Dear Colleagues,

It is our pleasure to present to you a summary report of the CRUSADE quality improvement initiative. In this EMCREG newsletter issue, over 200,000 patients teach us how we treat and can improve NSTE-ACS care. Health disparities, treatment patterns, and outcome trends remind us of how we can continue to learn and advance the care for our patients.

The following pages summarize findings from key CRUSADE registry publications and forward critical lessons gleaned from this amazing collaborative endeavor between cardiology and emergency medicine. This demonstration of “real world” care of patients with ACS should give us pause and promote further vigilance in the comprehensive care of this high risk patient population. CRUSADE is a remarkable example of true quality improvement where increased guideline compliance translates to improved patient outcomes.

We hope that you enjoy this publication as we seek to provide emergency care givers with the most comprehensive and up-to-date information regarding topics in the acute care field. Please look to our website www.emcreg.org to learn more about our organization, its members, news of upcoming events, reprints of previous publications, and more. We welcome your comments and suggestions at support@emcreg.org.

Sincerely,

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CRUSADE: Contemporary Evaluation and Management of 200,000 High-Risk NSTE-ACS Patients

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Objectives:
- Understand the role of a multidisciplinary approach to improving compliance with evidence-based therapies for impacting patients’ clinical outcomes
- Note the demonstrated links between guidelines compliance and in-hospital outcomes in high-risk NSTE-ACS
- Recognize that there are disparities in ACS care that should be addressed in a multidisciplinary fashion
- Realize that many of the bleeding complications encountered in contemporary ACS care can be avoided by the use of careful dosing regimens

Introduction

After six years and the enrollment of over 200,000 patients, the CRUSADE (Can Rapid Risk Stratification of Unstable Angina Patients Suppress Adverse Outcomes with Early Implementation of the ACC/AHA Guidelines) national quality improvement and educational initiative ended on January 31, 2007. This date brought to a close an invaluable and unprecedented compilation of data on the management of patients with non-ST-segment elevation acute coronary syndrome (NSTE-ACS), as well as important data on a smaller but very contemporary cohort of patients with acute ST-segment elevation myocardial infarction (STEMI). Born in late 2001 as a nationwide collaboration of emergency physicians, cardiologists, the data collection and analysis resources of the Duke Clinical Research Institute (DCRI),
CRUSADE: Contemporary Evaluation and Management of 200,000 High-Risk NSTE-ACS Patients

Initially targeting to enroll a modest 10,000 patients, more than 550 participating hospitals eventually contributed comprehensive data on 196,672 NSTE-ACS patients and another 8,856 patients with ST-segment elevation myocardial infarction (STEMI), for a total population of 205,526 ACS presentations! CRUSADE grew from humble beginnings to become an incredibly productive clinical and academic endeavor. For instance, customized reports for each participating institution allowed rapid and objective assessment and modification of ACS care processes. Nationally, CRUSADE data from many well-received articles and presentations will be integrated into new ACS guidelines both in the United States and Europe. In this monograph we will review some of the key overall findings of the CRUSADE initiative and also highlight some of the more focused CRUSADE analyses that have validated guidelines-based care, stimulated much constructive discussion and debate, and ultimately advanced care in the ACS community over the past six years. A list of some of the more important “lessons learned” about ACS care from the efforts of all the CRUSADE investigators is provided in the inset.

The CRUSADE Patients: High Risk, with Big Benefits of Improving Care

The entry criteria for the CRUSADE NSTE-ACS registry were a clinical presentation consistent with ACS with symptoms present within 24 hours of that presentation, plus an elevated serum marker of myocardial necrosis or dynamic ST-segment changes, or both. In the 31,665 patients entered between July 2005 and June 2006, 93% had elevated markers. One-third of patients had qualifying ischemic ST-segment changes, indicating significant overlap in these high-risk findings. Forty percent of the patients were female, one-third were diabetic, nearly one-quarter presented with signs of heart failure, and more than one in ten had documented renal insufficiency. Thirty-five percent were older than 75 years of age. In-hospital outcomes for that period included a mortality rate of 3.9%, reinfarction rate of 1.8%, heart failure rate of 7.0%, 0.6% incidence of stroke, and 9.4% rate of non-coronary artery bypass graft (CABG)-related blood transfusions.

