AHC Media

Vol. 33, Issue 6, June 2014
www.ahcmedia.com

Clinical Cardiology [ALERT]

Critical analysis of the latest clinical research in cardiovascular medicine

ABSTRACT & COMMENTARY

Should Asymptomatic Patients with Severe Mitral Regurgitation be Referred for Valve Repair?

By Jeffrey Zimmet, MD, PhD

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Dr. Zimmet reports no financial relationships relevant to this field of study.

SOURCE: Kang DH, et al. Early surgery versus conventional treatment for asymptomatic severe mitral regurgitation: A propensity analysis. *J Am Coll Cardiol* 2014; Mar 14. doi: 10.1016/j.jacc.2014.02.577. [Epub ahead of print.]

In patients with severe degenerative mitral regurgitation (MR), surgery is clearly recommended in the presence of any symptoms. In asymptomatic patients, current American College of Cardiology Foundation/American Heart Association (ACC/AHA) guidelines establish a class I recommendation for surgery in the presence of high-risk markers including reduced left ventricular ejection fraction (LVEF), increased LV end-systolic dimension (LVESD), and pulmonary hypertension. As surgical techniques and outcomes have improved, however, there has been a growing tendency to consider surgery in truly asymptomatic low-risk patients without high-risk descriptors, especially when mitral repair as opposed to replacement is felt to be feasible. This presumes the superiority of mitral repair as the surgical procedure of choice, due to lower perioperative mortality, better conservation of left ventricular geometry from preservation of valvular and subvalvular structures, and avoidance of long-term anticoagulation. Evidence for using severe MR

Financial Disclosure: *Clinical Cardiology Alert's* Editor, Michael H. Crawford, MD, reports no financial relationships relevant to this field of study, and peer reviewer, Ethan Weiss, MD, is a scientific advisory board member for Bionovo. Managing Editor, Neill Kimball, and Executive Editor, Leslie Coplin, report no financial relationships relevant to this field of study.

Clinical Cardiology [ALERT]

Clinical Cardiology Alert, ISSN 0741-4218, is published monthly by AHC Media LLC, One Atlanta Plaza 950 East Paces Ferry Road NE Suite 2850 Atlanta, GA 30326.

POSTMASTER: Send address changes to *Clinical Cardiology Alert*, P.O. Box 550669, Atlanta, GA 30355.

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Subscription Prices
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Print: 1 year with free AMA Category 1 credits: $349
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Back Issues: $42. Missing issues will be fulfilled by customer service free of charge when contacted within one month of the missing issue's date.

GST Registration Number: R128870672. Periodicals Postage Paid at Atlanta, GA, 30304 and at additional mailing offices.

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itself as an indication for surgery has been distinctly lacking, however. While ACC/AHA guidelines assign a IIa indication for mitral repair when the success rate is expected to exceed 90%, the European Society of Cardiology guidelines recommend close monitoring for these patients, with surgery to be recommended later with the appearance of symptoms or certain echocardiographic markers.

The performance of an appropriately sized randomized, controlled trial (RCT) in this setting has well-recognized difficulties. While it is not an RCT, the study by Kang et al adds significantly to the data in this arena. Over the course of the period between 1996-2009, 610 consecutive patients with asymptomatic severe MR and no high-risk features were collected and analyzed in a prospective fashion. A total of 235 of these patients underwent early surgery in a non-randomized manner. The remaining 375 patients had conventional treatment, consisting of observation and referral for surgery for dyspnea, decreased LVEF or increased LVESD, or elevated pulmonary pressures. Propensity score matching was performed for the entire cohort, yielding 207 matched pairs for follow up. The primary outcome was cardiac death, with a secondary outcome defined as a composite of events including all-cause mortality, operative mortality, repeat mitral surgery, and hospitalization for congestive heart failure.

In the propensity-matched groups, the early surgery group had a significantly lower cardiac mortality rate (1 ± 1% vs 6 ± 2% at 12 years, $P = 0.010$) as well as a composite event rate (4 ± 2% vs 19 ± 4% at 12 years, $P = 0.001$). A subgroup analysis was also performed according to age, showing that the benefit of early surgery was significant only in the group ≥ 50 years of age. The authors concluded that in patients aged ≥ 50 years with asymptomatic severe MR, early surgery is associated with reduced long-term cardiac mortality and major events compared with conservative management.

