

## Optimizing primary PCI beyond “door to intervention time”— are we there yet?

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### Abstract

**Aim:** To assess the effects of shortened door-to-intervention (DTI) time on appropriate clinical decisions regarding the four most critical and costly decisions during primary percutaneous coronary intervention (PCI): cath-lab activation (CLA), use of glycoprotein IIb/IIIa inhibitors (GPI), use of PCI, and deployment of drug-eluting stent (DES).

**Background:** STEMI PCI patients are frequently subject to decision making based on abbreviated medical encounter and limited medical information.

**Methods:** Clinical data were prospectively collected in a STEMI registry over 19 months. Retrospective chart reviews were conducted to determine the level of appropriateness of the above-mentioned decisions.

**Results:** Between June 2006 and December 2007, 200 EKGs with suspected STEMI were transmitted; 88 (44%) resulted in CLA. Compared to prior year, DTI times decreased from 145.7 to 69.9 min ( $P=.00001$ ). DTI was longer during nights and weekends (87.5 vs. 51.8 min,  $P=.001$ ) and the initial 6 months of the registry (86.8 vs. 66.8 min,  $P=.07$ ). Nineteen (21.6%) of the patients undergoing angiography did not require revascularization, 56 (63.6%) received GPIs, and 65 patients (73.8%) underwent at least one vessel PCI, and at least one DES was used in 39 patients (60% of PCI cohort). When assessed for appropriateness, CLA was appropriate in 81.8% of the time and rendered borderline or inappropriate in 5.7% and 12.5%, respectively. GPI use was appropriate in 66% of the patients but seemed borderline or inappropriate in 28.5% and 5.4%, respectively. PCI was appropriate in 90% of the lesions treated, and borderline or inappropriate in 7.1% and 2.9%, respectively. DES use was viewed appropriate in 38.4%, and borderline or inappropriate in 51% and 10.2% of the DES deployments, respectively.

**Conclusions:** (1) In view of expedited care, certain information required for decision-making process is either not available or ignored during primary PCI. (2) Appropriate use of resources in primary PCI needs to be better defined. (3) Measures of extracting patients' previous medical records and imaging studies along with in-lab immediate blood work and echocardiography and establishing new “time-out” protocols for STEMI patients may improve resource utilization and patient care and outcome.

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### Keywords:

ST-elevation myocardial infarction; Primary PCI; Glycoprotein IIb/IIIa inhibitors; Drug eluting stents; Bare metal stents; Door to intervention time

### 1. Introduction

The door-to-balloon initiative inspired many algorithms and innovations to reduce the time from the initial medical encounter of patients with STEMI to the reperfusion of the infarct-related artery.

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The University Hospital at Newark was the first hospital to report the use of simultaneous wireless network EKG transmission and cath-lab activation (CLA). This innovative strategy was prospectively assessed in a registry (STAT MI registry [1]). The simultaneous wireless transmission resulted in immediate notification of off-site cardiologists and cardiology fellows, emergency department and cath-lab personnel. The fellow with the interventional attending could assume at that point patient care and make triage decisions (allowing direct admission of suitable patients to the cath lab). The cardiology fellow could also attempt to extract patients' old records, EKGs, and imaging studies. Upon arrival to the cath lab, the patient is examined by the cardiac fellow, consented for coronary angiography and primary percutaneous coronary intervention (PCI), and undergoes coronary angiography. In a recent report based on the National Cardiovascular Data Registry (ACTION), it was determined that the use of prehospital EKG transmission was associated with better reperfusion times, higher use of reperfusion therapy, and a trend toward reduced mortality; however, only one quarter of the patients transported by EMS received prehospital EKG [2].