CRUSADE tracked acute and in-hospital therapies. “Acute” was defined as guideline recommended treatments occurring within 24 hours. Acute therapies including aspirin (ASA), anticoagulation, beta-blockers, platelet glycoprotein IIb/IIIa receptor inhibitors (GPIs), and clopidogrel, varied...
“LESSONS LEARNED” in the Care of High-Risk NSTE ACS in CRUSADE

- Guidelines-based therapy for NSTE ACS patients significantly improves inhospital outcomes.
- Despite strong evidence and clear recommendations in specialty society guidelines, aggressive antiplatelet therapy for NSTE ACS is significantly underused in contemporary practice.
- The use of guidelines-recommended therapy in the ED is associated with a greater likelihood that patients will receive guidelines-recommended care at the time of discharge.
- Patients with NSTE ACS in contemporary practice are at higher risk than those enrolled in clinical trials studying NSTE ACS.
- Even those NSTE ACS patients with objective high-risk features are likely to wait as long as 20 hours or more for diagnostic angiography, which increases the importance of guidelines-based, risk-driven medical management prior to catheterization.
- Many of the bleeding complications encountered in ACS patients can be avoided if appropriate dose adjustments are made by age and renal status for antithrombin and antiplatelet agents.
- Women, the elderly, patients with renal insufficiency, and patients who receive an excessive dose of antithrombin and antiplatelet drugs are at significantly increased risk for bleeding and transfusion during ACS care; further, transfusion is associated with increased mortality.
- Women, the elderly, diabetics, patients with renal insufficiency/failure, minorities, and patients presenting outside of “usual hours” with ACS are less likely to receive guidelines-recommended therapy.
- Quality improvement interventions, particularly those linked to evidence-based guidelines and distributed across specialty lines, can improve guidelines compliance and clinical outcomes.

**Figure 1:** Acute medication use overall and by age in NSTE-ACS patients in CRUSADE

**Figure 2:** Adherence to guidelines over time in NSTE-ACS patients in CRUSADE
both in the frequency of use and with age (Figure 1). The rate of utilization of advanced antiplatelet therapies (clopidogrel and GPs) remains generally low. As Figure 2 shows, however, compliance with recommended therapies steadily improved over time, showing the impact of the educational and research activities of the CRUSADE initiative. Data from CRUSADE also provided validation that improved early use of recommended aggressive medical management indeed resulted in better in-hospital outcomes among high-risk NSTE-ACS patients (Figure 3). Likewise, once CRUSADE data were cited in illustrating the importance of proper dosing of antithrombotics and antiplatelet agents in ACS management, the incidence of excessive dosing in CRUSADE hospitals decreased dramatically.

By the time that data collection was concluded in CRUSADE, 83% of high-risk NSTE-ACS patients without contraindication to catheterization were being taken to the catheterization laboratory on the index hospitalization. Given that a number of non-catheterization-capable hospitals were recruited to join CRUSADE, this is a reasonably good composite performance. Time to catheterization generally fell short of what might be expected. Only 67% of these patients went to catheterization within 48 hours of presentation as recommended in the guidelines. The median time to catheterization in these patients was consistently around 22 hours in CRUSADE, highlighting the pertinence and importance of early medical stabilization, starting in the ED, for patients whose definitive intervention may not occur until the day after presentation or even later. Around 12% of these high-risk patients required

It is critical for emergency physicians to realize that definitive therapy might not occur in a timely fashion and should consider this reality when making treatment decisions in the ED.

Figure 3: Impact of guidelines-recommended acute (within 24 hours of presentation) therapy in NSTE-ACS patients for patients <75 and >75 years of age.

Figure 4: Relationship of hospital composite guideline adherence with in-hospital mortality in NSTE-ACS patients in CRUSADE.
CABG on the index hospitalization, and this occurred at a median of around 3 days after presentation. It is critical for emergency physicians to realize that definitive therapy might not occur in a timely fashion and should consider this reality when making treatment decisions in the ED.

