A Summary Report by EMCREG-International

MARCH 2005 VOLUME 2

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Can Rapid Risk Stratification of Unstable Angina Patients Suppress ADverse Outcomes with Early Implementation of the ACC/AHA Guidelines: The CRUSADE National Quality Improvement Initiative

CRUSADE - A Roadmap for Change:

100,000 Patients Make a Difference

Interim Analysis of the 100,000 Patients Enrollment Milestone

March, 2005

Dear Colleagues:

It is with great pleasure that we present this EMCREG-International newsletter report describing the first 100,000 patients enrolled into the CRUSADE quality improvement initiative, particularly from the perspective of the emergency physician. This unique clinical program, coordinated by the **Duke Clinical Research Institute (DCRI)** in Durham, North Carolina represents a remarkable collaboration between Emergency Medicine and Cardiology in over 400 acute care hospitals across the United States.

The CRUSADE quality improvement initiative tracks the implementation of therapies and processes recommended by the 2002 ACC/AHA Unstable Angina/Non-ST-segment Elevation Myocardial Infarction Guidelines. Not just a clinical registry of non-ST-segment elevation acute coronary syndrome, the CRUSADE initiative provides quarterly reports for each hospital comparing acute therapy as well as discharge regimens compared to similar and all hospitals across the United States. In addition to providing comparative data for hospitals, the CRUSADE Steering Committee and DCRI provide quality improvement tools and actual site visits to improve performance. It appears that for many participating hospitals, the CRUSADE approach is working! The utilization of guideline recommended therapy for NSTE ACS patients is increasing.

We hope you enjoy this report and that it helps to improve the care of your patients with NSTE ACS at your institution.

Sincerely,

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Introduction

Although non-ST-segment elevation acute coronary syndromes (NSTE ACS) represent a well-recognized source of morbidity and mortality for patients with cardiovascular disease, evidence-based therapies shown to improve outcomes for NSTE ACS are frequently underutilized in appropriate patients, especially in the emergency department (ED). The American College of Cardiology/ American Heart Association (ACC/AHA) Guidelines for the Management of Unstable Angina/Non-ST-Elevation Myocardial Infarction [1] were promulgated in an effort to standardize and optimize the evaluation, diagnosis, and management of patients with NSTE ACS and to provide physicians with an evidence-based framework for clinical decision-making. Despite dissemination of these expert recommendations and ED-focused recapitulations of them in *Annals of Emergency Medicine* [2,3], significant barriers continue to limit the adoption of guidelines in clinical practice and appear to hinder the use of beneficial therapies and interventions in the ED. Unique quality improvement approaches are therefore needed to stimulate better adherence to practice guidelines and improve the quality of care for patients with NSTE ACS, starting in the ED.

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 provides an innovative, multi-faceted and multidisciplinary approach to the education of emergency physicians and cardiologists in the care of patients with NSTE ACS [4]. The CRUSADE Initiative is a cooperative effort involving more than 400 medical centers across the United States. It includes a large web-based registry designed to characterize demographic patterns and risk stratification results in patients who meet diagnostic criteria for high-risk NSTE ACS (chest pain syndrome >10 minutes and within 24 hours of presentation, plus either ECG ST-segment depression/transient ST-segment elevation or elevated cardiac biomarkers of myocardial necrosis, CK-MB and troponin). CRUSADE also measures the use of acute NSTE ACS treatment modalities including aspirin, heparin, beta-blockers, clopidogrel, platelet inhibitors, and early catheterization strategies as recommended in the ACC/AHA guidelines. Similarly, hospital discharge medications are evaluated. Finally, demographic and practice patterns are correlated with in-hospital morbidity and mortality outcomes. The results of a given institution's treatment patterns and outcomes in their NSTE ACS patients are reported back to the institution quarterly, along with comparisons to national norms for similar hospitals and goals for improved compliance with guidelines.

