

randomized trials [Connolly SJ et al. *JAMA* 2003; Raviele A et al. *Eur Heart J* 2004] that failed to prove the superiority of cardiac pacing over placebo for the prevention of syncopal recurrences in unselected patients who were affected by NMS. Prof. Brignole believes that the discrepancy between these findings may be explained by the current study's use of implantable loop recorders (ILRs) to document asystole in patients with NMS before beginning therapy.

This was a randomized, controlled, double-blind trial of cardiac pacing in 77 patients with NMS who had asystolic syncope  $\geq 3$  seconds or nonsyncopal asystole  $\geq 6$  seconds, as established with the use of an ILR. The primary endpoint was time to first syncope recurrence. Subjects with qualifying asystolic events had pacemakers implanted and were randomized 1:1 to either pacemaker on (PM on) or pacemaker off (PM off) groups. The study was stopped when a total of 27 primary endpoint events, irrespective of study arm, were reached. There were a total of 158 documented endpoints during the ILR screening phase; 56% patients had asystole, 23% had normal sinus rhythm, 10% had tachycardia, and 10% had bradycardia.

Baseline characteristics included a mean participant age of 63 years in each group, of which approximately half in each group was female (47% PM on, 59% PM off), and  $>60\%$  had a prior hospitalization for syncope. Over 80% in the cohort had tilt table testing, with fewer patients in the PM on group having positive results than in the PM off group (42% vs 72%). Diabetes was present in 29% of patients, while 23% had structural heart disease. Overall, patients were characterized by recurrent syncope that began in middle or older age with severe presentations; mean pause, captured by an ILR of 11 seconds; and frequent injuries that were related to absence of warning symptoms.

After 24 months, 75% of PM on patients were free from recurrent syncopal episodes compared with 43% of patients who were randomized to PM off (log rank RRR, 57%;  $p=0.039$ ). Complications were restricted to lead dislodgements ( $n=5$ ) and 1 incidence of subclavian vein thrombosis.

The authors concluded that dual-chamber permanent pacing is effective in reducing recurrence of syncope in patients aged  $\geq 40$  years with severe asystolic NMS and suggest that the use of this invasive treatment may be effective for relatively benign NMS. The overall strategy of using an ILR in order to determine suitable patients for pacing likely contributed to the positive findings and explains the discrepancy with the negative results of previous randomized controlled trials.

In selected patients, syncope is recurrent, unpredictable, and associated with a high risk of trauma and poor quality

of life. It often occurs while engaged in high-risk activity (eg, driving, machine operation, flying, competitive athletics). Prof. Brignole believes that the ILR screening phase is important in determining which patients should receive a pacemaker. Based on prior observations, 18% percent of patients who receive an ILR will be candidates for pacemaker therapy within 1 year, and approximately 40% will be candidates within 4 years.

## BRIDGE-ACS: Multifaceted Quality Improvement Program Ups the Use of Evidence-Based Care in Brazil

Written by Rita Buckley

Outcomes from the Brazilian Intervention to Increase Evidence Usage in Acute Coronary Syndromes Trial [BRIDGE-ACS; NCT00958958] show that a simple, multifaceted, educational intervention can lead to significant improvements in the use of evidence-based medications in patients with acute coronary syndromes (ACS). Otavio Berwanger, MD, PhD, Research Institute Hcor-Hospital do Coração, São Paulo, Brazil, presented results from the study.

BRIDGE-ACS was a cluster-randomized (concealed allocation) trial that was conducted among 34 clusters (public hospitals) in Brazil. It enrolled a total of 1150 patients with ACS from March through November 2011, with follow-up through January 2012. The primary endpoint was the percentage of eligible patients who received all evidence-based therapies (aspirin, clopidogrel, anticoagulants, and statins) during the first 24 hours [Berwanger O et al. *JAMA* 2012; Berwanger O et al. *Am Heart J* 2012]. Secondary endpoints included adherence to all eligible evidence-based therapies during the first 24 hours and the use of aspirin, beta-blockers, statins, and ACE inhibitors at discharge; a composite evidence-based medicine score; and major cardiovascular (CV) events. CV endpoints, including mortality, CV death, recurrent ischemic events, and bleeding, were also measured as secondary endpoints. Outcomes were reviewed by blinded outcome assessors. The analyses were performed using an intention-to-treat principle.

