The Dissociation Between Door-to-Balloon Time Improvement and Improvements in Other Acute Myocardial Infarction Care Processes and Patient Outcomes

Tracy Y. Wang, MD, MHS; Gregg C. Fonarow, MD; Adrian F. Hernandez, MD; Li Liang, PhD; Gray Ellrodt, MD; Brahmajee K. Nallamothu, MD, MPH; Bimal R. Shah, MD, MBA; Christopher P. Cannon, MD; Eric D. Peterson, MD, MPH

Background: Recent initiatives have focused on reducing door-to-balloon (DTB) times among patients with acute myocardial infarction undergoing primary percutaneous coronary intervention. However, DTB time is only one of several important AMI care processes. It is unclear whether quality efforts targeted to a single process will facilitate concomitant improvement in other quality measures and outcomes.

Methods: This study examined 101 hospitals (43,678 patients with AMI) in the Get With the Guidelines program. For each hospital, DTB time improvement from 2005 to 2007 was correlated with changes in composite Centers for Medicare and Medicaid Services/Joint Commission on Accreditation of Healthcare Organizations (CMS/JCAHO) core measure performance and in-hospital mortality.

Results: Between 2005 and 2007, hospital geometric mean DTB time decreased from 101 to 87 minutes (P<.001). Mean overall hospital composite CMS/JCAHO core measure performance increased from 93.4% to 96.4% (P<.001), and mortality rates were 5.1% and 4.7% (P=.09) in the early and late periods, respectively. Improvement in hospital DTB time, however, was not significantly correlated with changes in composite quality performance (r=-0.06; P=.55) or with in-hospital mortality (r=.06; P=.58). After adjustment for patient mix, hospitals with the most improvement in DTB time did not have significantly greater improvements in either CMS/JCAHO measure performance or mortality.

Conclusions: Within the Get With the Guidelines program, DTB times decreased significantly over time. However, there was minimal correlation between DTB time improvement and changes in other quality measures or mortality. These results emphasize the important need for comprehensive acute myocardial infarction quality-improvement efforts, rather than focusing on single process measures.

Arch Intern Med. 2009;169(15):1411-1419

Mean overall hospital composite CMS/JCAHO core measure performance increased from 93.4% to 96.4% (P < .001), and mortality rates were 5.1% and 4.7% (P = .09) in the early and late periods, respectively. Improvement in hospital DTB time, however, was not significantly correlated with changes in composite quality performance (r = -0.06; P = .55) or with in-hospital mortality (r = 0.06; P = .58). After adjustment for patient mix, hospitals with the most improvement in DTB time did not have significantly greater improvements in either CMS/JCAHO measure performance or mortality.

Yet, DTB time is only one of several acute myocardial infarction (AMI) quality measures and within-hospital performance on separate AMI metrics varies markedly. The underlying assumption of campaigns such as the D2B Alliance is that targeted improvement of a single care process may facilitate improvements in other care measures and outcomes. On the one hand, hospitals that improve DTB times likely do so via multidisciplinary collaborations which may, in turn, stimulate broad-scale process improvement across a variety of acute and secondary prevention therapies. On the other hand, singular attention on a given measure may detract a hospital from monitoring or improving other important care processes and outcomes. More broadly, it is also unclear whether and to what extent improvements in given care processes will be associated with measurable improvement in patient outcomes.
Thus, we analyzed hospitals participating in the American Heart Association Get With the Guidelines (AHA GWTG) program to correlate temporal trends in DTB times to performance of other quality measures, including both CMS/JCAHO core measures as well as other ACC/AHA guideline-recommended measures.10 We further assessed the relationship between improvements in DTB time, changes in other AMI performance measures, and overall in-hospital mortality.