Beyond a static registry, these CRUSADE reports are coupled with educational efforts such as investigator meetings for CRUSADE advocates and coordinators, instruction in an assortment of quality improvement tools for utilization in patient care (pocket cards, risk assessment tools, placards, standardized orders, treatment algorithms, etc), local and regional educational programs, and in-person or remote telephonic hospital consultations by the CRUSADE Steering Committee members. The CRUSADE Initiative has also yielded multiple scientific publications that demonstrate NSTE ACS risk stratification patterns, treatment effectiveness, and quality improvement results. Individual sites are also able to tailor the CRUSADE quality improvement feedback reports to address specific institutional treatment questions, down to details like service-specific or physician-specific outcome data. CRUADE educational efforts are targeted at key institutional leaders to maximize quality improvement efforts and improve the utilization of ACC/AHA guideline therapies in NSTE ACS patients. The CRUSADE Initiative represents a truly innovative approach to improving care for NSTE ACS patients in the ED as well as throughout their hospital stay and discharge.

Analysis of the First 100,000 CRUSADE Initiative Patients

In early June, 2004, the CRUSADE Initiative reached a significant milestone when it included its 100,000th high-risk NSTE ACS patient. This achievement culminated a two-and-a-half year effort, which began in January, 2002 and continues enrollment today. Patient inclusion in CRUSADE has surpassed investigators expectations and analysis of CRUSADE results continues to provide invaluable insights into the treatment of NSTE ACS patients in the United States. The CRUSADE Initiative represents the largest NSTE ACS registry ever assembled, and offers for the first time a true "real world" representation of United States treatment patterns for NSTE ACS.

The patients in CRUSADE, chosen after qualification for basic objective high-risk features, remain very high risk, with an average age of 67 years. Forty percent of the patients in CRUSADE are women, 33% diabetic, 31% have a prior MI, and 20% have previously undergone coronary artery bypass grafting (CABG). Thirty-nine percent of the CRUSADE patients have ST-segment depression on their presenting ECG, and 87% have an elevated troponin level. The in-hospital mortality for CRUSADE patients remains high at

4.9%, which is more than twice the 7-day mortality in published large randomized controlled NSTE ACS trials of "High-risk" patients [5,6,7]. The CRUSADE population has offered the unique opportunity to validate the predictive capabilities of troponin levels, CKMB levels, and clinical risk scores such as the one developed from the PURSUIT Trial [8,9,10]. However, patients considered to be at the highest risk for mortality, including those with advanced age, diabetes, heart failure, or high troponin levels are paradoxically treated less aggressively than their lower risk counterparts [11, 12].

Acute treatment patterns in the CRUSADE Initiative are summarized in Figure 1. As shown, early (<24 hours) utilization of aspirin, beta blockers, and anticoagulation with heparin or low-molecular-weight heparin (LMWH) remains fairly high in participating hospitals, whereas early utilization of glycoprotein (GP) IIb/IIIa inhibitors and clopidogrel represent targets for continued quality improvement efforts. Platelet inhibitor therapy remains underutilized in the ED despite the key role of platelets in the pathophysiology of NSTE ACS and the Class IA recommendations for GP IIb/IIIa inhibitor use in high risk patients with NSTE ACS who are destined for the catheterization laboratory for percutaneous coronary intervention (PCI) (Figure 2). Their relative under-utilization underscores the need for more coordination between the ED and cardiology in the preparation of these patients for an invasive PCI strategy.