■ COMMENTARY

In this relatively large cohort of propensity-matched patients with asymptomatic severe MR, early surgery was associated with lower rates of cardiac events and cardiac mortality. These results clearly back a strategy of referral to surgery based on severe MR alone. However, several points merit further discussion. In the overall cohort, only 92 events were recorded despite the relatively long-term follow-up. The baseline clinical and echocardiographic characteristics of the initial groups were not similar — the early surgery group had significantly larger regurgitant volume, LV and LA dimensions, and Charlson comorbidity index — necessitating the propensity score matching. This process, however, left us with only 61 outcome events, further weakening the quantitative value of the relative risk calculations.

One finding of the study was that fewer patients in the conventional watchful waiting group underwent mitral valve repair (as opposed to replacement), compared with the early surgery group (82% vs 94%, $P < 0.001$). The authors propose this as one of the findings of the study — that is, that a watchful waiting approach may lessen chances for repair compared with early surgery. Notably, we are not supplied with any information about why repair was not selected as often in the "conventional" group. In this non-randomized study, features unfavorable for repair may very well have been responsible for assignment to the watchful waiting group in the first place, thus weakening the value of that comparison.

While far from perfect, this study certainly adds to the growing body of knowledge supporting early surgery for asymptomatic severe MR. Until a definitive RCT is performed, these are among our best available data. ■

ABSTRACT & COMMENTARY

Long-Term Benefits of Cardiac Resynchronization Therapy in Patients with Left Bundle Branch Block

By Edward P. Gerstenfeld, MD

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Dr. Gerstenfeld does research for Biosense Webster, Medtronic, and Rhythmia Medical.

SOURCE: Goldenberg I, et al. Survival with cardiac-resynchronization therapy in mild heart failure. *N Engl J Med* 2014;370:1694-1701.

The Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy (MADIT-CRT) showed that implantation of a cardiac-resynchronization therapy with a defibrillator (CRT-D) in patients with left bundle-branch block (LBBB), Class I or II congestive heart failure (CHF), and an ejection fraction < 30% was associated with a significant reduction in heart-failure events over 2.4 years. In this study, post-trial follow-up was performed in 1691 surviving patients and 854 patients enrolled in the post-trial registries. Patients were followed for a median of 5.6 years after the trial was completed.

After 7 years of follow-up, the cumulative rate of death from any cause in patients with LBBB was 29% in the implantable cardiac defibrillator (ICD) only group compared to 18% in the CRT-D group (hazard ratio in the CRT-D group, 0.59; 95% confidence interval [CI], 0.43-0.80; $P < 0.001$). The cumulative rate of heart failure was also significantly lower among those randomized to CRT-D. The rate of death from any cause or congestive heart failure was no different between the ICD only and CRT-D groups in those patients without LBBB. The lack of survival benefit persisted for patients with non-LBBB regardless of QRS duration < 150 ms or > 150 ms, and among patients with right bundle-branch block (RBBB). The authors concluded that early CRT-D placement in patients with mild heart failure symptoms, left ventricular systolic dysfunction, and LBBB was associated with a significantly longer long-term survival.