**METHODS**

**DATA SOURCE**

The AHA GWTG program is a large, national observational registry started in 2000 to support and facilitate quality improvement in the care of patients with cardiovascular disease. Details of GWTG have been described previously.10 In brief, the GWTG coronary artery disease program enrolls patients hospitalized with a confirmed diagnosis of coronary artery disease (International Classification of Diseases, Ninth Revision codes 410-414). Trained data abstractors at participating GWTG hospitals collect detailed information on baseline demographic and clinical characteristics, in-hospital care processes and outcomes, and discharge treatment using a standardized set of data elements and definitions.13 Data are collected via a Web-based patient management tool (PMT; Outcome Sciences Inc, Cambridge, Massachusetts) that provides decision support with real-time online reporting features. With this Internet-based data entry system, data quality is monitored to assure completeness and accuracy of the submitted data. Because collected data are primarily used for institutional quality improvement and deidentified patient information is collected anonymously through retrospective medical record review, individual informed consent is not required under the common rule. However, participation in GWTG requires approval of the institutional review board of each hospital.

**STUDY POPULATION**

To best capture the impact of the ACC D2B campaign on hospital performance, we examined two 1-year periods before and after national introduction of the D2B Alliance, which resulted in an early period from January to December 2005 and a later period from July 2006 to June 2007 (Figure 1). We restricted this analysis to GWTG hospitals that submitted at least 20 AMI patient records in each period to define a threshold for stable hospital-level performance assessment, as well as to GWTG hospitals that reported DTB times in both the early and later periods (285 hospitals excluded). This yielded a total of 101 hospitals of varying size, teaching status, and surgical capability from all census regions of the United States. All 43,678 patients treated for AMI at these hospitals were included in the assessment of process measure performance.

To examine hospital-level changes in DTB time across periods, we excluded patients with non-STEMI (n=29,843), patients not treated with primary PCI (n=3,839), patients transferred in from other hospitals for primary PCI (n=2,900), patients with missing arrival or PCI times (n=371), and patients who received primary PCI more than 12 hours after hospital arrival (n=844). The final population for DTB time assessments included 5,881 DTB-eligible patients with STEMI undergoing primary PCI, among which 3,278 and 2,603 patients were treated in the early and later periods, respectively.

**STATISTICAL METHODS**

We evaluated hospital performance of the following process measures: (1) geometric mean DTB time; (2) CMS/JCAHO core pro-

---

**Figure 1. Flowchart of study population. AMI indicates acute myocardial infarction; DTB, door-to-balloon; GWTG, Get With the Guidelines; PCI, percutaneous coronary intervention; and STEMI, ST-segment elevation myocardial infarction.**
cess measures, which included aspirin and β-blocker use at admission and discharge, angiotensin-converting enzyme-inhibitor or angiotensin receptor blocker use at discharge among patients with an ejection fraction lower than 40%, in-hospital smoking cessation counseling, and door-to-needle time of 30 minutes or less; and (3) ACC/AHA guideline recommended measures which included, in addition to the aforementioned measures, in-hospital low-density lipoprotein assessment, lipid-lowering therapy use at discharge, clopidogrel use at discharge, cardiac rehabilitation referral, and dietary/weight management counseling among patients with a body mass index greater than 25 (calculated as weight in kilograms divided by height in meters squared). Composite process measure performance was calculated as the number of times the selected care process was provided to eligible patients divided by the total number of eligible patients (ie, absence of contraindications) for that measure who were treated at a selected hospital. Patients who died within the first 24 hours (n=855) were excluded from the denominator for assessment of admission process performance, and those who died (n=2068) or were transferred out to another institution for inpatient care (n=1589) were excluded from the discharge process performance assessment. On a hospital level, the median proportions of patients who died within 24 hours, died during hospitalization, and were transferred for further inpatient care did not change significantly between the early and later periods: 1.3%, 4.7%, and 2.1%, respectively, in the early period and 1.3%, 4.5%, and 2.3%, respectively, in the later period.

