Door to Balloon: The Big Deal

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Lecture Outline

- Pathophysiology of ACS
- History
- Door to balloon - ? The big deal
Myocardial ischaemia
Figure 1. The iceberg of coronary mortality. Only a minority of patients are enrolled in clinical trials.
Anatomy of the Atherosclerotic Plaque

- Lumen
- Intima
- Media
- Elastic laminae
- Internal
- External
- Lipid Core
- Fibrous cap
- Shoulder
The Evolution of Atherosclerosis

- **Foam Cells**
  - From 1st Decade
  - Growth Mainly by Lipid Accumulation

- **Fatty Streak**
  - From 3rd Decade
  - Smooth Muscle & Collagen

- **Intermediate Lesion**
  - From 4th Decade
  - Thrombosis, Hematoma

- **Atheroma**
  - Fibrous Plaque

- **Complicated Lesion/Rupture**

Time is gold .... myocardium
Cardiac Biomarkers of ACS – Troponin
Cardiac marker release after ACS

ESC guideline 2007
Troponin and risk involved

TIMI III B. Antman EM. NEJM 335:1342, 1996
Adverse Outcome by Initial ECG in ACS

- ST Elevation and Depression: n=78
- ST Depression Only: n=216
- ST Elevation Only: n=93
- T Wave Inversion Only: n=287
- No ST or T Wave Change: n=237

Death or MI % vs. Days
History

- Andreas Gruentzig (1939 – 1985)
History

The patient immediately agreed to Dr. Gruentzig's proposal because he happened to be sharing his hospital room with a patient recovering from bypass surgery. Having already been told that he would require surgery, approval came quickly when Gruentzig said he could take care of a stenosis without surgery. It seemed like a miracle.

Once the patient consented, the procedure was planned for the next day. Gruentzig thought he would need a perfusion pump during balloon inflation. At that time, no one had ever blocked a coronary artery in a conscious human being, so the pump was considered necessary to prevent fibrillation. He inserted the balloon catheter into the stenosis, with an ease that surprised even himself, and the patient tolerated the inflation very well. Indeed, when Gruentzig inflated his balloon, nothing happened—except that the patient no longer had angina. The balloon pump was never used.

The outcome in that first patient was excellent; he went from being seriously ill to healthy in a matter of minutes. I have followed this patient right up to the present day; he is now 63 years old and has never developed restenosis in that first lesion—a perfect result.
Our typical day

- Stent insertion
- Stent expansion
- Stent remains in coronary artery
Was it the cow tail soup?
Effect of Door-to-Balloon Time on Mortality in Patients With ST-Segment Elevation Myocardial Infarction

Robert L. McNamara, MD, MHS,* Yongfei Wang, MS,* Jeph Herrin, PhD,* Jeptha P. Curtis, MD,* Elizabeth H. Bradley, PhD,† David J. Magid, MD, MPH,§ Eric D. Peterson, MD, MPH,¶ Martha Blaney, PHARMD,# Paul D. Frederick, PhD,** Harlan M. Krumholz, MD, SM,†††† for the NRMI Investigators

*New Haven, Connecticut; Denver, Colorado; Durham, North Carolina; South San Francisco, California; and Seattle, Washington

OBJECTIVES We sought to determine the effect of door-to-balloon time on mortality for patients with ST-segment elevation myocardial infarction (STEMI) undergoing primary percutaneous coronary intervention (PCI).

BACKGROUND Studies have found conflicting results regarding this relationship.

METHODS We conducted a cohort study of 29,222 STEMI patients treated with PCI within 6 h of presentation at 395 hospitals that participated in the National Registry of Myocardial Infarction (NRMI)-3 and -4 from 1999 to 2002. We used hierarchical models to evaluate the effect of door-to-balloon time on in-hospital mortality adjusted for patient characteristics in the entire cohort and in different subgroups of patients based on symptom onset-to-door time and baseline risk status.

