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3 **Providing Optimal Care for Patients with ST-segment Elevation Myocardial**
4 **Infarction Across a Large Region: Issues Beyond Timeliness of Reperfusion**
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Abstract

Background: Although considered the evidence based best therapy for ST-segment elevation myocardial infarction (STEMI), many patients do not receive primary percutaneous coronary intervention (PPCI) due to health care resource distribution and constraints. Outcomes from Canadian PPCI programs are well described, however, few studies focus on the experiences and outcomes of all patients presenting with STEMI within a region, including those who did not receive PPCI.

Methods: Management and system related outcomes, and patients' uptake of risk reducing therapies/activities pre and post STEMI were compared between patients presenting to PCI and non-PCI capable hospitals in one integrated health region in Ontario. Regression models were developed to determine which variables were associated with mortality at 90 days.

Results: Between April 1 2010, and March 31 2013, data was collected on 2247 patients presenting with STEMI. Patients presenting to the PCI capable hospital were more likely to receive PPCI, and be treated within optimal treatment times. However, there was no appreciable difference in mortality at 90 days and other major cardiac outcomes between patient presenting to PCI and non-PCI capable hospitals, even after adjustment for acuity on presentation. Despite recognized risk factors, many patients were not taking evidence-based medications for risk factor modification prior to STEMI.

Interpretation: This study suggests that a systematic approach to STEMI focusing on timely access to best available therapies may be more important than the type reperfusion provided.

Key Words: Regional Program, Primary PCI, Fibrinolysis, Myocardial Infarction

Introduction

ST-segment elevation myocardial infarction (STEMI) is a cause of significant morbidity and mortality [1]. While early myocardial reperfusion is crucial in treating STEMI [2], patient clinical characteristics and available resources both determine how this is best achieved. Choosing the best course of STEMI care requires the coordination of various services, including emergency medical services (EMS), emergency medicine and interventional cardiology. When it can be accomplished in a timely manner, reperfusion with primary percutaneous coronary intervention (PPCI) is considered the evidence based standard of care [3]. However, PPCI may not be feasible for all patients due to population-based geographic distribution of resources, patient co-morbidity, and resource constraints. Certain patients may benefit from timely fibrinolysis coupled with a pharmacoinvasive approach [3,4] because fibrinolysis is available in all emergency departments (and some pre-hospital settings) and available to a broader population without the need for additional infrastructure. Thus, a regional STEMI program seeking to maximize patient and population outcomes requires a system approach devoted to ensure that the best available treatment is provided within the context under which it is delivered.

Previous studies across Canada describe outcomes from regional PPCI programs only [5-8]. Few studies describe the experiences and outcomes of all patients presenting with STEMI within a region, including those who did not receive PPCI (e.g. [4,9]). This paper will examine and describe the experiences and outcomes of STEMI care for all patients, including those receiving PPCI, fibrinolysis or no reperfusion therapy, presenting to a regional STEMI program in Ontario. Comparisons will be made between

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3 patients presenting to PPCI and non-PPCI capable centres. The intent is to identify gaps
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5 in care and areas for improvement in the provision of STEMI care beyond issues of
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7 improving timely access to PPCI.
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10 11 12 **Methods**

13 *Regional STEMI Program*

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Hamilton Niagara Haldimand Brant Local Health Integration Network (HNHB or LHIN-4) is the second largest LHIN in Ontario covering an area of over 7000 square kilometers with a mixture of large urban areas and small rural communities and a population over 1.4 million. Healthcare is provided by 3 tertiary care hospitals, 9 community hospitals, and 4 urgent care centres, served by 7 EMS programs coordinated by 2 base hospitals and 4 dispatch centres. PPCI is available at a single tertiary cardiac care centre located in a large urban community (Hamilton General Hospital (HGH), Hamilton) [10]. In April 2010, a regional STEMI program was initiated for the purpose of improving access, timeliness of care, and overall outcomes for regional STEMI patients. Information on how many patients were presenting to LHIN-4 emergency departments (ED) with STEMI, where they came from, and the treatment they received was collected through the implementation of a STEMI reporting process, whereby ED staff or a STEMI program coordinator would complete an identification form that would be sent along with a copy of the diagnostic electrocardiogram (ECG) via facsimile to the STEMI program office at HGH.

