Press Release Humedics

Improved diagnosis of sepsis-related hepatic dysfunction with the LiMAx test

Prospective study showed superior sensitivity and specificity of the LiMAx test compared to traditional tests and its value as predictor of survival

Berlin, Germany, January 23, 2014 – Humedics GmbH, a specialist for real-time and mobile measurement of the individual liver function at the bedside of the patient, today announced the publication of results from a prospective clinical study evaluating the LiMAx test during severe sepsis in comparison with biochemical and indocyanine green tests. Study results demonstrated that the LiMAx test provide an adequate tool to determine early liver dysfunction in sepsis and was found to be a good predictor of survival in septic patients.

Sepsis is a frequent infection with high mortality rates in intensive care units (ICU) and may occur in approximately 25% of ICU patients. Multiple organ failure caused by sepsis still remains the most frequent cause of death in intensive care. Hepatic dysfunction and liver failure deriving from severe sepsis might be associated with poor prognosis in critically ill patients.
A prospective clinical study showed that sepsis-related hepatic dysfunction can be diagnosed early and effectively by the LiMAx test. The extent of LiMAx impairment is predictive for patient morbidity and mortality. The sensitivity and specificity of the LiMAx test was superior to that of the indocyanine green test regarding the prediction of survival.

Erwin de Buijzer, Managing Director of Humedics GmbH, comments the positive study results: “In this study, our LiMAx breath test was investigated for the diagnosis of sepsis-related liver dysfunction for the first time and the results show that the test provides an early and more precise diagnosis for these critically ill patients. We are pleased that we can extend the indications for this new and sophisticated diagnostic tool and expect that the LiMAx test will find its way into the intensive care for improved diagnosis and treatment of sepsis patients.”

Study results clearly showed that septic shock leads to deterioration of LiMAx within two days after onset of sepsis in the vast majority of patients. Furthermore, the degree of functional impairment determined by the LiMAx test is closely related with the patient’s prognosis. In addition, follow up LiMAx allowed the determination of individual progress of the patients. PD Dr. Martin Stockmann from Charité – Universitätsmedizin Berlin at the Campus Virchow Hospital, Dept. of General, Visceral and Transplantation Surgery, explains: “The LiMAx test directly measures the liver function via the capacity of the liver specific cytochrome P450 enzyme system and thus provides reliable results on the metabolic capacity of the liver. This has not been possible until now with other tests described.” Stockmann assumes that the impact of hepatic dysfunction on therapy during sepsis may be underestimated at present. With respect to the potential toxicity of administered drugs in patients with organ failures, he concludes: “Therapy schemes and drug dosage may be adapted due to the liver function capacity. This could lead to an optimized therapy of the patient in this critical situation”

Study design

28 patients suffering from sepsis on a surgical ICU were investigated prospectively. All patients received routine sepsis therapy according to current sepsis guidelines (surgery, fluids, catecholamines, antibiotic drugs). The first LiMAx test was carried out within the first 24 hours after onset of septic symptoms, followed by day 2, 5 and 10. Other biochemical parameters and scores determining the severity of illness were measured daily. Clinical outcome parameters were examined after 90 days or at the end of treatment. The population was divided into 2 groups (group A: non-survivors or ICU length of stay (ICU-LOS) >30 days versus group B: survivors and ICU-LOS <30 days) for analysis.

The study was performed at Charité – Universitätsmedizin Berlin, Campus Virchow Hospital, Dept. of General, Visceral and Transplantation Surgery.

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About Humedics

Humedics has developed a breath test based diagnostic system (LiMAx test) including the medical device FLIP. More than 100 million people world-wide suffer from liver diseases (i.e. cirrhosis, hepatitis, fatty liver, metabolic disorders and tumors). The LiMAx test enables the clinician to quantitatively determine the individual liver function capacity for a patient within minutes. This allows for selecting treatment strategies optimally adapted to the individual patients liver status. Current applications include diagnosis of the liver function before and after liver transplantation, liver surgery planning (e.g. assessment of the amount of liver to be resected without potentially increasing the risk for liver failure) and assessment of diseases such as liver cirrhosis. Up to date the LiMAx test has been used almost 10,000 times and the results have been published in highly respected scientific journals. For the approval of the LiMAx test Humedics started a phase III clinical trial in January 2013.

Humedics is equity financed by Peppermint VenturePartners (managing the Charité Biomedical Fund) as lead investor together with VC Fonds Technologie managed by IBB-Beteiligungsgesellschaft, ERP Startfonds of the KfW, Ventegis and High-Tech Gründerfonds. The funds enable Humedics to complete the final development and early commercialization of its proprietary and CE-marked diagnostic system to determine the liver function of patients in real time.

LiMAx Test

The underlying principle of the LiMAx test involves the following steps: At first, a ^{13}C-Methacetin solution is administered intravenously. ^{13}C-Methacetin is metabolized in the liver to paracetamol and $^{13}CO_2$ and the latter is exhaled in the breath. The exhaled air is collected via a respiratory mask. Subsequent measurement of $^{13}CO_2$ using laser detection in the FLIP device provides a quantitative determination of the liver capacity and thus the liver function.

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