescue PCI, though the ejection fraction was unsatisfactory on discharge, in-hospital mortality was below 3%. Another study too, showed that there was a significant difference between the ejection fraction on discharge (47% vs. 53%; p = 0.014) but the composite endpoint of death, repeat PCI, recurrent MI, and CABG occurred in 26.7% in the rescue group and 35% of the patients in the primary PCI group (p = 0.36).

Fig. 1. A map of Sri Lanka, incorporating the Wagon Wheel model for triage and transfer of STEMI patients from peripheral, base, district and general hospitals to Institute of Cardiology, National Hospital of Sri Lanka for primary/rescue PCI or pharmacoinvasive strategy.
The RESCUE study revealed that rescue PCI, even though it does not increase resting ejection fraction (EF), there was evidence of improvement in exercise EF as well as prevention of death or severe heart failure.\textsuperscript{26} In our study, the resting EF on discharge showed an increase in both rescue and primary PCI. There was one patient in each group who developed heart failure. Given that our data represents a single-center experience where the operators are very experienced and the hospital is the best of its kind in the state sector in this country, it could explain the satisfactory ejection fraction values as well as the low mortality rates.

4.8. Usage of stents

The rates of stent usage was similar and was at a high rate of >90% in both strategies in our study. This is similar to a study conducted in Brazil based on a contemporary registry, where the stent usage was >80% in both groups. Furthermore, the procedural success rates (>90% in both groups) was also found to be similar to our study findings.\textsuperscript{10} Drug eluting stents (DES) were more frequently used than bare metal stents (BMS) in both rescue and primary PCI patients. Between the two groups, there was no significant difference in the usage of DES (76.9% vs. 66.7%, \( P = 0.251 \)) or BMS (19.2% vs. 25.9%; \( P = 0.251 \)).

4.9. Usage of glycoprotein IIb/IIIa inhibitors

Reopro was administered to >60% of the patients in our study, at similar rates to both groups (\( p = 0.092 \)). The CADILLAC trial studied the effect of this particular glycoprotein inhibitor and showed evidence of an uneventful 30 day period but did not seem to deliver any benefit at the end of 1 year after the procedure.\textsuperscript{27} There appears to be a rising trend in favouring the use of glycoprotein IIb/IIIa inhibitors in acute STEMI patients because of its potential in protecting the coronary microvasculature. A metaanalysis of 12 trials that included AMI patients who were treated with fibrin-specific agents showed frequent use of GP IIb/IIIa inhibitors as adjuvants.\textsuperscript{3} Patients undergoing rescue PCI are more often being prescribed with GP IIb/IIIa inhibitors.\textsuperscript{28} TIMI 14\textsuperscript{29} study revealed a lower risk of bleeding when half the normal dose of alteplase was combined with Reopro, however there was an increased risk of bleeding in patients who were administered streptokinase. The ongoing GUSTO 4 phase III study is currently analyzing the use of this combination of streptokinase and GP IIb/IIIa inhibitors for treatment during the acute period of myocardial infarction. In our study, 47 rescue patients received Reopro, of which, one patient (2.12%) had bleeding (haematoma) during the post-operative period. Another patient from the primary group, who was not administered Reopro, also had bleeding (haematoma) after the procedure.

4.10. Implications of our study

Institute of Cardiology, National Hospital Sri Lanka in Colombo is the only state funded cardiac center in Sri Lanka which offers primary PCI around-the-clock. Widespread state-funded primary/rescue PCI programs commencing from the urban areas and then extending to rural communities, coupled with funded educational campaigns to get patients to present earlier following onset of pain, as well as programs facilitating access to primary and secondary preventive measures, are essential for this region. There were several implications of our study. Widespread availability of primary/rescue PCI, although vigorously promoted,\textsuperscript{10} has yet to become a reality. We have shown in the first sizeable report from Sri Lankan state sector that rescue PCI is a viable therapeutic option and can be performed with excellent immediate- and short-term results despite relatively longer chest-pain-to-presentation time lapse.

4.11. Pitfalls

However, our study did have its own pitfalls. Firstly, this study was non-randomized and it reflects a single center experience where the operators are very skilled and the hospital is the best of its kind in the state sector of this country. Whether these results can be generalized to other hospitals in lower and middle-income countries (LMICs) is unclear. Secondly, although these are consecutive patients undergoing primary or rescue PCI, they do not represent all-comers who presented with acute STEMI. Many such patients opted for fibrinolysis. Thirdly, a significant proportion of delay-to-PCI comprises the time taken by patients to decide whether they can proceed with the procedure, based on financial constraints, transportation difficulties on reaching the PCI center, delay on getting the required medical equipment etc. (e.g. specific stents). We did not have the data to determine the intricacies of this delay. Finally, given the small population that was being analyzed, this study might not reflect all the island wide PCI procedures, therefore and larger studies are needed to validate these results.

4.12. Wagon wheel model of regional hospital network

In 2014, the Sri Lanka Heart Association has recommended the Hub and Spoke Wheel principle using the Wagon Wheel model for triage and transfer of STEMI patients, which is yet to be implemented in the future (Fig. 1). In addition to the three level identified in the Wagon wheel model for triage and transfer of STEMI patients from peripheral hospitals, we also strongly feel that the addition of a 4th and 5th level to the current Wagon Wheel model is important, as we are already receiving patients from faraway district hospitals that lie in the fourth and fifth levels of the Wagon Wheel model.

Description of the levels:
Level 1 – This is the hub with the Sri Lanka National Hospital’s catheterization lab, where patients could be directly admitted and primary PCI could be performed.
Level 2 – Hospitals in this level would receive patients and will; transfer them to the hub for primary PCI.
Level 3, 4 and 5 – These hospitals are the furthest away from the hub and therefore will adapt a pharmacoinvasive strategy of reperfusion; i.e. they would treat STEMI patients with thrombolysis and transfer them for angiography with or without PCI.\textsuperscript{31,32}
Levels 2–5 are determined by the geographical distance from the hub and the time taken to transfer patients.

5. Conclusion

Based on this comparative analysis between rescue and primary PCI, we conclude that patients presenting with early onset AMI treated with either strategy, had equal procedural success as well as similar in-hospital death rates, thereby further advocating the use of rescue PCI as a viable option in rural areas, where immediate fibrinolysis can buy time until PCI facility access is gained in more urban areas.\textsuperscript{33} Future research should be focused on large population studies and to compare the long term follow up results as well as the relationship between patients’ mortality rates with transfer time from rural hospitals.\textsuperscript{34}

Declaration of interests

Authors have no conflicts of interests.
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