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HEART DEVICES, PROCEDURES EVALUATED ACROSS PATIENT POPULATIONS

Researchers Measure Success by Gender, Race, Age

ATLANTA, GA (March 13, 2006) — Studies investigating procedure and device efficacy across patient populations have found varying results with regard to Implantable Cardioverter Defibrillators (ICD) and defibrillators. According to research presented today at the American College of Cardiology's 55th Annual Scientific Session, new studies take a closer look at women, minorities and athletes, as well as recall issues with ICDs. ACC.06 is the premier cardiovascular medical meeting, bringing together over 30,000 cardiologists to further breakthroughs in cardiovascular medicine.

"Consistent re-evaluation of commonly used devices and procedures ensures their efficacy across patient populations and helps identify new patient groups who may benefit from these procedures," said Douglas P. Zipes, M.D., Indiana University School of Medicine. "These data illuminates critical gaps in procedure and device effectiveness as well as procedural protocol across gender, race and age."

Does Gender Alter the Efficacy of Implantable Cardioverter Defibrillators? (Abstract 947-129)

Implantable Cardioverter Defibrillators (ICD) can be a life saving therapy for patients suffering from cardiovascular disease with an increased risk of fatal arrhythmias. However, the majority of studies involve male patients and, consequently, much less is known about ICD efficacy in women. Researchers from Hartford Hospital in Connecticut and the University of

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Connecticut investigated the use of ICDs in women and found that females have significantly lower survival rates with this procedure than their male counterparts.

The study authors reviewed previous studies on ICDs and evaluated five trials that met the following criteria: controlled trial versus standard of care, ICD as primary prevention, and available data on risk of death for both male and female patients. In total, ICD therapy reduced the risk of death by 24 percent in men, but only by 12 percent in women.

"This study strongly illustrates that ICDs are not the ideal primary prevention method for treating potentially fatal arrhythmias in women," said Nickole Henyan, Pharm.D., Hartford Hospital and lead author of the study. "Special attention needs to be paid to women's health, especially in examining new ways to help them achieve the same survival success rate as male patients."

Gender and Racial Differences in Invasive Diagnostic and Interventional Cardiac Procedures (Abstract 904-230)

Invasive cardiovascular procedures like percutaneous coronary intervention (PCI) are often the first-line and most successful treatment options for a heart attack patient. However, research has shown discrepancies in the frequency of use across gender and racial lines. Study authors from UMDNJ-Robert Wood Johnson Medical School in New Jersey completed a comprehensive study of more than 247,000 patients and found that female and African American patients have significantly lower rates of cardiac catheterization and intervention than white males.

Researchers examined the rate of diagnostic cardiac catheterization in a total of 247,637 patients admitted for their first heart attack between 1986 and 2002 in the statewide Myocardial Infarction Data Acquisition System (MIDAS). Results found that while overall PCI rates are increasing, there are still disparities between gender and race. White males were the most likely to receive cardiac catheterization (65 percent) followed by African American males (61 percent), while white and black women were the least likely to receive the catheterization (48 percent and 50 percent, respectively). In the most recent data, the probability of patients having PCI after catheterization was lower among women (47 percent for women compared to 55 percent for men), and was also lower for African Americans (45 percent vs. 53 percent for whites.)

"While the increase in catheterization and intervention is promising, there are still disparities that must be addressed," said William J. Kostis, Ph.D., UMDNJ-Robert Wood Johnson Medical School and lead author of the study. "Female and African American patients should be provided with the same access to and appropriate recommendations for use of these procedures to increase their chances of recovery post-heart attack."

Sudden Cardiac Death in Athletes: Rates of Defibrillation (Abstract 906-243)

Although cardiac defibrillators are becoming more common in sporting arenas to treat acute cardiac events among athletes, there is little data on the efficacy of defibrillator use in treating victims of sudden cardiac death (SCD) during athletic events. While researchers hypothesized in this study that defibrillator success rates are moderately low due to the potential severity of the underlying heart disease and the rigors of athletic competition, they found that defibrillator use can be extremely effective, regardless of patient age.

Researchers distributed an anonymous survey by mail to 1069 physicians who specialize in providing medical coverage at sporting events. A total of 468 respondents reported 21 episodes of SCD in athletes. Of the 15 athletes over the age of 30 who experienced SCD, 78 percent received defibrillation at the scene, and all survived to hospital discharge. Only one of the six athletes under age 30 who suffered from SCD received defibrillation at the scene and, consequently, survived to hospital discharge. Two additional patients were resuscitated during hospital transport, leading to a total survival rate of 50 percent for patients under age 30.

"Our study results are encouraging, and demonstrate the benefits of defibrillation use in athletes who have gone into cardiac arrest," said Dr. Christine E. Lawless, M.D., of the Ohio State University Medical Center. "The use of defibrillators, especially in the case of younger athletes, should be promoted to increase the chances of patient survival."

Implantable Cardioverter-Defibrillator FDA Recalls and Safety Alerts: Prevalence and Impact on Patient Mortality (Abstract 818-8)

The U.S. Food and Drug Administration (FDA) and device manufacturers have recalled several implantable defibrillators (ICD) over the past several years. These recalls vary in severity from warnings that products could cause serious health problems or death, to less serious warnings about products that are unlikely to cause adverse reactions, but violate labeling

regulations. Study authors from the Cleveland Clinic in Ohio recently examined the potential effects these recalls may have on patients and found that while ICD recalls or safety alerts impact more than 40 percent of patients, they are not necessarily associated with a higher risk of mortality.

"While ICD recalls affect a significant number of patients, their overall impact on patient survival is not significantly different," said Arthur C. Kendig, M.D., Cleveland Clinic Foundation and a co-author of the study.

The study analyzed 1,664 patients who had ICDs implanted at the Cleveland Clinic between August 1996 and May 2004, with 729 patients (44 percent) having ICDs that were subjected to FDA class I or II recalls or manufacturer safety alerts prior to market release.

Patients whose ICDs were issued a class I recall—the most severe recall—experienced no significant difference in mortality when compared to patients whose ICDs were not recalled (31 percent class I recall vs. 34 percent no recall) over an average follow-up period of 3.9 years. Patients with ICDs subjected to a class II recall—the most common type of recall—had a mortality rate of only 26 percent. Survival analysis showed no significant differences in mortality between the groups.

"This is positive news for patients who have had their ICDs subjected to an FDA recall or safety alert and hopefully will help to restore patients' confidence in their devices. Further larger studies are planned to determine the impact of FDA recalls on all patients who have had ICDs implanted," said Mina K. Chung, M.D., Cleveland Clinic Foundation and senior author of the study.

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The American College of Cardiology (www.acc.org) represents the majority of board certified cardiovascular physicians in the United States. Its mission is to advocate for quality cardiovascular care through education, research, promotion, development and application of standards and guidelines- and to influence health care policy. ACC.06 and the ACC inaugural i2 Summit, the first-ever meeting for interventional cardiologists, will bring together more than 30,000 cardiologists and cardiovascular specialists to share the newest discoveries in the treatment and prevention, while helping the ACC achieve its mission to address and improve issues in cardiovascular medicine.