Changes in DTB time (ΔDTB) and composite process measure performance were calculated as that of the later minus the early period. Although ΔDTB was analyzed as a continuous variable, hospitals were also divided into quartiles by ΔDTB for de-
Improvement in DTB Time

<table>
<thead>
<tr>
<th>Variable</th>
<th>First Quartile</th>
<th>Second Quartile</th>
<th>Third Quartile</th>
<th>Fourth Quartile</th>
<th>P Value for Trend</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitals, No.</td>
<td>25</td>
<td>25</td>
<td>26</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>Patients with AMI, No.</td>
<td>8129</td>
<td>11 322</td>
<td>13 125</td>
<td>11 102</td>
<td></td>
</tr>
<tr>
<td>Demographics, %</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, median (IQR), y</td>
<td>65 (54-76)</td>
<td>67 (55-78)</td>
<td>65 (55-77)</td>
<td>65 (55-77)</td>
<td>.22</td>
</tr>
<tr>
<td>Female sex</td>
<td>34.8</td>
<td>37.2</td>
<td>34.8</td>
<td>36.4</td>
<td>.77</td>
</tr>
<tr>
<td>Non-white race</td>
<td>27.9</td>
<td>19.3</td>
<td>17.9</td>
<td>27.4</td>
<td>.04</td>
</tr>
<tr>
<td>No insurance</td>
<td>9.2</td>
<td>7.4</td>
<td>9.5</td>
<td>13.1</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Clinical history, %</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prior MI</td>
<td>16.9</td>
<td>20.0</td>
<td>16.4</td>
<td>18.3</td>
<td>.12</td>
</tr>
<tr>
<td>Prior HF</td>
<td>12.8</td>
<td>16.5</td>
<td>9.6</td>
<td>12.3</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Prior stroke</td>
<td>7.6</td>
<td>8.1</td>
<td>6.4</td>
<td>7.9</td>
<td>.87</td>
</tr>
<tr>
<td>Peripheral arterial disease</td>
<td>7.9</td>
<td>8.7</td>
<td>8.0</td>
<td>8.0</td>
<td>.61</td>
</tr>
<tr>
<td>Diabetes</td>
<td>30.3</td>
<td>29.6</td>
<td>27.0</td>
<td>28.8</td>
<td>.31</td>
</tr>
<tr>
<td>Hypertension</td>
<td>64.5</td>
<td>62.8</td>
<td>57.9</td>
<td>60.4</td>
<td>.004</td>
</tr>
<tr>
<td>BMI, median (IQR)</td>
<td>28 (24-32)</td>
<td>28 (24-32)</td>
<td>28 (25-32)</td>
<td>28 (24-32)</td>
<td>.003</td>
</tr>
<tr>
<td>Renal insufficiency</td>
<td>9.5</td>
<td>9.5</td>
<td>5.9</td>
<td>8.4</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Systolic BP, median (IQR), mm Hg</td>
<td>135 (116-154)</td>
<td>135 (116-155)</td>
<td>136 (117-155)</td>
<td>134 (116-154)</td>
<td>.51</td>
</tr>
</tbody>
</table>

Abbreviations: AMI, acute myocardial infarction; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); BP, blood pressure; DTB, door-to-balloon; HF, heart failure; IQR, interquartile range; MI, myocardial infarction.

Changes in DTB Time

A total of 43,678 patients were treated for AMI during the 2 study periods, 24,162 early and 19,516 later. Between the early and later periods, DTB times among eligible patients with STEMI undergoing primary PCI improved significantly; hospital geometric mean DTB times decreased from 101 minutes during the early period to 87 minutes in the later period (P < .001). Changes in DTB times, however, varied considerably among US hospitals (Figure 2). When hospitals were stratified by quartiles of DTB, the mean changes in DTB time were −51 minutes, −22 minutes, −8 minutes, and +22 minutes, respectively, for quartiles 1 through 4, with hospitals in the lowest quartile actually having longer DTB times in the later period compared with the early period (P < .001). Changes in DTB times were smaller and less likely to be teaching hospitals and had higher starting DTB times. Baseline patient characteristics were similar among hospitals in each quartile of DTB (Table 2).
Changes in process measure performance and in-hospital mortality stratified by quartiles of change in DTB time