This region-wide reporting of STEMI facilitated the implementation of the following strategies to improve STEMI care: 1) a program of pre-hospital identification

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3 of STEMI across the region; 2) Paramedic redirection of STEMI patients to a tertiary
4 cardiac care centre for PPCI; 3) a standardized reperfusion algorithm to be used by all ED
5 staff (Appendix A); 4) standardized early discharge or early repatriation with “bridging”
6 clinic at 5-7 days post discharge for all patients receiving care at the tertiary cardiac
7 centre [11]; and 5) a case specific and aggregate electronic two-way audit and feedback
8 system among stakeholders (EMS, ED, and in-hospital providers) outlining quality
9 indicators. Other evidence-based best practices, such as the single call activation system,
10 rapid set up of the catheterization laboratory by staff, and oversight by a multi-discipline
11 collaboration team were also used as part of standard STEMI program operations [12,13].
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27 *Data Collection*

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29 Patient information derived from the STEMI report form was prospectively
30 collected and entered into a registry by the program coordinator. Chart reviews were
31 used to collect additional data regarding clinical characteristics, demographics, and
32 patient specific health and system related outcomes. A standardized telephone call was
33 carried out at 90 days to determine health status. Patients unavailable by telephone were
34 also contacted by mail. Patients were considered “lost to follow-up” if they did not
35 respond by mail and after 3 phone calls. Health outcomes included death (in hospital
36 and at 90 days), major bleeding, recurrent MI, and stroke. System related outcomes
37 included reperfusion received, hospital length of stay, door to reperfusion therapy time
38 interval (balloon inflation/first device or fibrinolysis administration), and proportion of
39 patients receiving reperfusion within optimal treatment intervals (i.e. first hospital contact
40 (ED arrival) to PPCI <90min for patients presenting to PCI site, and <120 min for
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3 patients transferred from another facility to PCI site; or door to fibrinolysis <30min).
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5 Medication prescription at discharge and adherence at 90 days were also considered. A
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7 cardiologist independently confirmed all STEMI cases and outcomes. Ethics approval
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9 for the project was obtained from all participating LHIN-4 hospitals.
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14 *Statistical Analysis*

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17 Primary analyses focused on describing demographics, clinical characteristics,
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19 and outcomes of patients presenting to ED at PCI and non-PCI capable hospitals within
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21 LHIN-4. Patients presenting by EMS and brought directly to the catheterization
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23 laboratories were included in the PCI centre group. Dichotomous variables were
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25 compared using chi-square tests. Group medians and means were compared using a
26
27 Wilcoxon rank sum test and Students t-test, respectively.
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32 Univariate logistic regression models were developed to determine which
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34 variables were associated with mortality at 90 days. Variables considered for inclusion
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36 were baseline characteristics (age ≥ 75 years], gender, history of diabetes, history of MI),
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38 Killip Class 3-4, anterior MI, medications given prior to admission (any of ASA,
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40 clopidogrel, statins, ACE, ARB, beta blockers), anemia, left ventricular ejection fraction
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42 (LVEF) $\leq 35\%$ during admission, reperfusion with primary PCI or fibrinolysis, symptom
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44 onset to ED arrival > 6 hrs, overall ST deviation ≥ 8 mm on diagnostic ECG, optimal time
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46 to treatment, estimated glomerular filtration rate (eGFR), presentation hospital (PCI or
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48 non PCI), and mode of presentation (EMS or self). Variables significant (at $p < 0.1$) in
49
50 the univariate models were included in a multiple variable logistic regression model,
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52 using backward elimination that included presentation hospital in every model. Final
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3 model selection was determined by those variables, for which the significance of the
4 Wald Chi-square was <0.15 and the lowest Akaike Information Criterion (AIC). Anemia
5 and LVEF $\leq 35\%$ were significant, however, these variables were not included in the final
6 model, as they were significantly correlated with eGFR and Killip Class, respectively.
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8 The final model included the variables outlined in Table 4. Bootstrap re-sampling
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10 technique was used to determine the predictors of mortality using methods outlined by
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12 Austin and colleagues [14]. All analyses were performed using Statistical Analysis
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14 Systems, version 9.2 for *unix* (SAS Institute, Cary, North Carolina).
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25 **Results**