Figure 1

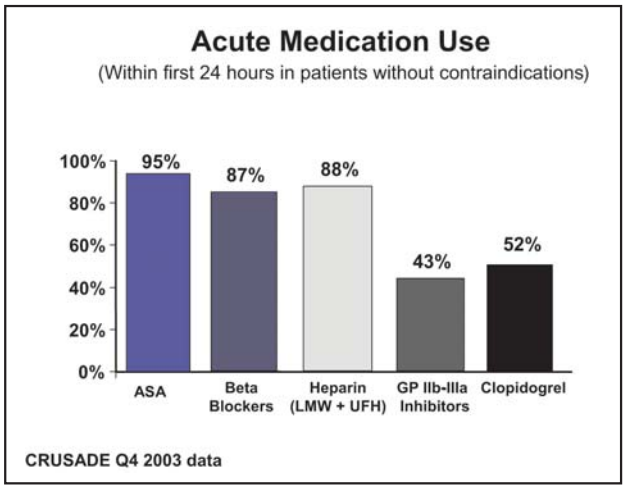
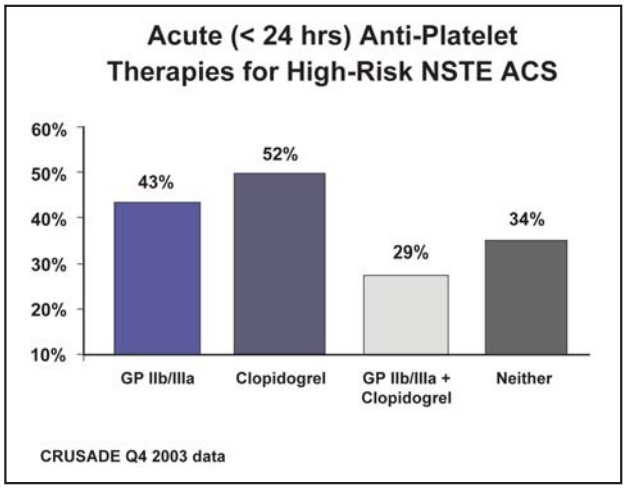


Figure 2

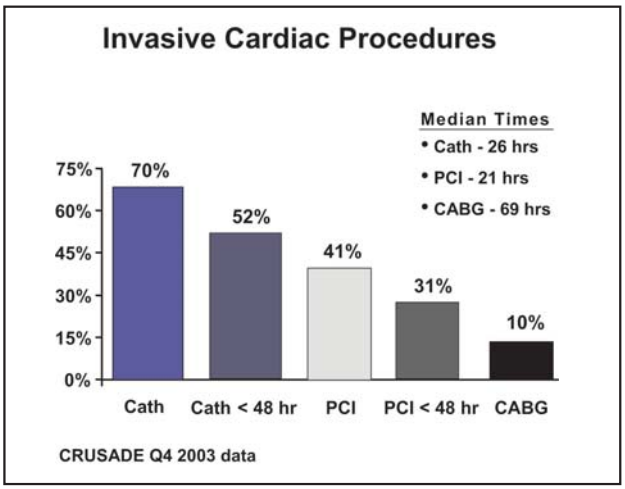


Interestingly, an inordinately high 34% of CRUSADE patients receive no advanced antiplatelet therapy (i.e., beyond aspirin) in the first 24 hours following presentation. Invasive diagnostic and management strategies are utilized in the majority of CRUSADE patients, with 70% of patients undergoing catheterization, 41% undergoing PCI, and 10% undergoing CABG (Figure 3). The time to catheterization in the United States remains suboptimal, however, with a median time to catheterization of 26 hours and with only 52% of patients receiving catheterization within 48 hours of hospital admission. These averages appear to be sub-optimal based on the guidelines. Longer delays to cardiac catheterization put NSTE ACS patients at risk for recurrent ischemia and recurrent MI in the pre-PCI time interval. These recurrent ischemia episodes have been shown to result in significant morbidity and mortality in randomized controlled trials, underscoring the need for aggressive up-front medical treatment of NSTE ACS in the ED and CCU.

Randomized controlled trials have repeatedly demonstrated that specific individual therapies for NSTE ACS are of most benefit in the highest risk patients. As such, the CRUSADE Initiative provides an invaluable research platform to investigate, in a retrospective fashion, the effectiveness of any given therapy. To date, abstracts have been presented examining the clinical utility of heparin/LMWH,

GP IIb/IIIa inhibitors, and early catheterization strategies in the CRUSADE population [13,14,15]. Whereas these retrospective analyses are not as powerful as prospective randomized clinical trials, they offer substantial insights into real-world treatment patterns and outcomes.