■ COMMENTARY

Cardiac resynchronization therapy has been demonstrated to improve symptoms and heart failure hospitalization among patients with reduced ejection fraction (EF), wide QRS, and Class III CHF. The MADIT-CRT trial extended thee findings to patients with milder Class I or II CHF. The current study shows that there remains a long-term (7-year) benefit in mortality and reduced CHF hospitalizations in patients with Class I or II CHF and LBBB who receive CRT-D. However, there was no clear benefit in patients without LBBB, even in the presence of a wide QRS. Should we no longer implant biventricular devices in patients with wide QRS and non-LBBB patterns? Certainly there is little evidence in patients with RBBB that there is benefit from CRT-D. In addition, patients with non-LBBB patterns and QRS durations < 150 ms are unlikely to benefit. However, patients with a wide QRS have been shown to benefit from CRT-D in several trials enrolling patients with reduced EF and Class III CHF. Many of these patients will be undergoing ICD placement, and CRT is often the last hope before undergoing transplant evaluation. Some of these patients may benefit from CRT and there is little additional risk. In patients with reduced EF and only mild CHF, one should carefully consider the added cost and complexity of adding a left ventricular lead in patients with non-LBBB patterns. The likely reason for lack of benefit is that the latest left ventricular activation may not be in the posterolateral wall in these patients. Improved technology to allow localization of the latest region of ventricular activation is being investigated using cardiac MRI. More information on where to place the LV lead in patients with non-LBBB patterns and real-time measurement of dyssynchrony during LV lead placement may lead to improved therapy in the future. For now, one should certainly strongly recommend placement of CRT-D devices in patients with EF < 30% and LBBB, regardless of CHF class. Groups with non-LBBB patterns and mild CHF require further study. ■

ABSTRACT & COMMENTARY

Antiplatelet Agents Plus Oral Anticoagulants in Atrial Fibrillation

By Michael H. Crawford, MD, Editor

SOURCE: Lamberts M, et al. Antiplatelet therapy for stable coronary artery disease in atrial fibrillation patients taking an oral anticoagulant: A nationwide cohort study. *Circulation* 2014;129:1577-1585.

In patients with stable coronary artery disease and atrial fibrillation (AF) on oral anticoagulants, adding antiplatelet agents is common and recommended in guidelines, especially during the first year after an acute coronary event or revascularization. However, concern has been expressed about the risk of bleeding. Thus, these investigators from Denmark evaluated nationwide Danish administrative registries to identify all AF patients hospitalized for myocardial infarction (MI) or a percutaneous coronary intervention (PCI) over 10 years between 2001-2011. Patients who were stable (without another event) after 360 days were entered into the analysis of the risk of cardiovascular or serious bleeding events in relation to ongoing antithrombic therapy, which included antiplatelet agents and oral anticoagulants. A total of 8700 patients were followed for a mean of 3 years. The crude rates of events per 100 person years are as follows: MI/coronary death 7.2, thromboembolism 3.8, and serious bleeding 4.0. Compared to oral anticoagulants alone (OAC), the risk of MI/death for OAC plus aspirin was 1.12 (hazard ratio [HR], 1.12; 95% confidence interval [CI], 0.94-1.34) and for OAC plus clopidogrel was 1.53 (HR, 1.53; 95% CI, 0.93-2.52). The risk of thromboembolism was comparable for all OAC conditions, but the risk of bleeding increased for OAC plus aspirin (HR, 1.5; 95% CI, 1.23-1.82) and for OAC plus clopidogrel (HR, 1.84; 95% CI, 1.11-3.06). The authors concluded that in stable CAD patients with AF, adding antiplatelet therapy (APT) to OAC treatment increased the risk of bleeding without any reduction in the risk of coronary events or thromboembolism.

■ COMMENTARY

This has been a bad month for aspirin. The FDA has withdrawn approval for its use in primary prevention and now it adds nothing to OAC therapy in patients with stable CAD and AF. In fact, it seems to cause harm in both populations. In some ways, these new data are not surprising because they support previous smaller studies, and the European Society of Cardiology has recommended dual antiplatelet therapy (DAPT) after an acute coronary event or PCI, plus OAC if the patient has AF, until 1 year and then they recommend OAC only if the patient's CAD is stable. These data support the latter.

Other interesting data were exhibited by this study, but only included in the discussion. They showed that single-agent APT only increased the risk of death and DAPT increased the risk of bleeding, confirming the results of other studies. Also, they confirmed that OAC was superior to single or DAPT for preventing thromboemboli, and the addition of APTs added no benefit. Other studies have shown that the benefits of APT are greatest early after CAD events, which may help explain these data.