As required by the state of New Jersey, we reported our door-to-intervention (DTI) times which have dramatically improved. We did however notice in various primary PCI setups that (1) the patients' blood work (chemistry, blood counts, and cardiac enzymes) were usually available only upon termination of PCI procedure. (2) Although echocardiography or, alternatively, ventriculography and aortography were readily available to us, these modalities were not always used prior to PCI. In a few memorable cases, we failed to pick up pathologies that were essential for our decision-making process (critical aortic stenosis, severe mitral regurgitation, and even an aortic dissection). (3) We also noticed that we have made inappropriate decisions in view of emerging clinical details extending from religious issues (refusal to receive blood products), social issues (drug addiction and dependence, poor compliance, dementia, lack of financial means and medical insurance, lack of social support), coexisting illnesses (undiagnosed iron-deficiency anemia, bleeding disorders, planned surgery, or aspirin and clopidogrel intolerance), and abnormal laboratory results (profound anemia, renal failure, hyperglycemia, hyperkalemia, and acidemia). It is all too frequent that the interventional cardiologist at the end of the procedure will state, "...I wish I knew that!"

Indeed, speed can compromise care on many other avenues (like trying to save time on essential patient-supporting measures such as mechanical ventilation, transvenous pacing, intra-aortic counterpulsation when these are required; or attempting challenging anatomy with inappropriate guiding catheter size or shape or suboptimal wiring). In this report the authors attempt to analyze the appropriateness of the decision-making process

with regard to the four key clinical decisions: CLA, use of glycoprotein IIb/IIIa inhibitor (GPI), PCI, and drug-eluting stent (DES) deployment. Since there is no clear consensus regarding the definitions of appropriateness, the authors attempt to define their perception of appropriateness, which is the basis of this analysis.

## 2. Methods

### 2.1. Patients

Analyzed were 88 consecutive patients enrolled in a registry to determine time intervals and outcomes for patients admitted using the wireless network activation.

### 2.2. Analysis of appropriateness

Analysis of appropriateness was performed in view of patient history and physical examination, previous medical records and imaging studies, admitting laboratory work, and echocardiogram. Social (including insurability, compliance, and drug addiction) and religious issues were not ascertained due to the difficulty to determine their impact on outcomes.

### 2.3. Criteria for appropriateness

Procedures and therapy in individual patients were categorized according to three categories: appropriate, when the authors believed the benefit is likely to exceed the risk of the therapy; borderline appropriate, when the procedure has marginal clinical justification and the potential benefit is in question; and inappropriate, when the expected harm exceeds any benefit.

### 2.4. Cath-lab activation

Cath-lab activation was viewed as appropriate when both typical chest pain and EKG changes (consistent with EKG criteria for STEMI based on fibrinolysis criteria) were present. They were rendered borderline if the EKG criteria did not meet the fibrinolysis criteria but demonstrated ST shifts and defined inappropriate when there was either no change from baseline EKG or that the EKG did not demonstrate any significant ischemic changes.

### 2.5. Glycoprotein IIb/IIIa inhibitor

GPIs were rendered appropriate only for major vessels (dominant proximal mid and distal RCA, proximal mid and distal LAD, proximal circumflex, mid or distal dominant circumflex), if time from onset of pain <12 h, and there are no increased bleeding propensity. Bleeding propensity markers were any of the following: age >80, renal dysfunction with creatinine  $\geq 1.8$ , hepatic failure with

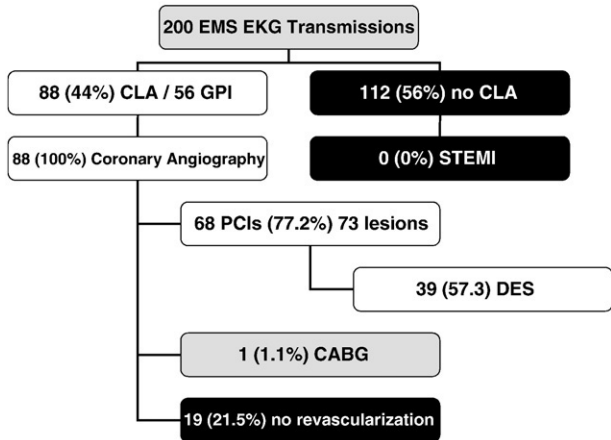


Fig. 1. Study flow.