**Overall Outcomes of Guidelines-Recommended Care**

Perhaps the “flagship” publication from the CRUSADE effort to date demonstrated in striking fashion the relationship between compliance with guidelines and improved short-term outcomes. Peterson et al. reported in JAMA in 2006 that “a significant association [exists] between care processes and outcomes,” “supporting the use of broad, guideline-based performance metrics as a means of assessing and helping improve hospital quality.” In fact, as seen in Figure 4, hospitals that could improve their guidelines compliance could expect in return a statistically significant 10% reduction in in-hospital mortality. This relationship persisted after adjustment for hospital characteristics and patient risk. Another finding of this study was that the adoption of newer therapies, such as GPIs and clopidogrel, was more closely associated with overall hospital outcomes than was compliance with more established therapies, such as beta-blockers. This emphasized the need for an educational platform such as CRUSADE to educate providers on new approaches and new evidence in ACS management: short-term mortality can be correlated in a dose-dependent fashion to practicing evidence-based care. Likewise, an ongoing effort to improve institutional compliance with guidelines may be the most important and enduring message to emerge from CRUSADE. This message has been repeated in many analyses focused on more specific aspects of ACS care. As of this writing, nearly 60 peer-reviewed manuscripts have been published from the CRUSADE data. More than 80 abstracts have been accepted. A current listing of CRUSADE publications and abstracts can be found at www.crusadeqi.com. Many additional analyses are in progress. All together, this work has characterized the breadth and complexity of ACS care, illuminated previously unrecognized paradoxes, and shown in a consistent fashion that following ACS guideline recommendations, individually and in aggregate, improves patient outcomes.

**More Focused CRUSADE Analyses**

Some of the more interesting studies from the CRUSADE data have included the finding patients cared for in the inpatient setting by cardiologists receive more guideline compliant medical and interventional care and have better overall in-hospital outcomes. Longer ED length of stay for high-risk NSTE-ACS patients has been shown to be associated with worse guideline compliance in medical management, and correspondingly, with poorer outcomes. On the other hand, quicker transition of care to the catheterization laboratory is associated with better outcomes, and indeed the higher the patient’s risk, the more disproportionately the patient benefits from catheterization within 48 hours of arrival.

CRUSADE investigations have addressed important issues of risk stratification and its impact on therapy and subsequent outcomes. For example, just as the ACC/AHA guidelines determined timing and validity differences between CK-MB and troponins in NSTE-ACS risk stratification, a CRUSADE analysis revealed that an elevated troponin level identifies patients at increased acute risk regardless of CK-MB status, while an isolated elevated CK-MB has limited prognostic value. Although using troponins may be straightforward to identify NSTE-ACS patients at high risk, another CRUSADE analysis showed that patients at highest risk are actually less likely to receive guideline-recommended therapies and interventions, perhaps because of complicating comorbidities.

A number of CRUSADE analyses have uncovered disparities in NSTE-ACS care. Women enrolled in CRUSADE are older than men (median age 73 vs. 65 years of age) and more often have diabetes and hypertension. Nonetheless, women
Elderly patients with ACS often receive less aggressive therapy than younger patients (Figure 1), but the sheer size of the CRUSADE registry allowed a close look at the “very elderly” defined as those patients 90 years of age and older. Compared to patients 75-89 years of age, the extremely elderly were less likely to be diabetic, smokers, or obese. Still, this cohort was less likely to receive acute therapy with GPIs and statins, and was less likely to undergo cardiac catheterization within 48 hours. The extremely elderly were more likely to die (12.0% vs. 7.8%) and experienced more frequent adverse events during the hospitalization. Increasing adherence to guideline-recommended therapies was associated with both increased bleeding and a graded reduction in risk-adjusted in-hospital mortality in both age groups. Therefore, even in the extreme elderly, increasing adherence to guideline-recommended therapies is associated with decreased mortality, although these findings from CRUSADE reinforce the importance of optimizing care patterns for the oldest patients with NSTE-ACS, while highlighting the need for novel approaches to reduce the risk of bleeding in this rapidly expanding patient population.