RESULTS Longer door-to-balloon time was associated with increased in-hospital mortality (mortality rate of 3.0%, 4.2%, 5.7%, and 7.4% for door-to-balloon times of ≤90 min, 91 to 120 min, 121 to 150 min, and >150 min, respectively; p for trend <0.01). Adjusted for patient characteristics, patients with door-to-balloon time >90 min had increased mortality (odds ratio 1.42; 95% confidence interval [CI] 1.24 to 1.62) compared with those who had door-to-balloon time ≤90 min. In subgroup analyses, increasing mortality with increasing door-to-balloon time was seen regardless of symptom onset-to-door time (≤1 h, >1 to 2 h, >2 h) and regardless of the presence or absence of high-risk factors.

CONCLUSIONS Time to primary PCI is strongly associated with mortality risk and is important regardless of time from symptom onset to presentation and regardless of baseline risk of mortality. Efforts to shorten door-to-balloon time should apply to all patients. (J Am Coll Cardiol 2006;47: 2180–6) © 2006 by the American College of Cardiology Foundation
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Importance of Prompt Treatment

Prompt treatment increases the likelihood of survival for patients with myocardial infarction with ST-segment elevation (Berger et al., 1999; Cannon et al., 2000, McNamara et al., 2006).

![Graph showing the relationship between door-to-balloon time and in-hospital mortality.](image)
Time and Myocardial Salvage

Potential outcomes:
- A → B: no benefit
- A → C: benefit
- B → C: benefit
- E → D: harm

Mortality Reduction (%)

Time to treatment is critical

Opening the artery is the primary goal (PCI > lysis)

Gersh et al. JAMA 2005;293:979
How to Overcome This?
Practice does not meet national guidelines, and performance is not improving.
National trend in median door-to-balloon time, 1999-2003

McNamara et al, JACC, 2006
Identified achievable process

Bradley et al, JACC, 2005
Please Complete Your Follow Up Survey

By now all D2B Alliance hospitals should have received an email with the D2B Follow Up Survey link. **We urge you to please complete your follow up online survey.** It should take only about 20 minutes. This information will help us understand your institution’s experience and improve future initiatives. Please help us achieve 100% participation!

For additional information, you can contact Matthew Fitzgerald at mfitzger@acc.org. Thank you for your time and consideration of this important initiative.

What is D2B?

D2B: An Alliance for Quality™ is a new Guidelines Applied in Practice (GAP) program launched by the American College of Cardiology (ACC) to save time and save lives by reducing the door-to-balloon times in U.S. hospitals performing primary PCI. A growing list of other organizations, including the American Heart Association (AHA) and the National Heart, Lung, and Blood Institute, are partners in this effort.
Characteristics of good D2B hospitals (< 90 mins)

- An explicit goal of reducing door-to-balloon times
- Visible support of senior management
- Innovative, standardized protocols
- Flexibility in implementing standardized protocols
- Uncompromising individual clinical leaders
- Collaborative interdisciplinary teams
- Data feedback to monitor progress and identify problems or successes
- Organizational culture that fostered persistence despite challenges and setbacks

Bradley et al. (Circulation 2006)
Institutional resources

- Primary PCI is the routine treatment for eligible STEMI patients 24 hours a day, 7 days a week
- Primary PCI is performed as soon as possible
- Institution is capable of providing supportive care to STEMI patients and handling complications
- Written commitment by hospital administration to support the program
  - Identifies physician director for PCI program
  - Creates multidisciplinary group that includes input from all relevant stakeholders, including cardiology, emergency medicine, nursing, and EMS
- Institution designs and implements a continuing education program
- For institution without on-site surgical backup, there is a written agreement with tertiary institution and EMS to provide for rapid transfer of STEMI patients when needed
Physician and Program requirements