<table>
<thead>
<tr>
<th>Variable</th>
<th>Overall</th>
<th>Improvement in DTB Time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Early</td>
<td>Late</td>
</tr>
<tr>
<td></td>
<td>P Value</td>
<td>Most → Least</td>
</tr>
<tr>
<td>Hospitals, No.</td>
<td>101</td>
<td>101</td>
</tr>
<tr>
<td>Patients with AMI, No. CMS/JCAHO</td>
<td>24162</td>
<td>19516</td>
</tr>
<tr>
<td>core measures, %</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Aspirin at admission                   | 92.3      | 97.4                     | <.001
| Aspirin at discharge                   | 97.8      | 97.6                     | .08
| β-Blocker use at admission             | 88.0      | 95.2                     | <.001
| β-Blocker use at discharge             | 96.5      | 97.1                     | <.001
| ACEI/ARB use at discharge if EF <40%   | 83.4      | 90.9                     | .01
| Time to fibrinolysis <30 min           | 37.4      | 43.8                     | .30
| Smoking cessation counseling           | 92.9      | 96.2                     | <.001
| Composite CMS/JCAHO score             | 93.4      | 96.4                     | <.001
| Other ACC/AHA recommendations, %       |           |                          |
| In-hospital LDL assessment             | 70.7      | 70.3                     | .34
| Lipid-lowering therapy at discharge    | 85.6      | 90.7                     | <.001
| Clopidogrel use at discharge           | 82.8      | 88.7                     | <.001
| Cardiac rehabilitation referral        | 44.9      | 47.3                     | <.001
| Dietary counseling if BMI >25          | 87.9      | 88.2                     | .40
| Composite ACC/AHA score                | 82.0      | 84.2                     | <.001
| In-hospital mortality, geometric mean (95% CI) | 5.1 | 4.7 | .09 | 5.5 | 4.8 | (4.8-5.4) | 4.4 (4.4-4.5) | 4.4 (4.5-5.0) | 4.8 (4.8-6.2) | 4.0 (4.0-5.5) | 5.4 (5.4-6.6) | 4.8 (4.8-6.1) | 3.7 (3.7-4.6) | 3.6 (3.6-4.7) | 4.4 (4.4-5.5) | 4.1 (4.1-5.2)

Abbreviations: ACC/AHA, American College of Cardiology/AHA, American Heart Association; ACEI, angiotensin-converting enzyme inhibitor; AMI, acute myocardial infarction; ARB, angiotensin receptor blocker; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); CI, confidence interval; CMS/JCAHO, Centers for Medicare and Medicaid Services/Joint Commission on Accreditation of Healthcare Organizations; DTB, door-to-balloon; EF, ejection fraction; LDL, low-density lipoprotein.

Table 3 gives the changes in individual care measures for hospitals stratified by ΔDTB. Among the CMS/JCAHO core measures, use of aspirin and β-blockers at admission, use of angiotensin-converting enzyme inhibitors and/or angiotensin receptor blockers among patients with left ventricular systolic dysfunction, as well as delivery of smoking cessation counseling showed the most improvement. Most of the other ACC/AHA guideline recommendations, such as use of lipid-lowering therapy and clopidogrel use at discharge and cardiac rehabilitation referral, also showed significant improvement. Overall, composite CMS/JCAHO core process measure performance improved significantly between the early and later periods, increasing from a mean of 93.4% to 96.4% (P < .001). The performance of the composite ACC/AHA guideline recommended measures also improved from 82.0% to 84.2% (P < .001).

As shown in Figure 3A and B, there was no significant correlation between ΔDTB and changes in process measure performance as assessed by either the composite CMS/JCAHO core process measures (r = -0.061, P = .55) or the composite ACC/AHA guideline recommended measures (r = -0.173; P = .08). This lack of association persisted after multivariable adjustment for differences in patient characteristics (Figure 4A and B).

Correlation between DTB time, process measures, and in-hospital mortality

Overall in-hospital mortality was 5.1 in the early and 4.7% in the later period (P = .09). There was no significant association between improvements in DTB time and changes in mortality (Table 3 and Figure 3C). This lack of asso-
were not statistically different across adjusted mortality differences from the early to later period differences in patient characteristics (Figure 4); the risk-association persisted after multivariable adjustment for differences in patient characteristics (Figure 4); the risk-adjusted mortality differences from the early to later period were not statistically different across ΔDTB quartiles.

Although not statistically significant, there was a suggestion of mortality reduction in hospitals with improvements in both DTB time and CMS/JCAHO composite quality performance. From the early to later periods, in-hospital mortality increased 0.9% in hospitals with DTB improvements alone, increased 0.1% with CMS/JCAHO core measure improvements alone, and decreased 0.5% in hospitals with improvements in both CMS/JCAHO and DTB performance (P value for trend, <.07).