The major weakness of this study is that it is observational, so you can't be certain about cause and effect relationships. The authors argue that the strength of the study is the large number of real-world patients. However, since drug therapy wasn't randomized, it is possible that selection biases could have influenced the results. For example, the patients kept on triple therapy (OAC + DAPT) may have been sicker than those kept on fewer drugs. In addition, in this type of administrative database study, it is difficult to control for unmeasured confounders such as smoking, body mass index, coronary anatomy, the type of AF (paroxysmal, persistent, permanent), the INR, the type of stents, and over-the-counter medications. Finally, the OACs used were warfarin or phenprocoumon. Whether novel OACs would have performed differently is unknown.

At this time, it seems reasonable to follow the recommendation of the European Society of Cardiology and use OACs only in CAD patients with AF who have been stable for 1 year. What to do prior to the 1-year point is still debatable, so individual judgment about the particular patients' risks and potential benefits of single, double, or triple therapy needs to be weighed. Also, patient preference may play a role in the decision. ■

ABSTRACT & COMMENTARY

Door-to-Balloon Time Isn't Everything: Transradial Access in Primary PCI May be Worth the Delay

By Jeffrey Zimmet, MD, PhD

Associate Professor of Medicine, University of California, San Francisco, Director, Cardiac Catheterization Laboratory, San Francisco VA Medical Center

SOURCE: Wimmer NJ, et al. Delay in reperfusion with transradial percutaneous coronary intervention for ST-elevation myocardial infarction: Might some delays be acceptable? *Am Heart J* 2014; April 7. [Epub ahead of print.]

The mortality benefit to percutaneous coronary intervention (PCI) is unquestioned when it comes to ST-elevation myocardial infarction (STEMI). Based on compelling observational data linking time to reperfusion with mortality, incentives have aligned strongly toward decreasing reperfusion times, with guidelines supporting door-to-balloon (D2B) times < 90 minutes in the United States and < 60 minutes in Europe. D2B time has become a central performance measure, with reimbursement and public reporting incentives aligning to drive down times. Despite D2B times decreasing steadily over recent years, however, concomitant gains in mortality have not been observed.

Transradial arterial access for PCI has likewise been steadily gaining ground worldwide, but considerable variability exists among countries, hospitals, and individual operators. In the United States in particular, penetration of transradial technique has been slow on the uptake, particularly in the realm of STEMI. This is despite growing evidence for a benefit to transradial access. In particular, the RIVAL and RIFLE-STEACS trials each reported a mortality benefit to transradial PCI, both for in-hospital and 30-day outcomes. Even for the experienced operators in these trials, however, there was at least a trend toward longer procedure times and crossover rates from radial to femoral of more than 5%. The time delay inherent to radial vs femoral access, especially in the hands of operators with lesser radial experience, establishes a significant barrier to the adoption of radial access for STEMI intervention.

In this study, Wimmer and colleagues present a model comparing radial with femoral strategies in primary PCI, where the primary outcome was 30-day mortality. They used published mortality data from the RIVAL and RIFLE-STEACS trials, along with published estimates of per-minute increases in mortality with delays in D2B time. They used their model to quantify the delay in D2B time with radial vs femoral access (the transradial delay) that would counterbalance the reported mortality benefit of the transradial approach. Notably, because these two studies were reported using the intention-to-treat principle, the pooled crossover rate (from radial to femoral) of 7.8% is inherent in the mortality estimates. In the base case, the full mortality benefit reported in the two published studies was assumed, along with the per-minute mortality penalty reported from the NCDR Cath PCI database. A separate analysis was performed using the higher mortality estimates from an older Medicare population.

The results are striking. In the base case, the authors estimate that a transradial delay of 83 minutes would be required to offset the full reported mortality benefit of transradial PCI from the two randomized trials. Because the magnitude of the mortality benefit seen in RIVAL and RIFLE has been questioned, the analysis was repeated using estimates of mortality benefit that were half and one-quarter of those reported. The break-even times for transradial delay for these cases were still significant, at 41.8 and 20.9 minutes. When the analysis was performed based on the higher per-minute mortality penalty reported in the Medicare population, a transradial delay of 61.5 minutes was found. Even combinations of the higher per-minute penalty with 50% or 75% lower transradial mortality benefit resulted in a significant time buffer, with 30.8 and 14.8 minutes of transradial delay associated with equivalent mortality. The authors concluded that substantial delays in transradial access are required to substantially reduce the mortality benefit observed with transradial PCI for STEMI in randomized trials. These results have significant implications for operators reluctant to use the transradial approach in primary PCI and D2B time standards.