26 *Demographics and Clinical Characteristics*

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29 Between April 1 2010, and March 31 2013, data was collected on 2247 patients
30 presenting in the region with a STEMI diagnosis. We excluded 66 patients from analysis
31 because they either died immediately upon presentation to the hospital (n=12, 0.5%) (i.e.
32 prior to any treatment), or were already admitted to hospital when they had their STEMI
33 (n=54, 2.4%). Approximately 85% of patients presented with a history of at least one
34 cardiac risk factor. With few exceptions, patients presenting to PCI and non-PCI capable
35 centres were similar (Table 1).
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48 *Management Strategy*

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50 Most patients were treated with PPCI, with a higher proportion in the PCI centre
51 group (82.5% vs. 65.2%; $p<0.001$). The fibrinolysis rate was higher in the non-PCI
52 centre group (0.8% vs. 19%; $p<0.001$). Of the 282 fibrinolysis patients, 190 (67.4%) were
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3 referred for rescue PCI, and 36 (12.8%) were referred for pharmacoinvasive PCI. This
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5 left 56 patients (19.9%) who did not undergo coronary angiography within 24 hours of
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7 fibrinolytic therapy. The proportion of patients treated within optimal treatment intervals
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9 at PCI and non-PCI capable hospitals were 70.8% and 58.7%, respectively. Of the 1311
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11 patients who contacted 911 and presented to hospital by ambulance, only 554 had ECG
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13 acquisition in the ambulance prior to hospital arrival.
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20 *Outcomes*

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22 A total of 138 (6.3%) patients died prior to discharge from hospital; with an
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24 additional 24 deaths at 90 days post STEMI (1.3%). There were no observed differences
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26 in either mortality or other major cardiac events at both time-points based on hospital of
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28 presentation (i.e. PCI vs. non-PCI centre). Treatment and health outcomes are presented
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30 in Table 2. Door-to-balloon time was significantly shorter for patients receiving PPCI
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32 who presented to the PCI capable centre, (compared to the non-PCI centres). There were
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34 no appreciable differences between groups regarding the other process variables (Table
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41 Table 4 shows the associated odds ratio and level of significance for each variable
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43 included in the final regression model iteration. A Hosmer and Lemeshow test
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45 demonstrated that the model was a good fit of the data ($p=0.079$). The c-statistic was
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47 calculated at 0.86, and the likelihood ratio chi-square for the final model was significant
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49 at $p<0.001$. The bootstrap analysis indicated that optimal time to treatment and symptom
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51 onset to ED arrival >6 hours were significant in 50% of the bootstrap samples, out of a
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3 1000 samples, and with history of diabetes in 40% of the samples. However, we felt that
4 these variables were clinically important, and thus, retained them in the final model.
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10 *Risk Factor Modification Post STEMI*

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12 Attendance in risk factor modification programs post-discharge was suboptimal.
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14 Only 35.7% of all patients either attended or had a scheduled appointment for cardiac
15 rehabilitation at 90 days and only 4.2% of patients attended a smoking cessation program.
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17 However, there was a significant drop in the proportion of patients reporting as “currently
18 a smoker” (40% at time of STEMI, and 15% at 90 days, $p < 0.001$).
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25 Approximately 85% of patients reported a history of at least 1 risk factor for
26 coronary disease at the time of presentation for STEMI. However, the baseline use of
27 medications for prevention of MI or risk factor modification prior to presentation was
28 low. Medication prescription at discharge was good with some attrition at 90 days (Table
29 5), and with similar rates observed between PCI and non-PCI hospitals.
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39 **Discussion**