INR >1.5, hemoglobin <10, or any two of the following: hemoglobin <12, female, age >70.

2.6. PCI

PCI was rendered inappropriate when the risk of the PCI outweighed the benefit; for example, performing side-branch PCI after >12 h of chest pain or in severe renal insufficiency. Performing non-infarct-related lesion or artery PCI during primary PCI was considered “borderline” if there were no clear contraindications for PCI (this may be “overforgiving” in view of current guidelines).

2.7. DES

The authors considered appropriate use of DES in STEMI in patients who are prone to restenosis and had any one of the following criteria: diabetes mellitus, chronic renal insufficiency, lesion length >20 mm, reference diameter ≤3 mm (even though the benefit of DES for STEMI in these patients was never demonstrated in a randomized clinical trial, it is assumed that these patient subsets will be more prone to restenosis). The authors also rendered patients with history of gastrointestinal bleeding, unexplained hemoglobin of

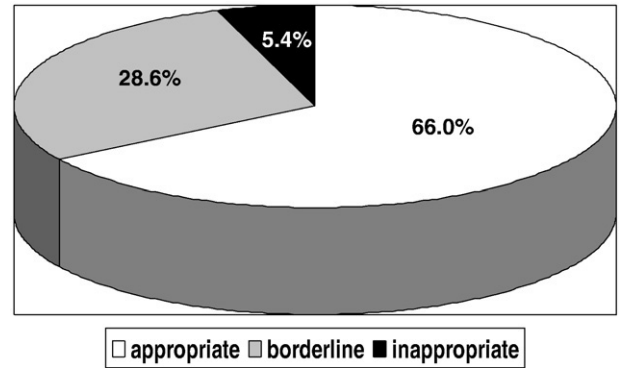


Fig. 3. Appropriateness of GPI use.

<10, or planned major cardiac or noncardiac surgery unsuitable candidates for DES.

3. Results

Between June 2006 and December 2007, 200 EKGs with suspected STEMI were transmitted from mobile intensive care units via the wireless network. Eighty-eight (44%) resulted in CLA (Fig. 1). Mean age was 55.7, 19.3% were female, and 26.1% were diabetic. Physician notification occurred on average 15.7 min prior to patient hospital arrival. Mean time from patient arrival to arterial access averaged 43.7 min. Compared to prior year, DTI times decreased from 145.7 to 69.9 min ( $P=0.0001$ ). DTI was longer during nights and weekends (87.5 vs. 51.8 min,  $P=0.001$ ) and the initial 6 months of the registry (86.8 vs. 66.8 min,  $P=0.07$ ). Sixty-nine (78.4%) had STEMI while 19 patients (21.6%) did not require revascularization. Fifty-six (63.6%) received GPIs, and 67 patients (76.1%) underwent at least one vessel PCI. At least one DES was used in 39 patients (60% of PCI cohort).

When assessed for appropriateness (Figs. 2–5), CLA was appropriate in 81.8% of the time and rendered borderline or inappropriate in 5.7% and 12.5%, respectively. GPI use was appropriate (large ischemic territory at risk with acceptable

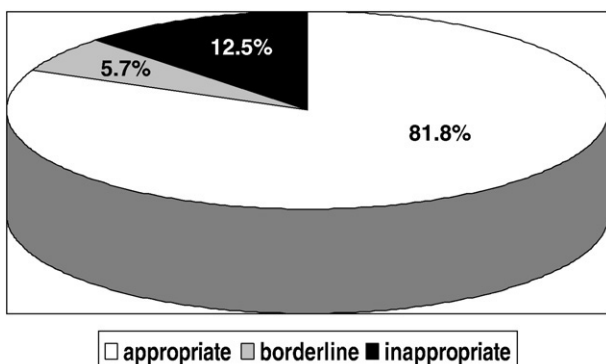


Fig. 2. Appropriateness of CLA.