■ COMMENTARY

This is a very thought-provoking analysis, but we should approach its interpretation with caution. The magnitude of the transradial mortality benefit estimated by the two available randomized, controlled trials (RCTs), as well as the ability to replicate these results in general practice, has been widely questioned. Indeed, the nearly 4% absolute mortality reduction reported in RIFLE is greater than what one would expect from the best-recognized advantage of transradial access, namely the reduction in access site bleeding. If we accept that a mortality advantage to transradial access is both plausible and true, however, we can start to look at the major barriers to adoption of transradial primary PCI. These barriers primarily include the higher crossover rate and likely delays in achieved D2B times with transradial access. In what we would consider the best case, assuming the full magnitude of mortality benefit estimated by the RCTs, the time delay required to offset the benefit of transradial access was calculated at an astounding 83 minutes. The inclusion of a series of sensitivity analyses with varying mortality benefit and crossover rates is especially compelling, with even the worst case resulting in a significant time buffer supporting radial access.

The intention here is not to argue for a radial approach for all settings and all operators. Guidelines from the Society for Cardiovascular Angiography and Intervention (SCAI) recommend that interventionalists first perform a minimum of

[The authors concluded that substantial delays in transradial access are required to substantially reduce the mortality benefit observed with transradial PCI for STEMI in randomized trials.]

100 elective PCIs from the transradial approach and achieve a femoral crossover rate of < 4% before considering a foray into transradial primary PCI. Substantial delays must still be avoided, and teams must be prepared to cross over to femoral access should the need arise. Experienced operators who are considering a switch may be reassured by the concept that the inevitable prolonged procedure times may be counterbalanced by the mortality benefits of transradial PCI.

Realistically, however, the data from this paper will be small consolation if D2B times suffer, given that so much is currently tied to this data point. Given that incremental decreases in D2B times have not resulted in decreased mortality, this study provides an opportunity to reassess the D2B metric. Whether it makes sense to reduce the emphasis on reperfusion times to allow for consideration of other improvements in care, such as decreasing false STEMI activations and transradial access, remains to be seen. ■

ABSTRACT & COMMENTARY

Current Utility of Exercise ECG Testing

By Michael H. Crawford, MD, Editor

SOURCES: Christman MP, et al. Yield of downstream tests after exercise treadmill testing. *J Am Coll Cardiol* 2014;63:1264-1274. Sinusas AJ, Spatz ES. Reframing the interpretation and application of exercise electrocardiography. *J Am Coll Cardiol* 2014;63:1275-1277.

Most current guidelines recommend exercise electrocardiographic (ECG) testing for suspected coronary artery disease (CAD) in patients who can exercise and have a normal resting ECG. If the results are inconclusive, often another stress test with non-invasive imaging is done. These investigators sought to analyze the results of this downstream testing and identify characteristics that would make such testing valuable or not. The patient sample was collected over 2 years and excluded patients with known CAD. The Bruce treadmill protocol was used and standard criteria for positive, negative, and inconclusive ECGs was used. They analyzed any subsequent testing done by the ordering physician for 6 months after the initial test. Also, the patients were followed for subsequent cardiac events (death, myocardial infarction, or revascularization). The study population included 3656 patients, of whom 90% (3270) had complete follow-up for a mean of 2.5 years. Negative tests were most common (68%), inconclusive next (28%), and positive least (4%). The most common reasons for an inconclusive test were suboptimal exercise (57%),

rapid resolution of ECG changes (13%), and test cessation for typical angina (10%). Further testing was performed in 11% (9% noninvasive imagining, 2% invasive angiography). Subsequent noninvasive imaging included stress nuclear perfusion (81%), stress echo (12%), coronary CT angiography (5%), and cardiac MRI (2%). The combined outcome endpoint occurred in those with a negative initial test was 0.2%, inconclusive 1.3%, and positive 12%. Multivariate analysis showed that younger age, female sex, higher exercise performance, and rapid recovery of any ECG changes predicted negative further testing and event free survival. The development of typical angina during the initial test predicted positive downstream testing and a worse prognosis. The authors concluded that these findings can be used to identify which patients would benefit from further testing after an initial exercise ECG test to diagnose CAD.