CRUSADE data have been informative on issues of treatment. Analyses show the benefit from early use (<24 hours) of GPIs and clopidogrel (as long as CABG, if required, is delayed for five days), but worse outcomes, even with multiple adjustments, after the early use of morphine in NSTE-ACS. Interestingly, early use of GPIs is a marker of better overall compliance with guidelines, although paradoxically they may be overused in the management of lower-risk NSTE-ACS patients. Finally, CRUSADE has also explored issues of the adverse effects of treatment, especially bleeding. Patients treated with GPIs have slightly improved outcomes and similar bleeding risks with LMWH than with UFH. In a widely discussed analysis by Alexander et al., excessive dosing of anticoagulants and GPIs was found to be common, with 40% of NSTE-ACS patients receiving at least one dose outside the recommended range. Factors associated with excess dosing included older age, female sex, renal insufficiency, low body weight, diabetes mellitus, and congestive heart failure (CHF). Bleeding increased relative to the degree of excess dose and to the number of agents administered in excess, and mortality and length of stay were higher among those patients. It was estimated that 15% of major bleeding complications in NSTE-ACS patients are associated with excessive dosing. A large CRUSADE analysis found that 15% of major bleeding complications in NSTE-ACS patients were associated with excessive dosing. It is not surprising, therefore, that the risk of bleeding increases with increasing age and weight, as well as with the addition of agents with overlapping actions, such as UFH and GPIs.

Obesity is a risk factor for developing ACS at a younger age, and obese patients typically receive more aggressive treatment and have less adverse outcomes compared with underweight and normal-weight patients. Diabetic patients, meanwhile, have a higher risk of mortality than nondiabetic patients, yet physicians adhere to the guidelines less often when treating diabetic patients, particularly those who are insulin-dependent. While type 2 diabetics were treated similarly to nondiabetic patients in one CRUSADE analysis, insulin-dependent diabetic patients were less likely to receive aspirin, beta-blockers, anticoagulation, GPIs, and catheterization or PCI, although they were more likely to undergo CABG. Perhaps not surprisingly, in-hospital mortality rates were higher in insulin-treated diabetic (6.8%) and type 2 diabetic (5.4%) than in nondiabetic (4.4%) patients, but this analysis raises the question of how much of this outcome disparity is true to the disease, and how much is due to confounding features or less aggressive management.
management may be attributable to excessive dosing, and in the more vulnerable female population, up to 25% of this sex-related risk difference in bleeding is avoidable.23

Another analysis highlighted the significance of renal insufficiency in bleeding risk and treatment issues. Patients presenting with moderate to severe chronic kidney disease (n=6,560) were older, more often diabetic, and more likely to present with signs of CHF, and had a 50% increased risk of mortality and a 70% increased likelihood of transfusion. Nonetheless, these patients were treated less aggressively than patients with normal renal function, perhaps because of that concern for bleeding.24 Finally, a CRUSADE analysis confirmed the requirement for transfusion during ACS management is an indicator of poor prognosis. Patients who received non-CABG-related transfusions had a greater risk of death (11.5% vs. 3.8%) and death or reinfarction (13.4% vs. 5.8%) than patients who did not undergo transfusion,25 emphasizing once more the importance of appropriate choice and dosing of antiplatelet and antithrombin therapy in NSTE-ACS.

Conclusion and “Call to ACTION”

In recognition of its many accomplishments, the CRUSADE Team was named to the AHA’s Top Ten list of major research for 2006. CRUSADE research will continue, as this remarkably robust database will continue to be explored and analyzed for years to come. Starting this year, however, data collection on NSTEMI and STEMI patients will occur as part of the American College of Cardiology’s ACTION Registry, which joins the efforts of the former CRUSADE, National Registry of Myocardial Infarction (NRMI), and ACC cardiac catheterization lab registries. Like CRUSADE before it, the ACTION registry will strive to promote a national standard by which to understand treatment patterns, clinical outcomes, drug safety, and the overall quality of care provided for ACS patients. Those interested in learning more about, or participating in the ACTION Registry should go to www.accncdr.org. As learned from CRUSADE, in the management of ACS, “knowledge is power.”26 Knowing one’s own clinical performance in detail, and the ability to compare that to the performance of other institutions, can point the way to targeted educational interventions that then can result directly, and dramatically, in improvements in clinical outcomes.