Our results did not differ substantially in several secondary analyses. When the population was restricted to those 50 hospitals (bottom half) with a lower starting CMS/JCAHO composite score (score ranging from 55.2%-94.8%), there remained no significant correlation between improvements in DTB time and change in CMS/JCAHO composite score (r = -.031; P = .83) or between improvements in DTB time and change in mortality (r = -.088; P = .54). Our results were consistent if we limited the analysis population to the 13,835 patients treated for STEMI. Among these patients, hospital mean composite CMS/JCAHO scores improved from 94.4% to 96.8% (P < .001), and the performance of composite ACC/AHA guideline recommended measures showed a trend toward improvement from 84.4% to 86.6% (P = .05). However, there was no correlation between improvements in DTB time and change in CMS/JCAHO composite score (r = .075; P = .46), between improvements in DTB time and change in ACC/AHA composite score (r = 0.11; P = .26), or between improvements in DTB time and change in in-hospital mortality (r = .026; P = .80).

The AHA GWTG program provided a unique opportunity to examine the influence of a national campaign targeting a single AMI process measure (DTB time) on overall quality of care and outcomes for patients with AMI. Our study found that while hospital DTB times improved significantly over time, this was not associated with improvements in the performance of other hospital process measures or with a reduction in mortality.

Recent efforts, such as the D2B Alliance and Mission: Lifeline Initiative, have increased national awareness of the need for timely reperfusion. Door-to-balloon time measures are now firmly defined within professional guideline recommendations and are further established as a publicly reported quality metric as well as a component of quality incentivization programs.5,9,17,18 Our study, echoing previous observational findings, shows that a significant improvement in DTB times over time among community-based hospitals of varying size and location are likely a result of these quality-improvement initiatives.19-21 However, DTB time is only one of several quality measures delineated by the ACC/AHA clinical practice guidelines.10 The evidence favoring implementation of these other AMI quality measures is similarly robust, with hospital adherence to these recommendations correlating directly with risk-adjusted survival among patients with AMI.3 Yet, these evidence-based care processes are still not optimally used.22
loration between the improvement in DTB time and changes in the performance of other care processes.

Several potential reasons may explain this dissociation between ΔDTB and improvements in other quality-measure performance. First, GWTG hospitals have high starting median CMS/JCAHO composite scores; thus, a ceiling effect may have limited the degree to which any institution could improve their performance. However, the lack of correlation between ΔDTB and performance of other ACC/AHA guideline recommended measures, for which there is greater variability in performance across hospitals, makes this explanation less likely. Furthermore, when the analysis was repeated only among hospitals with lower starting CMS/JCAHO composite scores (ie, hospitals with more room for improvement), there was still no significant correlation between ΔDTB and performance of process measures.

Second, the effort required to implement performance change varies with the particular care process selected. Strategies to reduce DTB time involve facilitated communication between care teams to expedite patient arrival to the catheterization laboratory. Performance improvement of the DTB metric, therefore, requires increasing the efficiency of processes already in place, and can be directly influenced by patient volume with minimal incremental demands on overall health system resources. In contrast, quality improvement in other process measures is built more on educational efforts, investment and implementation of quality-improvement tools, medical record review with data feedback, and availability of counseling and rehabilitative resources. Thus, the discordance in performance improvement may reflect varying levels of institutional commitment and invested resources.

Third, extensive focus on changing the performance of a single measure may be “crowding out” institutional attention and resources for other important care processes. Making structural changes requires both financial and personnel investment. Ideally, sufficient resources are available to address all quality concerns effectively but, in reality, with finite hospital quality-improvement budgets, initiatives may be forced to compete against each other. Increasing the visibility of a particular initiative, such as DTB time, may displace support from other important programs. The magnitude of this effect depends in part on how complementary the advocated measure is with other care processes. Champions of a particular quality measure need to be sensitive to this “side effect” and actively promote other care goals, especially since making key strategies or overcoming barriers to successfully implement change in one quality measure are likely to motivate and nurture more widespread changes across quality indicators.