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41 In this large regional program, use of PPCI and fibrinolysis-based management
42 strategies tailored to local resources and geography yields favourable patient outcomes.
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44 Specifically, our study showed no difference in 90-day mortality rates between patients
45 presenting to PCI vs. non-PCI capable centres. Once the patient entered the STEMI
46 program, the system identified the best management strategy to improve outcome within
47 the patient’s clinical and geographic context. Importantly, this is one of the few studies
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3 to present the experiences and outcomes of all patients presenting with STEMI in
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5 contemporary practice within a large geographic region in Canada.
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8 Research and organization of care for STEMI has focused on both ensuring timely
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10 access, and increasing the proportion of patients receiving PPCI over fibrinolysis
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12 [9,12,13,15-18]. Our data suggests that even where best practices for regional STEMI
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14 care are implemented, some patients may still require fibrinolysis. We observed that
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16 numerous patients self-presented to non-PCI capable hospitals, especially in rural areas of
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18 the LHIN, which makes it less likely they would be able to access PPCI within the
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20 recommended benchmarks. The presented regression model is consistent with the
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22 accepted paradigm that time to reperfusion is an important predictor of STEMI outcomes.
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24 However, our data suggests that other clinical and process variables are equally or more
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26 important. We also observed that the proportion of patients not receiving any reperfusion
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28 therapy was less than 10%, which is consistent with recent reports from Europe
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30 highlighting that in well-established systems of STEMI care, the rate of non-reperfusion
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32 is much less than the commonly accepted rate of approximately 30% [19,20]. More
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34 importantly there was a subset of patients not requiring acute reperfusion as demonstrated
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36 by the subgroup of patients referred for primary PCI but not receiving any intervention.
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38 We infer that establishing a regional framework of STEMI care and providing health care
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40 workers with clear options for best care enhances optimal and safe care.
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48 Several issues relating to further improvements in coordination of care and
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50 prevention were identified as potentially impacting care and outcomes: 1) a minority of
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52 patients eligible for diagnostic catheterization within 24 hours of fibrinolytic therapy
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54 actually received it. There is accumulating evidence that where PPCI is not possible,
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3 reasonable outcomes could be achieved with fibrinolysis administration combined with
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5 an early pharmaco-invasive approach [21-24]; 2) implementation of an EMS bypass
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7 strategy was only achieved in 2 of the 7 LHIN EMS programs; 3) fewer patients were
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9 discharged within 3 days post STEMI in the non-PCI hospitals compared to the PCI
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11 capable hospital. Length of stay at the PCI hospital was less variable, likely due to the
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13 implementation of a formal and standardized discharge program for low risk STEMI
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15 patients [11]; 4) participation in cardiac rehabilitation and risk modification programs
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17 was suboptimal despite a formalized discharge practice and availability of a bridging
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19 clinic/phone call at 7 days post-discharge; 5) >50% of patients self reported hypertension
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21 and >30% reported dyslipidemia upon presentation. Although these risk factors are
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23 modifiable, many patients were not taking medications for coronary artery disease
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25 prevention [25,26]. Although we could not determine the influence of resource
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27 limitations or other access barriers on patient outcomes, this study highlights the need for
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29 a better understanding of patient behavior and raises the possibility that targeted
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31 education and improved resource allocation for rehabilitation programs and medication
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33 access/adherence may maximize benefits [27].
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41 A significant proportion of patients did not access care via EMS, including over
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43 half of those presenting to non-PCI capable hospitals. The large discrepancy in the
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45 utilization of EMS between PCI and non-PCI hospitals can in part be explained by the
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47 direct transfer strategy of the STEMI program, where patients diagnosed in the field
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49 could bypass the closest ED in favour of the PCI centre. The overall rate of EMS STEMI
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51 patients arriving by ambulance was consistent with previous studies [28-31]. While it
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53 may be that many patients can present to ED faster via self-transport, utilizing EMS may
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3 provide quicker and safer access to STEMI reperfusion [32]. Paradoxically, health
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5 outcomes were worse in the EMS group, even after adjustment for advanced age,
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7 diabetes, EGFR, and Killip Class. The extent to which this was due to co-morbidities not
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9 considered in the models and patient self-selection of “sicker” patients calling 911
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11 requires further investigation. However, improving the appropriate uptake of EMS may
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13 both improve timeliness of care (i.e. time to first diagnostic ECG, door-to-balloon/needle
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15 time, etc.), and increase the proportion of patients who would be eligible for PPCI (via
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17 triage directly to the PCI centre), and thus, likely improve outcomes in a segment of the
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19 regional STEMI population.
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27 *Limitations*