■ COMMENTARY

The major limitation of this trial is that it is an observational study done at one center. However, since randomized trials are unlikely to be conducted on this topic, the data can help inform our decisions in this complex and controversial area. Treadmill exercise ECG testing is commonly used as the initial diagnostic test in patients with symptoms that could represent myocardial ischemia, with the caveat that they can exercise near maximally and have a normal resting ECG. Prior observational studies have shown that these requirements are only present in about one-third of patients referred for stress testing. Most undiagnosed patients either have abnormal ECGs, can't fully exercise, or have unstable angina. Even in this academic center series, more than half of the patients with an inconclusive test were not able to exercise fully. In my practice, anyone > 80 years of age or obese, I automatically eliminate exercise testing.

Interpreting this study is challenging because some of the downstream testing was obviously indicated, such as the patients with typical angina, but a normal ECG. In such patients, it is not inappropriate to do an imaging study or invasive angiography. In this study, 100% of those with obvious angina on stress testing had a significant coronary lesion that was stented. On the other side, a negative stress test would rarely indicate a need for further testing and in this study, the incidence of the combined endpoint was 0.2% in such patients. However, someone with angina symptoms and a negative stress test may have vasospasm or small vessel disease and further sophisticated imaging could be appropriate. There are nuanced areas in ischemic heart disease that may trump usual thinking.

Perhaps the most interesting data from this study are the subgroup with an inconclusive ECG exercise test because of rapid reversal of ST changes in recovery (< 60 seconds). There is considerable prior literature that suggests this may be characteristic of a false-positive test. In this study, such patients had an excellent prognosis. They had no positive downstream tests and no deaths or myocardial infarctions. Their data support the notion that this finding represents a false-positive test.

[In this study, 100% of those with obvious angina on stress testing had a significant coronary lesion that was stented.]

Another major limitation of this study is that we do not know the pre-test probability of disease. According to Bayes' Theorem, this markedly affects the outcome of testing. For example, not everyone in the study had further testing, so there may be a section bias toward the more likely to have CAD patients. This would make further testing seem more valuable.

My conclusion is that in the small group of patients who meet criteria for an exercise ECG test, it is still a reasonable test. If typical angina is provoked despite non-diagnostic ECG changes, further testing is indicated. Lacking angina, if there are ECG changes suggestive of ischemia that resolve in < 60 seconds of recovery, this is likely a false-positive test. ■

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CME Questions

1. Rapid resolution of ischemic ECG changes in recovery from treadmill exercise usually indicates:
   a. mild myocardial ischemia.
   b. false-positive test.
   c. left ventricular aneurysm.
   d. digitalis effect.

2. Cardiac resynchronization therapy for class II-IV systolic heart failure patients is most successful with:
   a. complete LBBB.
   b. incomplete LBBB.
   c. RBBB.
   d. QRS < 150 msec.

3. New data suggest that mitral valve repair may be indicated in:
   a. severe MR, all ages.
   b. moderate MR, all ages.
   c. moderate MR, age < 50 years.
   d. severe MR, age > 50 years.

4. Studies of the use of transradial access for PCI in STEMI have shown:
   a. reduced mortality.
   b. shorter door to balloon times.
   c. more access site bleeding.
   d. All of the above

5. The safest treatment for stable CAD patients with atrial fibrillation is:
   a. aspirin.
   b. clopidogrel.
   c. oral anticoagulants.
   d. dual antiplatelet therapy.

CME Objectives

Upon completion of this educational activity, participants should be able to:

- discuss the most current information related to cardiac illness and the treatment of cardiac disease;
- explain the advantages and disadvantages, as well as possible complications of interventions to treat cardiac illness;
- discuss the advantages, disadvantages, and cost-effectiveness of new and traditional diagnostic tests in the treatment of cardiac illness; and
- discuss current data regarding outpatient care of cardiac patients.