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## **EOLIA trial results show a decrease in mortality when ECMO used in severe ARDS patients**

May 24, 2018  
Gothenburg, Sweden

**The ECMO to Rescue Lung Injury in Severe ARDS (EOLIA) trial is a significant milestone, being the first ever randomized multicenter international trial on ECMO, with 64 centers participating worldwide. The EOLIA trial results demonstrate that care of the patient with appropriate ventilation management combined with planned early Extracorporeal Membrane Oxygenation (ECMO) is an effective strategy for treatment of patients suffering from severe acute respiratory distress syndrome (ARDS).**

The EOLIA trial results will be discussed on May 25 at the EuroELSO Congress (Prague) in a session titled “EOLIA and Beyond”.

Following on the discussion resulting from the landmark CESAR trial, the EOLIA trial was designed to answer the question of whether optimized mechanical ventilation therapy with planned early initiation of ECMO improves mortality versus optimized mechanical ventilation therapy alone. The Sponsor of the EOLIA trial was Assistance Publique - Hôpitaux de Paris: this investigator-initiated, randomized control trial was conducted and managed by the clinicians enrolling patients. Getinge’s German subsidiary Maquet Cardiopulmonary GmbH collaborated by supplying devices used in the trial.

The trial was designed as an interventional study with two arms of treatment; standard of care management with lung protective ventilation or the same ventilation strategy with the addition of early use of ECMO.

“Severe ARDS patients randomized to the early ECMO arm of the EOLIA trial had an 11% lower mortality than controls, although the difference did not reach statistical significance. Noticeably, 28% of controls who became very sick despite the universal use of neuromuscular blocking agents and prolonged prone-positioning, crossed over to rescue ECMO for refractory hypoxemia.” says Alain Combes, MD, PhD, Professor of Intensive Care Medicine at the Sorbonne University of Paris, and head of the ICU department at the “Institut de Cardiologie”, Hôpital Pitié-Salpêtrière, AP-HP, Paris, France.

“Historically ECMO was associated with many complications, including frequent brain hemorrhage, making it to be used as the last resort treatment. This was not seen in the EOLIA trial, where the stroke rate was very low.”

Pr. Combes concludes that “the observed favorable trend seen despite the high crossover rate suggests that utilization of immediate VV-ECMO by adequately trained clinicians and centers might be a safe and effective option in patients with very severe ARDS.”

### **High crossover rate resulted in early end to trial**

For ethical reasons the trial design took into consideration the need for patients randomized to the conventional management to cross over to the ECMO if they had exhausted all conventional treatment options and were still in need of care. In other words: The trial design allowed a switch to ECMO use in patients of the control group if death of these patients was assumed to be probable.

The trial outcome showed the group receiving early ECMO treatment had an 11% lower mortality rate compared to the standard of care, although parts of the standard group also received ECMO in order to rescue the patient. It was determined withholding of ECMO to those that were not responding to conventional treatment was unethical. Given the existing evidence of the relevance of ECMO therapy in patients failing all other therapies, ethical considerations resulted in that 35 of 125 patients that failed all conventional treatment crossed over to ECMO during the trial.

Despite the delay in initiating ECMO, the survival rate in the crossover group was 43%. This is a high percentage given how critically ill and near death these patients were when ECMO was initiated. The high crossover rate has confounded the results making the trial more about the timing of initiating of therapy versus whether ECMO is better than standard of care.

With the crossover it was determined by the Data Safety Monitoring Board that there was little likelihood of reaching the 20% relative difference in mortality end point with the projected enrollment and thus it was determined to end the study early.

“Globally, Getinge maintains the highest commitment to improving patient outcomes in ARDS. Our global product portfolio of advanced ventilation therapies, patient monitoring and ECMO therapies is uniquely positioned to positively impact our clinical partners’ ability to improve their patients’ lives. The EOLIA trial results are an important milestone in adding to the clinical evidence around optimized treatment of ARDS patients”, says Jens Viebke President Acute Care Therapies, Getinge.

### **Facts on ECMO and ARDS**

After more than 50 years of research, severe acute respiratory distress syndrome (ARDS) continues to have a high mortality rate. ECMO can be an important option when standard procedures fail. The use of ECMO for adult ARDS has increased over the last decade with more and more specialized centers using ECMO today generating clinical reports suggesting that ECMO

therapies deliver improved outcomes for adult ARDS patients.

Despite the well-established advances in its supportive treatment, ARDS remains an oftentimes misdiagnosed syndrome, carrying a high burden in terms of patient morbidity and mortality, as well as healthcare costs. In the LUNGSAFE study, clinicians missed almost 40% of ARDS diagnosis, despite a specific online training on ARDS diagnosis, which was offered to all investigators. Even among severe ARDS, diagnosis was missed in at least one patient out of five.

ARDS patients require intensive treatment in high cost hospital settings. In a large study (LUNGSAFE) conducted in 50 countries the incidence of ARDS reported was 10.4% of total ICU admissions and 23.4% of all patients requiring mechanical ventilation. ARDS patients studied in this trial had an mean duration of ICU stay of 10 days, mean duration of mechanical ventilation of 8 days, and a mean duration of hospital stay of 17 days. For patients with severe ARDS, the mean duration of mechanical ventilation for hospital survivors was 14 and the mean hospital length of stay for survivors was 26 days. Two additional studies conducted in ICU's across Europe show that moderate & severe ARDS cases represent 6.1% to 10.6% of ICU admissions (Brun-Buisson and Sakr).

The EOLIA trial results were published in the New England Journal of Medicine. Read more on study [here](#).

### **About Getinge at EuroELSO:**

EuroELSO is the European branch of the Extracorporeal Life Support Organization (ELSO) an international consortium of health care professionals and scientists who are dedicated to the development and evaluation of novel therapies for support of failing organ systems. Registered visitors are invited to visit Getinge on booth 1 from May 23 – 26 2018, Prague Congress Centre, 5. května 65, Prague 4 140 21, Czech Republic.

Join the discussion on Friday May 25th, 2018:

Adult 2 South Hall 1 (A+B), 15:30-17:00 “EOLIA and beyond”  
Chairs: Daniel Brodie (USA), Alain Combes (France), Luciano Gattinoni (Italy)  
The EOLIA trial - Alain Combes (France)  
What is next after EOLIA? - Luciano Gattinoni (Italy)

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## **About Getinge**

Getinge is a global provider of innovative solutions for operating rooms, intensive-care units, sterilization departments and for life science companies and institutions. Based on our first-hand experience and close partnerships with clinical experts, healthcare professionals and medtech specialists, we are improving the every-day life for people, today and tomorrow.