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29 Follow-up at 90 days was incomplete in 7% of the total population. However,
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31 although those lost to follow-up were on average younger, there were no other
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33 appreciable differences in known characteristics (sex, Killip class and history of diabetes)
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35 between those who were contacted and those who were lost to follow-up, as well as
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37 between PCI and non-PCI hospitals. No data was collected on patients who suffered
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39 STEMI, but died prior to presentation to hospital. Thus we were unable to determine the
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41 magnitude of unmet care. Understanding why such patients died prior to accessing care
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43 may reveal gaps in the provision of STEMI services. An additional 6.3% of patients
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45 were discharged with a prescription for an emerging antiplatelet therapy (i.e. prasugrel or
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47 ticagrelor), however, this data was not routinely collected at 90 day follow-up, and
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49 subsequently not included in our results.
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Conclusion

This study is one of few to examine service provision and outcomes for all patients receiving STEMI care in a large geographic region, and suggests that a systematic approach to STEMI with good access to care is more important than the type of care provided (i.e PPCI vs fibrinolysis). Additionally, we were able to reveal gaps in care beyond timeliness of care. Ongoing system measures aimed at minimizing these gaps and ensuring best available treatments given the context under which the patient presents may result in even better health outcomes to patients suffering STEMI.

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	PCI centre		Non-PCI centre		Chi-Square p-value
	n (731)	%	n (1450)	%	
Age >75	138	18.9	269	18.6	0.85
Female	207	28.3	399	27.5	0.16
History of:					
CAD	154	21.1	268	18.5	0.15
PCI	81	11.1	138	9.5	0.25
CABG	29	4.0	37	2.6	0.07
MI	124	17.0	216	14.9	0.21
CHF	17	2.3	22	1.5	0.18
Stroke/TIA	47	6.4	64	4.4	0.04
Diabetes	176	24.1	282	19.4	0.01
hypertension	381	52.1	749	51.7	0.84
dyslipidemia	271	37.1	573	39.6	0.26
Anemia	120	16.4	170	11.7	0.002
Current smoker	298	40.8	582	40.1	0.78
eGFR <60	168	24.0	315	22.5	0.43
Killip class 3 or 4	132	18.1	224	15.4	0.12
TIMI STEMI >3	342	49.4	650	47.0	0.30
Anterior MI	280	38.3	604	41.7	0.13
ST segment deviation >8mm	485	66.3	929	64.1	0.29
Intubation/ventilation	68	9.3	104	7.2	0.08
CPR/defibrillation	60	8.2	147	10.1	0.15
inotropes	55	7.5	111	7.7	0.91
LVEF≤35%	130	19.7	237	18.8	0.64
presented via EMS	598	81.8	713	49.2	<0.001
Symptom onset <12 hours	640	87.6	1239	85.4	0.18

Table 1: Patient clinical characteristics and demographics

	PCI centre		Non-PCI centre		Chi-Square p-value
	n (731)	%	n (1450)	%	
PPCI	603	82.5	946	65.2	<0.001
Catheterization only	84	11.5	121	8.3	0.02
Fibrinolytic therapy	6	0.8	276	19.0	<0.001
No reperfusion	38	5.2	107	7.4	0.05
Death in hospital	48	6.6	90	6.2	0.74
Death (90 days)	55	7.5	107	7.4	0.90
Repeat MI	7	1.0	21	1.4	0.34
Stroke	5	0.7	8	0.6	0.70
Major bleed (without CABG)	15	2.1	19	1.3	0.19
CABG	38	5.2	74	5.1	0.92
LOS ≤3 days	317	46.8	455	33.5	<0.001