Figure 3



Targets for Quality Improvement Efforts

The efforts of the CRUSADE Initiative would be in vain if there were no correlation between ACC/AHA guideline adherence and clinical outcomes. In a recent analysis of the CRUSADE database, composite guideline adherence was significantly correlated with in-hospital morality [16]. Hospitals whose ACC/AHA guideline adherence was in the lower quartile demonstrated a significantly higher mortality than hospitals with top quartile guideline adherence (5.8% versus 4.0%). Yet, as noted above, large gaps still exist between CRUSADE patterns of care and the recommended guideline treatment outlined in the ACC/AHA guidelines. Twelve percent of NSTE ACS patients in CRUSADE still don't receive an antithrombin (heparin/LMWH) in their first 24 hours of treatment, and 57% don't receive a GP IIb/IIIa inhibitor. Time intervals to cardiac catheterization remain relatively high, and utilization of invasive procedures remains relatively low despite demonstrated mortality reductions in patients who undergo an invasive strategy as part of their care [17].

In addition to under-utilization of specific therapies, it appears that the patients who are highest risk for adverse outcomes are not being treated as aggressively as they should. Despite demonstrated higher mortality and morbidity in CRUSADE patients with high PURSUIT risk scores, the utilization of aspirin, beta blockers, antiplatelet therapies, and catheterization strategies remains relatively low in high risk versus low risk patients [10]. This paradoxical shift in care patterns allows the under-treated high risk patients to disproportionately drive the 4.9% in-hospital mortality rate in CRUSADE. Quality improvement measures aimed at aggressive utilization of therapies in high risk patients has the potential to significantly lower mortality in the CRUSADE population, and across the nation.

Finally, it appears that the educational efforts of the CRUSADE Initiative may not be aimed at all the key participants in NSTE ACS care. Significant gaps exist between acute NSTE ACS treatments administered by cardiologists versus primary care providers such as internists, hospitalists, and family practitioners. Utilization of all acute therapies, especially anti-platelet and catheterization therapies, are reduced significantly when internal medicine or family medicine physicians are primarily responsible for providing care [18]. It appears the CRUSADE initiative educational efforts should be targeted at these groups as well.

Effectiveness of CRUSADE Educational Interventions

The CRUSADE Initiative has been active for two-and-a-half years, allowing participating hospitals to receive up to eight quarterly reports of their ACC/AHA guideline adherence. The results, in terms of improved guideline adherence, have been most gratifying. There has been a consistent increase in guideline adherence during this time. Utilization rates for all acute therapies have increased from quarter 1, 2002 to quarter 4, 2003 across CRUSADE participating hospitals. Catheterization rates have increased and the time to catheterization has decreased. The upward trends in acute therapy utilization demonstrate that the active monitoring and targeted educational interventions CRUSADE provides sites can impact clinical practice and help improve outcomes.

It is not entirely clear whether this improvement in guideline-driven care is due to the CRUSADE Initiative, or simply the result of improvement in national practice patterns, but the correlation of improvement with CRUSADE educational efforts is difficult to discount. Still, some hospitals have been more successful than others in promoting change, particularly in the ED management of these patients. In a recent survey of ED directors and advocates at CRUSADE hospitals, factors which were correlated with improved guideline adherence included a strong hospital administration commitment to quality improvement, strong collaboration between the ED and hospital administration, ongoing collaboration between the ED and cardiology, and an identified algorithm for NSTE ACS care in the ED [19]. These are the educational principles which CRUSADE supports, both educationally as well as logistically. CRUSADE provides the educational tools and expertise, and the participating hospitals and their patients benefit.

Conclusion

In its first two-and-a-half years, the CRUSADE Initiative has enjoyed remarkable success. The CRUSADE NSTE ACS registry now includes over 100,000 patients, providing important insights into NSTE ACS treatment patterns in the United States. More importantly, CRUSADE provides visibility into areas where NSTE ACS care can improve, and it provides the tools to facilitate those improvements. Judging from the first 100,000 patients, continued education and quality improvement efforts are needed to improve risk stratification and identification of high risk NSTE ACS patients who may benefit most from NSTE ACS treatments. In addition, improvement is needed in the utilization of guideline-driven ED treatments in high risk NSTE patients. Finally, coordination of care between the ED, cardiology, and other care givers is needed to truly optimize the care of NSTE ACS patients. The CRUSADE initiative has proved to be an excellent tool to change clinical practice and improve patient outcomes for NSTE ACS.

