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CLEVIDIPINE DURING HEART SURGERY IMPROVES BLOOD PRESSURE CONTROL
*Also, Peptide Measurement Helps Evaluate Heart- vs. Lung-Related Shortness of
Breath in General Public*

NEW ORLEANS, La. (March 27, 2007) — Researchers today reported that an investigational anti-hypertensive therapy may perform better in controlling blood pressure than standard treatments for patients undergoing heart surgery, during a presentation at the American College of Cardiology's 56th Annual Scientific Session. Another study found that measuring a certain peptide can help evaluate dyspnea (shortness of breath) as heart- or lung-related in the general population. ACC.07 is the premier cardiovascular medical meeting, bringing together cardiologists and cardiovascular specialists to further breakthroughs in cardiovascular medicine.

Blood Pressure Control With Clevidipine Compared With Nitroglycerin, Sodium Nitroprusside, or Nicardipine in the Treatment of Perioperative Hypertension: Results of the Three Randomized ECLIPSE Trials (Abstract 415-8)

While nitroglycerin and sodium nitroprusside have been utilized effectively in patients undergoing cardiac surgery to control blood pressure, a new therapy called clevidipine may perform even better, according to researchers at Global Perioperative Research Organization at Duke Clinical Research Institute. Three separate studies evaluated clevidipine, a novel third-generation intravenous (IV) dihydropyridine calcium channel blocker, to measure

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2 – 2 – 2 ECLIPSE Trial

blood pressure control against standard alternative agents.

The studies, collectively known as ECLIPSE (Evaluation of Clevidipine In the Postoperative Treatment of Hypertension Assessing Safety Events), compared clevidipine to each of three therapies: nitroglycerin, nitroprusside or nicardipine. The studies assessed blood pressure control by calculating the magnitude and duration of episodes when patients' blood pressure went above or below predetermined acceptable ranges, based on the area under the blood-pressure-monitoring curve (AUC) that was outside the upper or lower limits of the range during surgery and for 24 hours afterwards.

The analysis showed that clevidipine maintained better blood pressure control compared to the other agents consistently across different BP ranges. For example, for the widest ranges of 75-145 mm Hg pre- and post-operatively and 65-135 mm Hg during surgery, the BP excursion was about half as much for clevidipine compared to the other agents collectively (3.8 vs. 7.8 mm Hg x min/h, $p = 0.0004$). For the narrowest BP ranges of 105-145 mm Hg pre- and post-operatively and 95-135 mm Hg during surgery, the BP excursion was also less for clevidipine compared to the other agents (87.7 vs. 111.5 mm Hg x min/h, $p = 0.0002$). The trial also showed that the rate of death was significantly lower with clevidipine than with sodium nitroprusside (1.7% vs. 4.7%, $p = 0.045$). Otherwise, the primary endpoints – rates of death, stroke, heart attack and kidney dysfunction – were similar for clevidipine compared to the other three agents.

“More research is needed to confirm the benefits of clevidipine, but these initial results against three very commonly used therapies demonstrate a new potentially valuable alternative, which is very encouraging,” said Solomon Aronson, M.D., of Duke University Medical Center and lead author of the study. “With a better understanding of how to effectively control blood pressure during cardiac surgery, we believe we can significantly improve the outcomes of those operations, all while ensuring patient safety.”

Dr. Aronson will present this study Tuesday, March 27 at 12:00 p.m. in Hall A.

Plasma Pro-B-Type Natriuretic Peptide in Discriminating Between Cardiac and Pulmonary Dyspnea in the Population (Abstract 415-4)

Natriuretic peptides are demonstrating utility in helping emergency room doctors distinguish

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between lung-related or heart-related dyspnea, or shortness of breath. These peptides are natural antagonists to renin, an enzyme produced in the kidneys that leads to high blood pressure. Shortness of breath from heart complications is much different from shortness of breath caused by pulmonary complications, carrying separate risks and requiring different treatment regimens. Researchers in Denmark sought to determine the usefulness of measuring pro-B-type natriuretic peptide levels in screening the general public for an accurate diagnosis of dyspnea.

Using data from nearly 3,000 patients who participated in the Copenhagen City Heart Study, researchers found that those with dyspnea (n=959) had significantly higher levels of pro-BNP than healthy counterparts. Heart conditions were responsible for a 2.6-fold increase in pro-BNP levels in those with dyspnea, compared to those without heart conditions, but pulmonary dysfunction was not associated with any increase of pro-BNP levels in those with dyspnea. After adjusting for age and gender differences, researchers found smaller but significant differences in pro-BNP levels among those with heart conditions compared to those without.

"Prior research has demonstrated the benefit of measuring pro-BNP to distinguish cardiac versus pulmonary dyspnea in the emergency room setting, but ours is the first to successfully assess the source of dyspnea among the general population based on pro-BNP," said Rasmus Mogelvang, M.D., of the University of Copenhagen and lead author of the study. "Given the importance of understanding which type of dyspnea is present, our hope is that measuring pro-BNP will be used frequently as a screening tool in both emergency and non-emergency settings to help doctors evaluate their patients' likelihood of heart disease and treat accordingly."

Dr. Mogelvang will present this study Tuesday, March 27 at 11:00 a.m. in Hall A.

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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.07 and the i2 Summit is the largest cardiovascular meeting, bringing together cardiologists and cardiovascular specialists to share the newest discoveries in treatment and prevention, while helping the ACC achieve its mission to address and improve issues in cardiovascular medicine.