- Interventional cardiologists meet ACC/AHA criteria for competence
- Interventional cardiologists participate in, and are responsive to formal on-call schedule
- Minimum of 36 primary PCI procedures and 400 total PCI procedures annually
- Program is described in a "manual of operations" that is compliant with ACC/AHA guidelines
- Mechanisms for monitoring program performance and ongoing quality improvement activities
Other features of ideal system

- Robust data collection and feedback including door-to-balloon time, first door-to-balloon time (for transferred patients), and the proportion of eligible patients receiving some form of reperfusion therapy
- Earliest possible activation of the cardiac cath lab, based on prehospital ECG whenever possible, and direct referral to PCI-hospital based on field diagnosis of STEMI
- Standardized ED protocols for STEMI management
- Single phone call activation of cath lab that does not depend on cardiologist interpretation of ECG
Gaps and barriers to timely access to primary PCI

- Busy PCI hospitals may have to divert patients
- Significant delays in ED diagnosis of STEMI may occur, particularly when patient does not arrive by EMS
- Manpower and financial considerations may prevent smaller PCI programs from providing primary PCI for STEMI 24 hours a day
- Reimbursement for optimal coordination of STEMI patients needs to be realigned to reflect performance
- In most PCI centers, cath lab staff is off-site during off hours, requiring a mandate that staff report with 20-30 minutes of cath lab activation

Granger et al. (Circulation 2007)
Strategy: systems & roles

- Use of ambulance ECG – for clear STEMI – for early alert
- Direct activation of Cath Lab by ED – for clear STEMI
- ED target < 10 minutes for ECG, < 20 minutes to notify Cath Lab
- Clear expectations for staff Cath Lab arrival time
- Pre-stocked STEMI cart in Cath Lab

D2B : Massachusetts General Hosp
Identified achievable benchmarks

<table>
<thead>
<tr>
<th>Step</th>
<th>Minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. EMS arrives with patient at triage in ED; STEMI confirmed</td>
<td>0 5 10 15 20 25 30 35 40 45 50 55 60</td>
</tr>
<tr>
<td>2. ED stabilizes patient; initiates MI protocol; communicates with cath lab</td>
<td>Patient arrives in ED</td>
</tr>
<tr>
<td>3. ED transports patient to cath lab</td>
<td>Patient arrives in cath lab</td>
</tr>
<tr>
<td>4. Final check and written consent</td>
<td>Patient reperfusion</td>
</tr>
<tr>
<td>5. Catheterization and PCI</td>
<td></td>
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<tr>
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<th>Minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Pt arrives in ED, ECG is completed, ED physician diagnoses STEMI</td>
<td>0 5 10 15 20 25 30 35 40 45 50 55 60 65 70 75 80</td>
</tr>
<tr>
<td>2. ED calls operator to page on-call cath lab staff and interventionalist</td>
<td>Patient arrives in cath lab</td>
</tr>
<tr>
<td>3. ED stabilizes pt; initiates MI protocol; communicates with cath lab</td>
<td>Patient reperfusion</td>
</tr>
<tr>
<td>4. Cath lab staff and interventionalist go to end arrive at cath lab</td>
<td></td>
</tr>
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</tr>
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Bradley et al, JACC, 2005
# Key strategies associated with reduced D2B times

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<tr>
<th>Strategies</th>
<th>Minutes saved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activate lab with EM physicians (23% do this)</td>
<td>8.2 minutes</td>
</tr>
<tr>
<td>Activate w/single call from ED to operator (14%)</td>
<td>13.8 minutes</td>
</tr>
<tr>
<td>Activate based on information from pre-hospital ECG while patient is still en route to hospital (9%)</td>
<td>15.4 minutes</td>
</tr>
<tr>
<td>Expect cath team to arrive in 20-30 mins (13%)</td>
<td>19.3 minutes</td>
</tr>
<tr>
<td>Provide real-time data feedback to ED/lab (42%)</td>
<td>8.6 minutes</td>
</tr>
<tr>
<td>Have attending cardiologist always on site (4%)</td>
<td>14.6 minutes</td>
</tr>
</tbody>
</table>

Effective Strategies

Study finds six hospital interventions significantly reduce door-to-balloon times

Door-to-balloon times reduced by...

