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NEWS RELEASE
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FOR POST-OPERATIVE ATRIAL FIBRILLATION, TWO COMMON TREATMENTS – RATE CONTROL AND RHYTHM CONTROL – SHOW EQUAL OUTCOMES

Both Approaches Deemed Safe and Effective in Research by Cleveland Clinic and Cardiothoracic Surgical Trials Network

Monday, April 4, 2016, Chicago: Cleveland Clinic researchers, as part of the Cardiothoracic Surgical Trials Network (CTSN), have found that two common approaches to post-operative atrial fibrillation – rhythm control and rate control – are equally safe and effective.

Post-operative atrial fibrillation is the most common complication after cardiac surgery, occurring in 20 percent to 50 percent of patients and leading to major adverse effects such as increased morbidity, long-term mortality, reoccurring hospitalizations and increased cost.

Post-operative AF is managed by using one of two methods:

- Rate control, which slows the heart rate with medications, such as digoxin, calcium-channel blockers, and beta blockers, or;

- Rhythm control, which restores the heart's normal sinus rhythm through antiarrhythmic drugs or through direct current cardioversion that uses an electrical shock to convert the heart rhythm back to normal.

The multicenter, randomized trial found that each strategy was associated with equal numbers of hospital days, similar rates of complications and low rates of persistent AF after 60 days. The study showed that the physician should tailor the treatment strategy to an individual patient's clinical situation.

"This is the first large, randomized controlled clinical trial examining treatment strategies for this common complication," said Marc Gillinov, M.D., a cardiothoracic surgeon in Cleveland Clinic's Sydell and Arnold Miller Family Heart & Vascular Institute. "Based

upon these results, it may be reasonable to begin with a strategy of rate control, which limits the risk of toxicity from rhythm control agents."

The findings are being presented by Dr. Gillinov, at the American College of Cardiology 65th Annual Scientific Sessions in Chicago and published simultaneously in the New England Journal of Medicine (NEJM).

The study consented 2,109 patients undergoing elective cardiac surgery to treat coronary artery disease (40 percent), heart valve disease (40 percent) or a combination of both (20 percent). Of those patients, 33 percent developed new onset post-operative atrial fibrillation, out of whom 523 were randomized to a treatment strategy of either rate or rhythm control. Post-operative atrial fibrillation developed in 28 percent of patients who underwent an isolated CABG, 33.7 percent of isolated valve surgery patients, and 47.2 percent of patients who underwent combined CABG and valve surgery.

The primary outcome – the numbers of days in the hospital from the date patients were randomized until 60 days later – did not differ between the patient groups assigned to rate control or rhythm control. There were no differences in overall serious adverse events between the two groups. The average time to onset of post-operative atrial fibrillation was 2.4 days (0-7 days) from surgery.

In the study, rhythm control medications resolved AF faster but came with stronger side effects and more patients had to switch treatment due to intolerance. Rate control led to a slightly higher prevalence of AF during follow up. At 60 days, more rhythm control patients were free of AF, but neither treatment was deemed superior.

"These trial results will serve as valuable guidance to help manage patients after heart surgery," said Michael J. Mack, M.D., chair, Cardiovascular Service Line, Baylor Scott & White Health; cardiovascular researcher, Baylor Scott & White Research Institute; and contributing author to the study.

"Postoperative atrial fibrillation is a common complication of cardiac surgery and adversely affects patient recovery. In patients with postoperative atrial fibrillation, one strategy does not appear to have a net clinical advantage over the other, but there are clinical differences between these strategies. The results of this trial fill an important knowledge gap and should better inform therapeutic decisions for this common complication," said Annetine C. Gelijns, Ph.D., the Edmond A. Guggenheim Professor of Health Policy and Chair of the Department of Health Evidence and Policy at the Icahn School of Medicine at Mount Sinai, and the principal investigator for the Data Coordinating Center based at Mount Sinai.

This CTSN trial was conducted at a total of 21 centers in the U.S. and Canada. Core sites include Baylor Research Institute, Cleveland Clinic, Duke University, Institut Universitaire de Cardiologie et de Pneumologie de Québec, Hôpital Laval, Montefiore-Einstein Heart Center, Montreal Heart Institute, Suburban Hospital, University of Virginia, University of Pennsylvania, University of Southern California and 11 additional

Consortium sites participated as well. The CTSN Data Coordinating Center is located at the Icahn School of Medicine at Mount Sinai and directs each of the CTSN clinical trial designs and methodologies, regulatory and trial conduct and study data analysis and reporting.

This study was supported by a cooperative agreement (U01 HL088942) funded by the National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Neurological Disorders and Stroke (NINDS) of the National Institutes of Health (NIH), Bethesda, MD, and the Canadian Institutes of Health Research (CIHR).

About Baylor Scott & White Health

Formed from the 2013 merger between Baylor Health Care System and Scott & White Healthcare, the system referred to as Baylor Scott & White Health is the largest not-for-profit health care system in the state of Texas. With total assets of $9 billion** and serving a population larger than the state of Georgia, Baylor Scott & White Health has the vision and resources to provide its patients continued quality care while creating a model system for a dramatically changing health care environment. The system now includes 48 hospitals, more than 900 access points, 6,000 active physicians, and 40,000 employees, plus the Scott & White Health Plan, Baylor Scott & White Research Institute and Baylor Scott & White Quality Alliance — a network of clinical providers and facilities focused on improving quality, managing the health of patient populations, and reducing the overall cost of care. For more information visit:

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**Based on unaudited 2015 fiscal year statements

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Editor's Note: Cleveland Clinic News Service is available to provide broadcast-quality interviews and B-roll upon request.

About the Mount Sinai Health System

The Mount Sinai Health System is an integrated health system committed to providing distinguished care, conducting transformative research, and advancing biomedical education. Structured around seven hospital campuses and a single medical school, the Health System has an extensive ambulatory network and a range of inpatient and outpatient services—from community-based facilities to tertiary and quaternary care.

The System includes approximately 6,100 primary and specialty care physicians; 12 joint-venture ambulatory surgery centers; more than 140 ambulatory practices throughout the five boroughs of New York City, Westchester, Long Island, and Florida; and 31 affiliated community health centers. Physicians are affiliated with the renowned Icahn School of Medicine at Mount Sinai, which is ranked among the highest in the nation in National Institutes of Health funding per investigator. The Mount Sinai Hospital is ranked as one of the nation's top 10 hospitals in Geriatrics, Cardiology/Heart Surgery, and Gastroenterology, and is in the top 25 in five other specialties in the 2015-2016 "Best Hospitals" issue of U.S. News & World Report. Mount Sinai's Kravis Children's Hospital also is ranked in seven out of ten pediatric specialties by U.S. News & World Report. The New York Eye and Ear Infirmary of Mount Sinai is ranked 11th nationally for Ophthalmology, while Mount Sinai Beth Israel is ranked regionally.

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