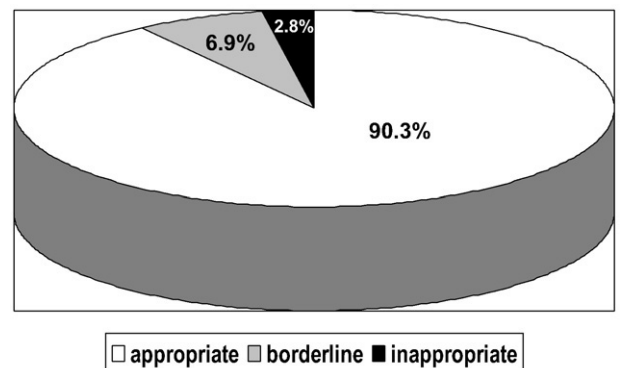


Fig. 4. Appropriateness of PCIs (per lesion).

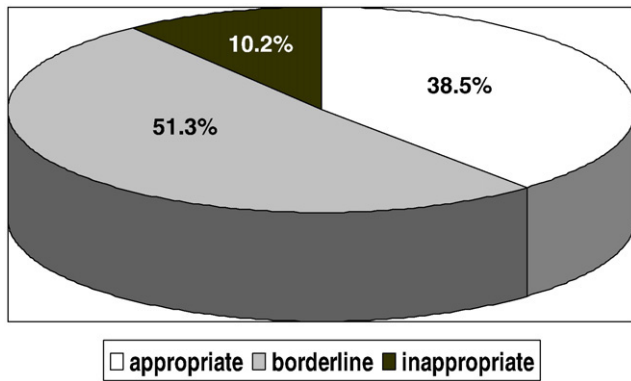


Fig. 5. Appropriateness of DES use.

bleeding propensity) in 66% of the patients but seemed borderline or inappropriate in 28.5% and 5.4%, respectively. GPI use was exclusively eptifibatide and abciximab in 89.3% and 10.7%, respectively. Abciximab was only used in the initial 8 months of the registry. Only 13 (23%) patients received their GPI prior to arrival in the cath lab mostly during the first year of the registry. “Bolus only” or abbreviated eptifibatide infusion ( $\leq 8$  h) after the initial bolus was used in 31 (55%) of 56 patients.

PCI was rendered appropriate in 90% of the lesions treated and borderline or inappropriate in 7.1% and 2.9%, respectively. Three of these five cases viewed as borderline-appropriate PCI were related to second non-infarct-related lesion done during primary PCI. DES deployment was viewed appropriate in 38.5%, and borderline or inappropriate in 51.3% and 10.2%, respectively.

Table 1 shows the frequency of abnormal baseline laboratory results (usually not available during PCI) that could potentially have an impact on the decision process.

#### 4. Discussion

This study attempts to evaluate the performance of primary PCI in a new way. While many studies have engaged in an attempt to assess timeliness and outcome (using clinical

or laboratory endpoints) of primary PCI, this study engages in an attempt to analyze appropriateness.

Inappropriate use of therapeutic modalities may carry an immediate clinical impact (like excessive bleeding with GPI) or a delayed impact (like excessive very late in-stent thrombosis or bleeding with DES). Beyond the potential clinical effect on patient outcome, uniformly any one of the four elements assessed (CLA, GPI, PCI and DES) carries a considerable and measurable impact on immediate costs as well as delayed spending (like the indefinite use of dual antiplatelet therapy for DES).

##### 4.1. Inappropriate CLA

In a previous multicenter report, Larson et al. [3] reported that 14% (95% CI, 12.2–16%) of 1335 patients suspected as having STEMI had no culprit lesion, whereas 9.5% had no coronary artery disease and 11.2% had negative cardiac biomarkers. Prasad et al. [4] reported that among 594 patients referred for primary PCI, 13% had normal coronaries, whereas an additional 1.5% had no discernable culprit lesion. These authors suggested that in retrospect only 55% of these patients had EKG criteria qualifying for STEMI. In our report, inappropriate CLA occurred in 12.5% based either on absence of EKG criteria for STEMI or on the presence of similar previous EKG in the hospital electronic files (MUSE). We referred to cases as borderline (5.7%) if no culprit lesion was found; however, EKG criteria for STEMI were met and there was no previous EKG to compare to or significant EKG change has occurred. With the exception of lack of EKG criteria and typical EKG evolution, we could not identify any demographic or clinical predictors for patients who eventually did not require a PCI. Having the availability to view hospital EKG records could have substantially reduced inappropriate CLA and coronary angiography.

