

Reduction in Treatment Times Through Formalized Data Feedback

Results From a Prospective Multicenter Study of ST-Segment Elevation Myocardial Infarction

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Objectives This study sought to evaluate the effect of systematic data analysis and standardized feedback on treatment times and outcome in a prospective multicenter trial.

Background Formalized data feedback may reduce treatment times in ST-segment elevation myocardial infarction (STEMI).

Methods Over a 15-month period, 1,183 patients presenting with STEMI were enrolled. Six primary percutaneous coronary intervention hospitals in Germany and 29 associated nonpercutaneous coronary intervention hospitals participated. Data from patient contact to balloon inflation were collected and analyzed. Pre-defined quality indicators, including the percentage of patients with pre-announced STEMI, direct handoff in the catheterization laboratory, contact-to-balloon time <90 min, door-to-balloon time <60 min, and door-to-balloon time <30 min were discussed with staff on a quarterly basis.

Results Median door-to-balloon time decreased from 71 to 58 min and contact-to-balloon time from 129 to 103 min between the first and the fifth quarter ($p < 0.05$ for both). Contributing were shorter stays in the emergency department, more direct handoffs from ambulances to the catheterization laboratory (from 22% to 38%, $p < 0.05$), and a slight increase in the number of patients transported directly to the percutaneous coronary intervention facility (primary transport). One-year mortality was reduced in the total group of patients and in the subgroup of patients with primary transport ($p < 0.05$). The sharpest fall in mortality was observed in patients with primary transport and TIMI (Thrombolysis In Myocardial Infarction) risk score ≥ 3 ($n = 521$) with a decrease in 30-day mortality from 23.1% to 13.3% ($p < 0.05$) and in 1-year mortality from 25.6% to 16.7% ($p < 0.05$).

Conclusions Formalized data feedback is associated with a reduction in treatment times for STEMI and with an improved prognosis, which is most pronounced in high-risk patients. (Feedback Intervention and Treatment Times in ST-Elevation Myocardial Infarction [FITT-STEMI]; NCT00794001) (J Am Coll Cardiol Intv 2012;5:848–57) © 2012 by the American College of Cardiology Foundation

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Current guidelines stress the importance of a system of care for ST-segment elevation myocardial infarction (STEMI) that optimally includes acquiring a pre-hospital electrocardiogram (ECG), transmitting this ECG to a percutaneous coronary intervention (PCI) center, and initiating adequate and rapid reperfusion therapy (1–4). Several trials have established the importance of minimizing treatment times for STEMI patients (5,6). In real-world settings, contact-to-balloon (C2B) times frequently exceed the established target of <120 min (7) and door-to-balloon (D2B) times often exceed 90 min (8). Efforts to reduce these times have resulted in recommendations that include implementing regional STEMI networks and providing feedback (9). In a previous single-center project, we demonstrated that treatment times were reduced in a regional STEMI network after implementing systematic data analysis with quarterly interactive feedback to all network participants (10). The current multicenter, prospective study, the FITT-STEMI (Feedback Intervention and Treatment Times in ST-Elevation Myocardial Infarction) trial, was designed to determine the effect of systematic data analysis and standardized feedback intervention on treatment times and outcomes across several different regional care STEMI networks.

Methods

Participating hospitals. Six hospitals with primary PCI capacity and 29 cooperating non-PCI hospitals participated. Inclusion requirements included 24-h PCI capability for at least 1 year before inclusion, 2 interventional cardiologists who could take calls, 250 PCI procedures, as well as 50 PCI procedures in STEMI patients per year. Before participating in the project, all 6 key strategies of the American College of Cardiology D2B initiative (emergency department [ED] physician activates the catheterization lab; single-call activation system activates the catheterization lab; catheterization lab team is available within 20 to 30 min; prompt data feedback occurs; senior management honor commitment; team-based approach is used) were endorsed by the hospitals. All hospitals ensured prompt transfer of patients with STEMI to the PCI centers, minimizing time to treatment. Institutional protocols were in place that aimed to: 1) obtain pre-hospital 12-lead ECG; 2) bypass non-PCI hospitals; and 3) bypass the ED with direct transfer to the cardiac catheterization laboratory when feasible. The overall geographic catchment area served a

population of ~2 million with more than 1,000 STEMI patients per year (Table 1).

Patient inclusion. All patients who were diagnosed with ST-segment elevations (1–3) or with new left bundle branch block with typical symptoms of at least 30 min with the intention to perform primary PCI were included. The only exclusion criteria were the duration of symptoms or the documentation of ST-segment elevations >24 h. Patients in cardiogenic shock and patients who were undergoing or had undergone cardiopulmonary resuscitation were not excluded. Patients intended to have angiography and PCI were included even if they did not ultimately have either of these procedures.

Study protocol, data assessment, and outcome measures.

The study was approved by the ethics committee of the University of Göttingen. The study protocol consisted of a prospective design over 5 consecutive 3-month periods (quarters) with the first quarter being the reference quarter. Data were collected from October 2007 on, using a web-based system with independent monitoring for data validation (“source data verification”).

Time points from initial contact with the medical system to balloon inflation, including time of arrival on scene, out-of-hospital-treatment time, transport to the hospital, transfer to the catheterization laboratory, puncture, and first balloon inflation were assessed (Fig. 1). From these data and additional information, risk stratification by TIMI (Thrombolysis In Myocardial Infarction) risk score was performed.

Clinical endpoints were assessed at the time of discharge, at 30 days, and at 1 year with telephone follow-up.

The primary outcome was C2B. Secondary outcome measures included D2B, mortality, and New York Heart Association functional class. Outcomes are generally reported as results in Quarter 5 compared with results in Quarter 1.

Formalized data feedback. Quarterly feedback was performed during the first month of each quarter beginning in the second quarter. It consisted of interactive sessions with participants involved in the treatment or referral of STEMI patients, including emergency medical service, ED, and catheterization lab staff; interventional cardiologists; and

Abbreviations and Acronyms

C2B = contact-to-balloon

D2B = door-to-balloon

ECG = electrocardiogram

ED = emergency department

PCI = percutaneous coronary intervention

STEMI = ST-segment elevation myocardial infarction

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