REFERENCES


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Diagnosis of TIA and Stroke in the ED: How Can This Be Made Uniform in Your ED?
Brian A. Stettler, MD - Assistant Professor, Department of Emergency, University of Cincinnati; Member, Greater Cincinnati/N. Kentucky Stroke Team

Treating Ischemic and Hemorrhagic Stroke: Why the Controversy?
Arthur M. Pancioli, MD - Associate Professor and Vice Chairman of Research, Department of Emergency Medicine, University of Cincinnati; Member, Greater Cincinnati/N. Kentucky Stroke Team

Hypertension in Patients with Ischemic and Hemorrhage Stroke: What’s the Optimal Approach?
Arthur M. Pancioli, MD - Associate Professor and Vice Chairman of Research, Department of Emergency Medicine, University of Cincinnati; Member, Greater Cincinnati/N. Kentucky Stroke Team

Judd E. Hollander, MD - Professor and Clinical Research Director, Department of Emergency Medicine, University of Pennsylvania

Markers for Diagnosing Sepsis in the ED.
Andra L. Blomkalns, MD - Associate Professor and Vice Chairman of Education, Department of Emergency Medicine, University of Cincinnati

Treatment of Sepsis: How to make Goal Directed Therapy a Consistent Approach in Your ED?
Emanuel P. Rivers, MD, MPH - Professor and Vice Chairman, Department of Emergency Medicine, University of Pittsburgh

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Risk Stratification of Patients with Possible ACS: The Total Package.
Gerald X. Brogan, MD - Professor and Associate Chairman, Department of Emergency, Northshore University Hospital

Optimal Management of NSTE ACS: The Role of Anti-thrombotic Therapy in the ED.
James W. Hoekstra, MD - Professor and Chairman, Department of Emergency, Wake Forest University

What’s the Optimal Anti-platelet Regimen for NSTE ACS?
Charles V. Pollack, MD - Professor and Chairman, Department of Emergency, University of Pennsylvania

Best Treatment for STEMI: PCI or Fibrinolytics?
Brian R. Holroyd, MD Director, Division of Emergency Medicine, University of Alberta

Acute Decompensated Heart Failure Management in the ED.
Alan B. Storrow, MD Associate Professor and Research Director, Department of Emergency Medicine, Vanderbilt University

Diagnosis and Treatment of DVT and PE in the ED.
Charles B. Cairns, MD Associate Professor, Department of Emergency Medicine, Duke University

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CME Questions

After you have read the monograph carefully, record your answers by circling the appropriate letter answer for each question.

1. Which of the following statements best describes the CRUSADE initiative?
   a) CRUSADE examined only the care of STEMI patients in the US.
   b) CRUSADE enrolled all patients with chest pain presenting to the ED.
   c) CRUSADE was a randomized, controlled clinical trial.
   d) CRUSADE was a multidisciplinary quality improvement initiative that examined the evaluation and management of high-risk NSTE-ACS patients.

2. Which of the following statements DOES NOT accurately reflect findings from the CRUSADE registry?
   a) Patients seen in contemporary clinical practice for NSTE-ACS are at higher risk for adverse outcomes than those enrolled in clinical trials.
   b) Broader use of guidelines-based care improved outcomes in NSTE-ACS patients.
   c) Elderly patients have similar rates of adverse outcomes with NSTE-ACS as younger patients.
   d) Advanced antiplatelet therapy (glycoprotein IIb/IIIa receptor antagonists and clopidogrel) is significantly underused in contemporary NSTE-ACS practice, compared to evidence-based recommendations.

3. Which of the following statements about bleeding complications and transfusion in NSTE-ACS care is NOT TRUE?
   a) Excessive dosing of antithrombotic and antiplatelet agents increases the risk of bleeding complications and transfusion.
   b) There is no differential bleeding risk associated with the gender of the patient with NSTE-ACS.
   c) Transfusion is associated with higher in-hospital mortality rates.
   d) Education about excessive dosing issues with antithrombotic and antiplatelet agents can reduce the incidence of overdosing.

4. Which of the following groups does not appear to be affected by a systematic disparity in the provision of guidelines-based NSTE-ACS care?
   a) Female patients
   b) Elderly patients
   c) Hispanic patients
   d) Diabetic patients
   e) Patients taken to diagnostic angiography within 12 hours of ED arrival.

5. Which ONE of the following statements about guidelines-recommended therapy in NSTE-ACS have been validated in the CRUSADE registry?
   a) The early use of glycoprotein IIb/IIIa receptor antagonists in high-risk patients is associated with a reduction in in-hospital ischemic outcomes.
   b) Insulin-treated diabetics are equally likely to receive evidence-based treatments as type 2 diabetics.
   c) Obese patients have poorer outcomes than normal-weight patients.
   d) Patients enrolled in both ACS clinical trials and CRUSADE were less likely to receive evidence-based therapies.

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