ICU
MANAGEMENT & PRACTICE

Large Scale CIRC Trial Concludes with Significant Results

ZOLLMedical Corporation, a manufacturer of medical devices and related software solutions, has announced the successful conclusion of the ZOLL-sponsored CIRC trial. The trial's Data Safety Monitoring Board (DSMB) closed enrollment when an analysis of the data showed the load-distributing band (AutoPulse® Non-invasive Cardiac Support Pump) to be equivalent to manual chest compressions.

The CIRC trial compares the rates of survival to hospital discharge from out-of-hospital cardiac arrest of patients treated with the load-distributing band device to those receiving manual CPR. The trial commenced in 2007 and enrolled approximately 4,000 patients. The trial was governed by an independent DSMB that reviewed interim outcome and safety data on seven separate occasions.

Manual CPR is the standard for providing temporary circulatory support and oxygen delivery during cardiac arrest. Delivery of manual CPR is not provided consistently. Significant decreases in quality have been seen after as little as one minute. The physical challenges associated with providing consistent manual CPR are recognised as a key factor in CPR quality. Manual CPR has the highest treatment recommendation (Class I) in the American Heart Association Resuscitation Guidelines. Mechanical chest compression devices have been developed to overcome the difficulties in consistent performance of manual CPR.

The principal investigator for the CIRC trial was Lars Wik, M.D., Ph.D., National Competence Center of Emergency Medicine, Oslo University Hospital, Oslo, Norway. The trial was an international effort with trial sites in the United States, Austria, and The Netherlands. More than 500 ZOLL AutoPulse units were deployed and more than 5,000 medics were trained on the use of the device.

"On behalf of all the CIRC investigators, we are excited about the conclusion of enrollment and look forward to presenting complete results later this fall. This is the first large-scale, randomised resuscitation trial to come to a successful conclusion with a statistically significant result," said Dr. Wik. He added, "EMS around the world will look at the CIRC result as positive for AutoPulse. They know how difficult it is to perform manual CPR on a regular basis. My gut feeling is that the CIRC results will increase AutoPulse interest."

Richard A. Packer, CEO of ZOLL commented, "We are pleased to see the CIRC trial successfully concluded and the AutoPulse equivalent to a Class I AHA recommended therapy. While we would have liked to have seen a superior outcome, this finding unequivocally confirms the AutoPulse's role in improving resuscitation." Mr. Packer continued, "It will be some time before the complete picture unfolds as there are still some 400 patients that have yet to be entered into the database, and numerous sub-analyses to be completed. We look forward to publication of the trial's details. We believe the CIRC trial is the largest privately funded trial ever undertaken in the field of resuscitation. We introduced this technology to the market on the strength of earlier studies and with FDA clearance."

"The AutoPulse is currently included in the just released 2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science as a Class IIb intervention with a recommendation for additional studies," he added. Mr. Packer concluded, "This outcome, had it been available, could have improved the recommendation related to the AutoPulse in the Guidelines. The CIRC trial, when published, will be a milestone in resuscitation research for both its conclusion and the quality of trial design. We expect to see the AutoPulse become a standard element of an integrated approach to resuscitation."

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