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DISCLOSURES

In accordance with the ACCME Standards for Commercial Support of CME, the authors have disclosed relevant relationships with pharmaceutical or device manufactures. The discloures reflect honoraria and/or research support received either directly or indirectly.

Dr. Blomkalns: Millennium, Schering-Plough, Aventis, Scios, Biosite, i-STAT, and Inovise Medical.
Dr. Gibler: Millennium, Schering-Plough, Aventis, Scios, Biosite, i-STAT, and Inovise Medical.
Dr. Hoekstra: Aventis, Millennium, and Biosite.
Dr. Miller: Millennium and Biosite.
Dr. Ohman: Millennium, Bristol-Myers-Squibb, Sanofi, Schering-Plough, and Berlex.
Dr. Peterson: Millennium Pharmaceuticals, Schering-Plough, and Bristol-Myers Squibb/Sanofi
Dr. Pollack: Aventis, Millennium, Schering-Plough, Bristol-Myers-Squibb, and Sanofi.
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Supported in part by an unrestricted educational grant from Millennium Pharmaceuticals/Schering-Plough and Bristol-Myers Squibb/Sanofi.

CME Post - Test Answer Form Evaluation Questionnaire

(Please circle answers below)

1) According to the 2002 Updated ACC/AHA guidelines, which of the following therapies is a Class IA recommendation for patients destined to undergo coronary catheterization and percutaneous coronary intervention (PCI):
   a. Aspirin
   b. Heparin
   c. GP IIb/IIIa inhibitor
   d. Clopidogrel
   e. All of these are Class IA recommendations for such patients

2) Which of the following statements best describes the CRUSADE Initiative?
   a. It is a prospective randomized trial of patients with ACS.
   b. The CRUSADE registry has a lower in-hospital mortality rate than randomized controlled ACS trials.
   c. CRUSADE is an academic collaborative project between emergency physicians and cardiologists.
   d. CRUSADE sites include roughly 100 hospitals across the United States and Europe.
   e. The CRUSADE initiative has not been able to change ACC/AHA guideline adherence over time in participating hospitals.

3) The CRUSADE Initiative 100,000 patient data analysis has demonstrated which of the following?
   a. CRUSADE patients are high risk, with a high percentage having coronary disease, elevated troponin levels, or ECG changes.
   b. Lipid lowering agents are over utilized at discharge in CRUSADE patients
   c. Less than half the eligible CRUSADE patients receive ASA within the first 24 hours after admission
   d. The majority of patients in the CRUSADE registry receive a IIb/IIIa inhibitor in the first 24 hours after admission
   e. All of the above

4) The CRUSADE Initiative includes which of the following educational interventions:
   a. A multicenter, interdisciplinary patient registry for NSTE ACS patients
   b. Educational programs by key CRUSADE faculty at participating hospitals
   c. A toolbox of CQI interventions to improve compliance with the ACC/AHA guidelines
   d. All of the above
   e. None of the above

5) In the CRUSADE initiative, in-hospital mortality in ACS has been correlated with overall ACC/AHA guideline adherence. T F

6) In the CRUSADE initiative 100,000 patient data set, 34% of patients receive aspirin alone as their antiplatelet therapy for the first 24 hours after admission. T F

7) In the CRUSADE Initiative 100,000 patient data set, the median time to diagnostic catheterization is over 24 hours. T F

8) In the CRUSADE Initiative, ACS patients with high risk by PURSUIT score receive more aggressive acute therapy than low risk patients. T F

Evaluation Questions

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

ADDRESS ENVELOPE TO: Office of Continuing Medical Education, University of Cincinnati College of Medicine, PO Box 670567, Cincinnati OH 45267-0567

CME EXPIRATION DATE: April 1, 2006

On a scale of 1 to 5, with 1 being highly satisfied and 5 being highly dissatisfied, please rate this program with respect to:

	Highly satisfied				Highly dissatisfied
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