Table 2: Patient clinical outcomes

	PCI centre		Non-PCI centre		2-sample Wilcoxon test p-value
	median	Interquartile range	median	Interquartile range	
Symptom onset to first ED (min)	86	57-144	80	48-160	0.19
ED Arrival to first ECG (min)	8	5-14	8	3-18	0.59
Door to Balloon time (min)	73	53-93	113	96-142	<0.01
Door to needle time (min)	22.5	16-32	32	17-57	0.30

Table 3: Performance Variables. Time intervals were calculated for patients receiving either primary PCI or fibrinolysis and presenting within 12 hours or symptom onset and where first ECG was the diagnostic ECG.

	Odds Ratio	95% CI	p-value
Killip Class 3 or 4 (yes vs. no)	5.43	3.67-8.02	<0.001
EGFR ≤60 (yes vs. no)	3.24	2.2-4.78	<0.001
Age ≥75 years	2.26	1.52-3.36	<0.001
Transportation (EMS vs. Self)	1.98	1.24-3.17	0.004
Reperfusion (yes vs. no)	0.61	0.41-0.91	0.015
History of Diabetes (yes vs. no)	1.65	1.10-2.48	0.015
Optimal Time to Treatment (yes vs. no)	0.54	0.33-0.87	0.012
Symptom Onset to ED arrival >6 hours (yes vs. no)	1.47	0.97-2.23	0.067
PCI Hospital presentation (yes vs. no)	0.86	0.58-1.29	0.479

Table 4: Mortality prediction based on multiple logistic regression model.

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Medication	Prior to presentation (n=2181)		At Discharge (n=2043)		At 90 days post MI (n=1757)	
	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>
ASA	445	20.4	1957	95.8	1603	91.2
Clopidogrel	106	4.9	1688	82.6	1400	79.7
Statin	552	25.3	1878	91.9	1564	89.0
Beta Blocker	343	15.7	1743	85.3	1377	78.4
ACE Inhibitor	435	19.9	1622	79.4	1295	73.7
ARB Inhibitor	215	9.9	125	6.1	139	7.9
ACE/ARB Inhibitor	636	29.2	1740	85.2	1414	80.5
Coumadin	43	2.0	133	6.5	92	5.2

Table 5: Rate of medication use at presentation, discharge, and follow-up. Note: 90 day follow-up data excludes those who died or were lost to follow-up.

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STEMI ALGORITHM FOR LHIN IV

Brantford General • Haldimand War Memorial Hospitals • Hamilton Health Sciences • Joseph Brant Memorial
Niagara Health • Norfolk General • St. Joseph's Healthcare • West Haldimand General • West Lincoln Memorial

STEMI definition

Symptoms and ST-segment elevation ≥ 0.1 mV (1 mm) in at least 2 contiguous precordial leads or 2 adjacent limb leads.

Contraindications for Fibrinolysis

Absolute:

- Intracranial hemorrhage
- Cerebral vascular lesion
- Intracranial neoplasm
- Ischemic stroke within 3 months except acute ischemic stroke < 3 hours
- Suspected aortic dissection
- Active bleeding or bleeding diathesis
- Facial trauma within 3 months

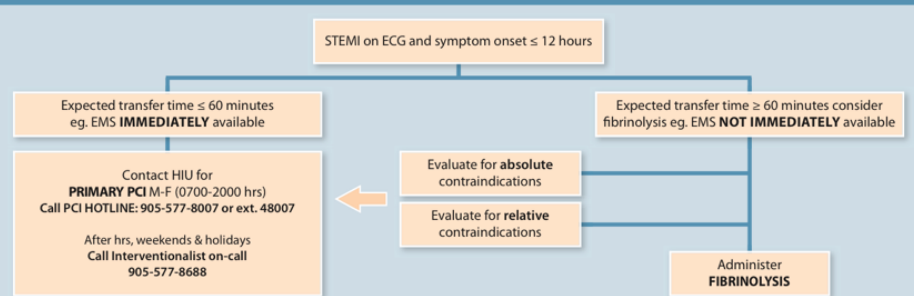
Relative:

