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Original Article

Trends in use of anti-thrombotic agents and outcomes in patients with non-ST-segment elevation myocardial infarction (NSTEMI) managed with an invasive strategy

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ABSTRACT

Objective: To analyze trends in utilization of anti-thrombotic agents (ATA) and in-hospital clinical outcomes in non-ST-elevation myocardial infarction (NSTEMI) patients managed with an invasive strategy from 2007 to 2010.

Methods & results: Using ACTION Registry®-GWTG™ data, we analyzed trends in use of ATA and in-hospital clinical outcomes among 64,199 NSTEMI patients managed invasively between 2007 and 2010. ATA included unfractionated heparin (UFH), low molecular weight heparin (LMWH), glycoprotein IIb/IIIa inhibitors (GPI) and bivalirudin. Although the proportion of NSTEMI patients treated with PCI within 48 h of hospital arrival was similar in 2007 and 2010, percentage use of bivalirudin (13.4–27.3%; $p < 0.01$) and UFH increased (60.0–67.5%, $p < 0.01$), and that of GPI (62.3–41.0%; $p < 0.01$) and LMWH (41.5–36.8%; $p < 0.01$) declined. Excess dosing of UFH (75.9–59.3%, $p < 0.01$), LMWH (9.6–5.2%; $p < 0.01$) and GPI (8.9–5.9%, $p < 0.01$) was also significantly lower in 2010 compared with 2007. Though in-hospital mortality rates were similar in 2007 and 2010 (2.3–1.9%, $p = 0.08$), the rates of in-hospital major bleeding (8.7–6.6%, $p < 0.01$) and non-CABG related RBC transfusion (6.3–4.6%, $p < 0.01$) were significantly lower in 2010 compared with 2007.

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Abbreviations: NSTEMI, non-ST-elevation myocardial infarction; ATA, anti-thrombotic agents; GPI, glycoprotein IIb/IIIa inhibitor; ACS, acute coronary syndrome; MI, myocardial infarction; NCDR, National Cardiovascular Database Registry; STEMI, ST-elevation myocardial infarction; DCF, data collection form; UFH, unfractionated heparin; LMWH, low molecular weight heparin; CABG, coronary artery bypass surgery; CHF, congestive heart failure; PCI, percutaneous coronary intervention; PAD, peripheral arterial disease.

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Conclusion: Compared with 2007, patients with NSTEMI, who were managed invasively in 2010 received GPI and LMWH less often and bivalirudin and UFH more frequently. There were sizeable reductions in the rates of excess dosing of UFH (though still occurred in 67% of patients), GPI and LMWH. In-hospital major bleeding complications and post-procedural RBC transfusion were lower in 2010 compared with 2007.

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1. Introduction

Anti-thrombotic agents (ATA) are the cornerstone for treatment of non-ST-segment elevation myocardial infarction (NSTEMI).[1,2] Parenteral anticoagulants and concomitant GP IIb/IIIa inhibitors (GPI) prevent recurrent ischemic events and peri-procedural myocardial infarction (MI) among patients with NSTEMI.[3,4] However, due to the inherent nature of an invasive procedure coupled with use of anticoagulants, this ischemic benefit is accompanied by increased bleeding risk. Numerous studies have shown worse clinical outcomes, including mortality, among patients with major in-hospital bleeding complications.[5–7] Hence, bleeding avoidance strategies have received considerable attention as increased focus has been placed on patient safety. These include alternative approaches for vascular access and access site hemostasis, appropriate dosing of antithrombotic medications and selection of antithrombotic strategies with lower bleeding risk profiles. In the last few years, landmark trials such as REPLACE-2 (The Randomized Evaluation in PCI Linking Angiomax to Reduced Clinical Events), ACUITY (Acute Catheterization and Urgent Intervention Triage Strategy), ISAR-REACT 3 (Intracoronary Stenting and Antithrombotic Regimen—Rapid Early Action for Coronary Treatment 3) and EARLY-ACS (Early Glycoprotein IIb/IIIa Inhibition in non-ST-segment elevation acute coronary syndrome) have provided a better understanding of the risks and benefits of antithrombotic therapy for acute coronary syndrome (ACS) patients undergoing PCI.[8–12] Although these clinical trials have offered insights into selection of antithrombotic agents for NSTEMI patients, patterns of use of these agents (type of agent and frequency of excess dosing) and outcomes among NSTEMI patients following the publication of these key trials have not yet been analyzed. Hence, our study used data from the National Cardiovascular Data Registry's (NCDR) ACTION Registry®-GWTG™ (ACTION Registry® – Get with the Guidelines™) from 2007 to 2010 to analyze the use of intravenous antithrombotic agents among NSTEMI patients managed with an invasive strategy and to further examine in-hospital ischemic and bleeding outcomes during this period.

2. Methods

2.1. Registry

The NDCR ACTION Registry®-GWTG™ is a national quality improvement registry of ST-segment elevation myocardial infarction (STEMI) and NSTEMI patients who began enrolling on January 1, 2007.[13] Patients are eligible for inclusion in ACTION, if they present within 24 h from onset of ischemic symptoms and receive a primary diagnosis of NSTEMI or STEMI.

De-identified data are extracted from existing medical records onto a web-based case form by trained data collectors at each center. Study participation at each center was approved by local institutional review boards. The NCDR has a data quality program in place to ensure consistent and reliable data. Quality assurance measures, such as data quality reports and random site audits by trained nurse abstractors, are used to maximize the completeness and accuracy of all records submitted.

2.2. Study population

Starting from 158,540 NSTEMI patients enrolled in 569 US hospitals of ACTION Registry®-GWTG™ from January 1, 2007 to December 31, 2010, the following patients were excluded sequentially: Patients in centers using limited data collection form (DCF) ($n = 10, 346$), patients managed medically ($n = 35, 705$), transfer-out patients ($n = 3, 475$), patients in hospitals without PCI capability ($n = 3, 021$ in 49 centers), dialysis patients ($n = 2884$), patients from hospitals that did not enroll patients consecutively annually ($n = 32,627$), and patients from hospitals entering fewer than 25 patients annually ($n = 6283$ in 37 centers). Thus, the final analysis population consisted of 64,199 patients from 100 ACTION Registry®-GWTG™ centers.

2.3. Definitions of antithrombotic agents and excess dosing

Use of unfractionated heparin (UFH) or low molecular weight heparin (LMWH) was defined as use on the day of or the day immediately following admission without the use of other anticoagulants during that period or having the agent initiated after arrival in the cardiac catheterization laboratory. We examined only the use of small molecule GPI (eptifibatide or tirofiban) and defined use as initiation on the day of or the day immediately following hospital arrival.

Standardized dosing regimens recommended in the ACC/AHA guidelines for unstable angina/NSTEMI[14] were used to define appropriate and excess dosing of each antithrombotic agent (except bivalirudin). Excess dosing for intravenous UFH was defined as: a bolus dose >60 units/kg (max 4000 units) or infusion >12 units/kg/h (max 1000 units/h). The recommended daily dose of enoxaparin sodium was (1 mg/kg bid) for patients with a creatinine clearance of ≥30 mL/min and

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