The trial included general public hospitals from major urban areas with an emergency department that treated patients with ACS. Eligible subjects were consecutive patients who met standardized definitions of ACS (STEMI, NSTEMI, and unstable angina) as soon as

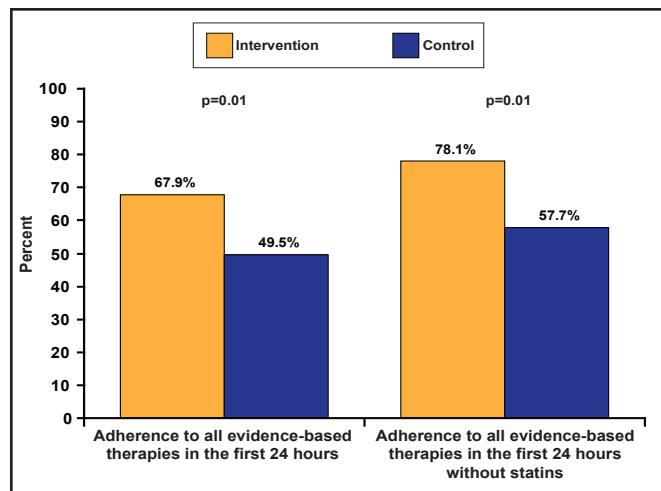
they presented in the emergency department. Private hospitals, cardiology institutes, and hospitals from rural areas were excluded from the study.

The quality improvement (QI) intervention included printed reminders that were attached to the clinical evaluation form; a checklist; educational materials; an algorithm for risk stratification and recommendation of evidence-based therapies for each risk category; and color-coded bracelets according to risk stratification category.

Clusters that were randomized to the QI program received on-site training visits that were complemented by web-based and telephone training. In addition, two health professionals (a physician who acted as the local leader and a research nurse case manager) attended a workshop on how to implement the QI intervention.

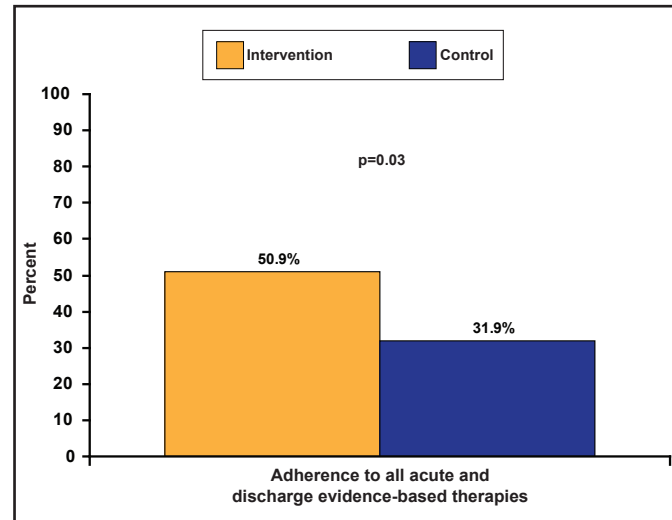
Among the 80.3% of patients who were eligible for all of the study interventions, 67.9% of those in hospitals that were randomized to the QI program received all of the evidence-based therapies in the first 24 hours versus 49.5% of patients who were randomized to hospitals without the QI program ( $p=0.01$ ; Figure 1). Similarly, use of all evidence-based therapies during the first 24 hours and at discharge among eligible patients was higher in the intervention clusters versus controls (50.9% vs 31.9%;  $p=0.03$ ; Figure 2). Overall, composite adherence scores were higher in QI intervention clusters than in control group clusters (89% vs 81.4%;  $p=0.01$ ). There was no heterogeneity in the primary endpoint among major subgroups, including institution characteristics, such as teaching versus nonteaching, PCI availability, and cardiac surgery availability.

**Figure 1. Adherence to All Evidence-Based Therapies in the First 24 Hours.**



ZBerwanger O et al. JAMA 2012.

**Figure 2. Adherence to All Acute and Discharge Evidence-Based Therapies.**



Berwanger O et al. JAMA 2012.

Overall, the intervention had no significant difference on clinical outcomes. The rates of major CV events were 5.5% for patients from clusters that were randomized to the QI intervention versus 7.0% in control group clusters ( $p=0.35$ ). There was a trend toward a reduced odds of myocardial infarction (OR, 0.25; 95% CI, 0.05 to 1.26;  $p=0.09$ ) but an increase in major bleeding (OR, 6.88; 95% CI, 0.93 to 51.10;  $p=0.06$ ) with intervention.

According to Dr. Berwanger, the tools that were tested in the BRIDGE-ACS trial are both simple and feasible. As such, they can become the basis for developing quality improvement programs to maximize the use of evidence-based interventions for the management of ACS.

## ROMICAT II: More Data Evaluating CT-First for Acute Chest Pain ED Triage

Written by Rita Buckley

The use of coronary computed tomography (CCTA) for screening patients that present in emergency departments (EDs) with acute chest pain shortens length of stay (LOS) compared with standard ED evaluation, according to the Rule Out Myocardial Infarction Using Computer-Assisted Tomography II Trial [ROMICAT II; NCT01084239]. ROMICAT II also showed that use of CCTA early into an ED evaluation improved clinical decision-making for ED triage compared with the standard approach. Udo Hoffmann,