- Cardiac arrest with prolonged CPR
- Cardiogenic shock
- Killip class ≥ 3
- Symptom onset > 3 hours
- Severe uncontrolled hypertension
- Recent or high risk of bleeding
- Active peptic ulcer
- Diagnosis of STEMI is in doubt

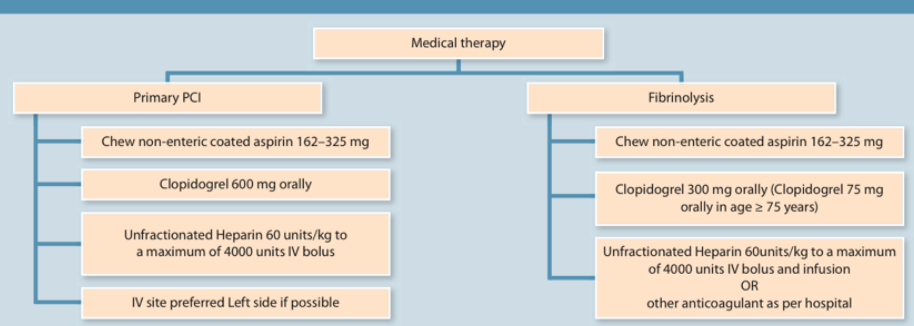
High Risk STEMI ECG criteria

- 2 mm ST-elevation in two anterior leads
- 1 mm ST-elevation in two inferior leads coupled with 2 mm ST-depression in the anterior leads

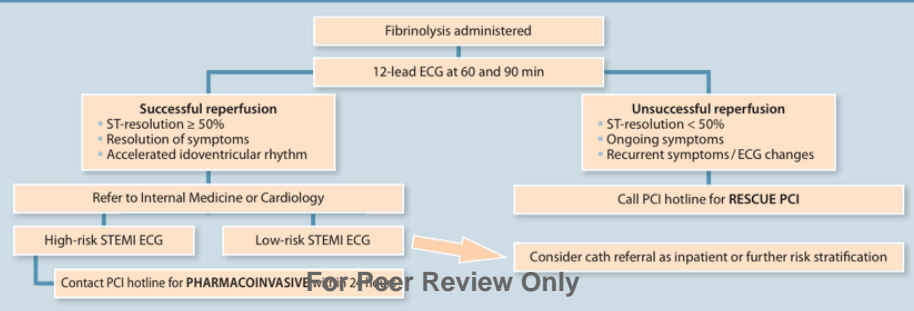
Step 1: Select Reperfusion strategy in STEMI PRIMARY PCI vs. FIBRINOLYSIS



Step 2: Consider Adjuvant Therapy in STEMI



Step 3: Assessment Post Fibrinolysis (In ED or as an Inpatient) RESCUE and PHARMACOINVASIVE



Suggested EMS/Dispatch Communication Strategy

- Physician or designate to place call to Ambulance Communication Center (Ambulance Dispatch).
- Communicate the following sequence:
 - This is Dr. ___ from ___ (hospital), I have a transfer for EMERGENCY ANGIOPLASTY.
 - Patient is critically ill, requesting Code 4 transfer to Hamilton General Hospital, patient has been accepted by the Heart Investigation Unit.
 - Patient's Diagnosis: Acute Myocardial Infarction
 - State what equipment and/or escorts will be accompanying patients on transfer.
 - Is patient a DNR, or do they have a communicable disease?
 - Patient is prepared and READY TO GO.
- Obtain and provide a Medical Transfer Number to CACC. However, do not delay transfer while waiting for number.

Note: The ambulance service may not be able to provide return transport for escorts. Therefore, the sending facility should be prepared to make arrangement for escorts to return to their facility (if applicable)