##### 4.2. GPI

To date, not even a single randomized clinical trial showed mortality benefit for the use of GPI in primary PCI. Pooled data from 6 STEMI RCTs did not detect significant mortality reduction [5]. Myocardial infarction at 30 days was

Table 1  
The frequency and effect of abnormal admission blood tests

| Admission labs                             | Frequency | Favors LHC/PCI <sup>b</sup> | Favors GPI <sup>c</sup> | Favors DES <sup>d</sup> |
|--|-----------|-----------------------------|-------------------------|-------------------------|
| Glucose >200                               | 22.7%     | None                        | ++                      | +++                     |
| Potassium >6                               | 2.3%      | -/-                         | None                    | None                    |
| Hemoglobin <12                             | 18.2%/    | -/-                         | -                       | -                       |
| Hemoglobin <10                             | 4.5%      | --/--                       | --                      | --                      |
| Creatinine >1.9                            | 10.2%     | --/--                       | -                       | ++                      |
| Elevated CPK and TnI                       | 25%       | -/-                         | None                    | -                       |
| Platelets <100,000                         | 0%        | -/-                         | --                      | ---                     |
| Bicarbonate <17                            | 10%       | -/-                         | None                    | None                    |
| Positive drug screen (applied selectively) | 9.1%      | None                        | None                    | --                      |

LHC, left heart catheterization; CPK, creatine phosphokinase; TnI, troponin I.

significantly reduced by 2.3% (4.6% vs. 6.9%; RR, 0.63; CI, 0.56–0.70) at the cost of excessive major bleeding [increased by 1.4% (4.6 vs. 3.2; RR, 1.26; CI, 1.09–1.46)] and with no accounting for the excessive thrombocytopenia, minor bleeding, vascular complications, transfusions or allergic reactions. Multivariate and propensity analyses [6] compared the combined end point of in-hospital death, reinfarction, and major bleeding in 38,691 patients in the National Registry of Myocardial Infarction-4 (2000–2003); 65% received GPI only, 16.1% clopidogrel only, and 18.8% received both. The event rate was higher among patients who received both drugs than clopidogrel alone (odds ratio, 1.31; 95% CI, 0.99–1.72). GPIs still receive a IIa–IIb [7] recommendation (abciximab vs. eptifibatid and tirofiban) in the recently published European STEMI guidelines.

Since there is no compelling reason to use these agents, they should be reserved especially for high-risk patients (diabetics, heart failure, cardiogenic shock) with extensive infarct territory, undergoing complex PCI in the absence of high bleeding propensity. We believe that even though our definitions for appropriateness allowed liberal use of GPI, there was still excessive inappropriate use of these agents.

Three notable trends are seen in this registry: (1) reduction of early (preangiogram) administration of GPI especially in view of abbreviated door-to-arterial access time (in the spirit of the FINESSE trial [8]); (2) use of eptifibatid almost exclusively in view of concern of thrombocytopenia and cost containment; (3) “bolus only” or bolus and abbreviated (6–12 h) drip protocols to “bridge” to platelet inhibition by clopidogrel.

#### 4.3. PCI

Only two procedures were rendered inappropriate. While five procedures were viewed as borderline appropriate, three of these were procedures were done on critical lesions of a non-infarct-related lesion or artery with relatively low risk. The recently published guidelines render PCI of the non-infarct-related lesion or artery as inappropriate [9]. There are however very limited scenarios in which such PCI could be justified. While the observed injudicious use of PCI is relatively low, the number can considerably rise in nonselective cohorts of primary PCI and can be further escalated in a noncommunicating patient (stroke, mechanical ventilation, dementia or language barrier) in the absence of readily available laboratory data (like chemistry and cardiac markers) and absence of in-lab echocardiography.