8.2 minutes
- Having ED physician activate the cath lab

8.6 minutes
- Providing real-time feedback to ED and cath lab staff

13.8 minutes
- Using a single-call page system

14.6 minutes
- Staffing a full-time attending cardiologist on site

15.4 minutes
- Having EMS diagnoses STEMI en-route to the hospital and alert the ED

19.3 minutes
- Requiring cath lab staff to arrive within 20 minutes of being paged

Source: Bradley et al., NEJM, 11/30/06

Bradley et al, NEJM, 2006
<table>
<thead>
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<th>Strategies</th>
<th>Hospitals (%)</th>
<th>Median DTB</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>137 (38.8)</td>
<td>110</td>
</tr>
<tr>
<td>1</td>
<td>130 (35.9)</td>
<td>100</td>
</tr>
<tr>
<td>2</td>
<td>56 (15.5)</td>
<td>88</td>
</tr>
<tr>
<td>3</td>
<td>31 (8.6)</td>
<td>88</td>
</tr>
<tr>
<td>4</td>
<td>8 (2.2)</td>
<td>79</td>
</tr>
</tbody>
</table>

Overall P value for trend: < .001

Bradley et al, NEJM, 2006
Yearly average and median DTB

Year

- 2004
- 2005
- 2006
- 2007

D2B : Massachusetts General Hosp
D2B Alliance recommendations to achieve goal of 75% within 90 minutes

- Evidenced-based strategies:
  - ED physician activates the catheterization lab
  - One call activates the catheterization lab
  - Catheterization team ready in 20 – 30 minutes
  - Prompt data feedback
  - Senior hospital management commitment
  - Team-based approach
  - Optional: Activate based on pre-hospital ECG
Summary

Time is myocardium
Door to balloon time of < 90 minutes is achievable
Adopt the recommended strategies to ensure D2B
Thank you
Effect of Door-to-Balloon Time on Patient Mortality

The study by McNamara et al. (1) from the National Registry of Myocardial Infarction (NRFMI) found that door-to-balloon time (DBT) was strongly associated with mortality in both high- and low-risk patients and in patients presenting early or late after the onset of symptoms. These findings differ from our analysis from a large randomized trial and a single-center registry, both of which found that DBT impacts mortality primarily in high-risk patients and in those presenting early after the onset of symptoms (2,3).

Several possible explanations account for these differences. Prolonged DBT may be confounded with other unmeasured variables that impact mortality. First, DBT may be a surrogate for quality of care—hospitals with long DBTs may provide suboptimal treatment. Data from single-center registries and randomized trials would be less likely to have this bias. Second, NRMI data on time from symptom onset to presentation collected from retrospective chart reviews may be unreliable because the time of symptom onset is often not documented in hospital charts. This is less of a problem in randomized trials or carefully constructed prospective registries. Finally, and perhaps most importantly, prolonged DBTs often reflect the underlying severity of illness, with “sicker” patients requiring longer time for evaluation, stabilization, or treatment of complications prior to percutaneous coronary intervention (PCI) (e.g., cardiopulmonary resuscitation, intubation, defibrillation, or insertion of temporary pacemakers or intra-aortic balloon pumps). These confounding variables are deprives these patients of the benefits of higher rates of reperfusion, less reinfarction, less intracranial hemorrhage, and in many cases lower mortality. A recent meta-analysis of randomized trials with primary PCI versus fibrinolysis has shown primary PCI reduced mortality even with treatment delays up to 2 h (4). Decisions regarding triage of patients for primary angioplasty should thus be based on an assessment of time and risk, and should utilize common sense. High-risk patients presenting early after the onset of symptoms with long delays to primary PCI are probably best treated with fibrinolytic therapy. Most other patients are best treated with transfer for primary PCI despite longer treatment delays.

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