Interestingly, improvement in hospital DTB times did not correlate with changes in in-hospital mortality, suggesting that, from a hospital perspective, many other variables influence patient outcomes. There is a suggestion of mortality reduction among hospitals with improvements...
in both DTB time and performance of composite process measures. Although part of this is mediated via a direct treatment effect (ie, more consistent use of therapies results in better patient outcomes), one concern is that most care metrics are discharge measures that, theoretically, should not influence in-hospital mortality. Hospital performance of these discharge care processes likely correlates with performance of other acute measures that are not routinely assessed but are closely associated with patient outcomes. While identification of these additional measures may more effectively quantify the quality of provided care, our results emphasize the importance of overall quality improvement for AMI rather than focusing on a single process measure. In fact, with increasing complexity of hospital care, clinical outcomes rather than process measures may have intuitive appeal and provide a more complete assessment of hospital quality.

Our results should be interpreted in the light of several considerations. First, while the observational nature of this study permits real-world assessment of care patterns, the association between care processes and outcomes do not necessarily prove causality. Second, currently, GWTG only reports in-hospital outcomes. It will be important to assess the association of DTB time and other improvements in process measures with longitudinal outcomes. Third, while GWTG represents a spectrum of hospital types and sizes, participation is voluntary, reflecting an inherent interest in quality improvement, and thus may not be representative of national care patterns and outcomes. This study population was also limited to mostly tertiary care centers that provided DTB time information. Finally, during the study period, study results emerged that led to modified guideline recommendations (eg, the COMMIT [Clopidogrel and Metoprolol in Myocardial Infarction Trial] study\textsuperscript{2} and early β-blocker use). Because these changes were not effected in the CMS/JCAHO core measures until March 2009, we assessed process measures as they were during the study period, acknowledging that practices may have changed but biases should be similarly distributed across hospitals.

In conclusion, there is evidence that national campaigns to minimize reperfusion delays have been successful in improving this component of AMI care yet have had little impact on the performance of other quality metrics and outcomes. Our results highlight the importance of overall quality-of-care improvement for AMI rather than focusing on single process measures.

Accepted for Publication: April 27, 2009.

Correspondence: Tracy Y. Wang, MD, MHS, Duke Clinical Research Institute, 2400 Pratt St, Durham, NC 27705 (tracy.wang@duke.edu).


Financial Disclosure: Dr Wang has received research grants from the Medicines Co, Sanofi/BMS partnership, Schering Plough, Heartscapes, and Lilly/Daiichi Sankyo alliance. Dr Fonarow has performed research and served as a consultant and speaker for Bristol-Myers Squibb, Schering, and Biosite. Dr Hernandez has received research support from Roche Diagnostics and has received honoraria from and has spoken on the speakers bureau for Novartis. Dr Cannon has received research grants from Accutometrics, AstraZeneca, Glaxo Smith Kline, Merck, Merck/Schering Plough Partnership, Sanofi-Aventis/Bristol-Myers Squibb Partnership, and Schering Plough. Dr Peterson has received research grants from Bristol-Myers Squibb, Bristol-Myers Squibb/Sanofi Pharmaceuticals Partnership, Bristol-Myers Squibb/Merck, and Schering Corp.

Funding/Support: The Get With the Guidelines Program is supported by the American Heart Association in part through an unrestricted education grant from the Merck Schering Plough Partnership.

Role of the Sponsor: The funding organization did not participate in the design, analysis, preparation, review, or approval of this manuscript.

REFERENCES

Numerical Error. In the article titled “Disorders of Balance and Vestibular Function in US Adults: Data From the National Health and Nutrition Examination Survey, 2001-2004,” by Agrawal et al, published in the May 25th issue of the Archives (2009;169[10]:938-944), a value was reported erroneously. On page 940, “Results” section, right-hand column, fifth paragraph, the second sentence should have read as follows: “We found that these participants had a nearly 12-fold increase in the odds of falling (odds ratio, 12.3; 95% confidence interval, 7.9-16.7) compared with participants with neither of these risks in adjusted analyses (data not shown).”