#### 4.4. DES

In a meta-analysis [10] of eight randomized clinical trials of DES in STEMI ( $n=2786$ , most patients limited to 12 months follow-up), there was no significant reduction in mortality or stent thrombosis in patients receiving DES. The major benefit observed from DES use was 8.1% absolute reduction in reintervention (5% vs. 13.1%; HR,

0.38; 95% CI, 0.29–0.50). Certain registries have documented the safety of DES up to 6–12 months in various clinical setups including myocardial infarctions [11]. Concerns continue to emerge regarding excess of very late stent thrombosis (beyond 12 months) with DES [12]. A recent GRACE registry report disclosed that unadjusted mortality for DES was slightly lower (5.3% vs. 3.9%,  $P=.04$ ); however, excessive mortality after DES deployment (when compared to BMS) was noted between 12 and 24 months (HR, 7.06;  $P=.002$ ) [13]. The 3-year follow-up of the BASKET trial suggests the advantage of DES over BMS is limited to stents  $\leq 3$  mm in diameter [14]. This has prompted an international committee to suggest conservative use of DES in STEMI until more data become available [15].

Although very liberal definition of “appropriate use” was incorporated into this study, the data suggest that unjustifiable use of DES is still excessive.

#### 4.5. Cost containment

Primary PCI is considered among the most cost-effective procedures in interventional cardiology. Cost-effectiveness can be considerably diminished by adding cost without considerable impact on outcome (this analysis viewed borderline or inappropriate use of therapy as unjustifiable expense). In view of current US pricing, the immediate excess of cost for a single DES over BMS is \$1300. This does not take into account the excessive cost of prolonged dual antiplatelet therapy. Although DES reduces the requirement for a repeat procedure in STEMI, it is possible that this benefit is overridden by the excess of bleeding complications seen in most randomized clinical trials that exposed subjects to prolonged dual antiplatelet therapy. Using very liberal definition of appropriateness, 19 patients (1/3 of the patients receiving GPI) did not receive this therapy appropriately. Individual cases treated with GPI resulted in cost excess of \$1177–1765 (for bolus and drip eptifibatid and abciximab, respectively).

#### 4.6. Future refinements

It is the authors’ opinion that these four major primary PCI decisions should be individualized bearing in mind the patient demographic, clinical, and laboratory characteristics. Any attempt to apply a unified strategy to all STEMI patients is likely to harm certain patients and reduce cost-effectiveness. The role of the interventional cardiologist is to extract patient and event information and individualize decisions. The optimal cath lab should provide the interventionalist immediate access to previous medical records, EKGs, and imaging studies. Laboratory results that may have immediate impact on the decision process (hemoglobin, creatinine, cardiac markers) should be available immediately. Table 1 shows the frequency of abnormal lab results and their impact on the decision process. To complement anatomic and functional data, in-lab echocardiography should be available

especially in complex or clinically vague presentations. Modified “time out” routines can further assist the interventionalist in the decision process. It is time to assess not only how fast we do primary PCI but also how appropriate and cost-effective is our PCI service.

## 5. Limitations of the study

- This is a retrospective chart review of a selective STEMI cohort that may not necessarily represent the entire primary PCI cohort.
- Definitions of appropriateness have been decided among the authors according to their interpretation of current medical knowledge but do not reflect an international consensus.
- Certain issues (mostly socioeconomic issues) that carry a major impact on appropriateness (especially on multiyear commitment like DES) could not be accounted for in appropriateness analysis due to inherent complexity.

## 6. Conclusions

- With the authors' current understanding of appropriateness, it is very likely that inappropriate use of costly and potentially harmful therapy (like DES and GPI) occurs frequently in the setting of primary PCI, although criteria for appropriateness should be better defined.
- Since certain therapeutic decisions during primary PCI should be individualized based on patient data, rapid access to previous medical records (reports EKGs, imaging studies), and in-lab blood analysis and echocardiography can potentially enhance the decision process and subsequently reduce cost and improve patient outcome.

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