

Press Release Humedics

LiMAX test shows reversibility of fatty liver disease after obesity surgery

Clinical study provides evidence for functional liver recovery after weight loss.

Berlin, Germany, September 1, 2015 – Humedics GmbH, a specialist for real-time and mobile measurement of the individual liver function at the bedside of the patient, today announced results of a clinical study performed at the RWTH Aachen University Hospital. The aim of the study was to assess alterations in liver function capacity with the LiMAX test after bariatric surgery of obese patients. Study results demonstrated that fatty liver disease is reversible after weight reduction and that the LiMAX test is a reliable tool to measure functional liver recovery after obesity surgery.

The prevalence of overweight and obesity has increased dramatically in recent years. Approximately half or more than half of the Western world's population is overweight or obese. The hepatic manifestation of the metabolic syndrome is nonalcoholic fatty liver disease (NAFLD), which is presently considered to be the most common liver disease in Western countries. NAFLD may progress to nonalcoholic steatohepatitis (NASH) and liver fibrosis. Both, NAFLD and NASH are reversible when effective weight reduction can be achieved. However, current noninvasive approaches to diagnosis, staging, and management of NAFLD and NASH are deficient.

Bariatric surgery provides long-term weight loss and improvement of obesity-associated liver diseases. In a prospective cohort study from October 2011 to May 2014, morbidly obese individuals receiving bariatric surgery were investigated for functional liver recovery. Liver function was determined by the LiMAX test preoperatively, 6 and 12 months postoperatively.

Investigator Prof. Ulf Neumann, Department of General, Visceral and Transplantation Surgery, RWTH Aachen University Hospital, said: "We applied the LiMAX test to assess the liver function of morbidly obese patients and to monitor the functional liver recovery after bariatric surgery. The non-invasive LiMAX breath test validly determines liver function capacity. It may avoid the inaccuracy seen with blood parameters and the risks of invasive liver biopsies which, moreover, do not necessarily reflect the liver function. Our study results show that LiMAX values correlate to the NAFLD activity score (NAS). Thus, the LiMAX test is an interesting method to diagnose and monitor NAFLD and NASH."

Study results showed that the mean liver function capacity significantly increased from preoperatively severely impaired values to normal values within 6 months after surgery and further improved over the period of the survey with a final measurement after one year.

Erwin de Buijzer, CEO of Humedics GmbH, stated: "The study at the Aachen University Hospital clearly demonstrated the usefulness of our LiMAX test in obesity-related liver diseases and represents the first study to noninvasively assess the impact of weight loss on changes in the liver function. The dramatic increase of obesity and obesity-associated diseases is a major problem in the Western world. We are very pleased to provide physicians with a novel diagnostic test to better assess obesity patients and to monitor disease course and therapy success."

The LiMAx test, together with the corresponding FLIP device and the diagnostic drug offers a clinically proven significant added value for patients with liver diseases and liver surgery.

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Please visit us at

ILCA 2015, International Liver Cancer Association 9th Annual Conference. September 4-6, 2015. Paris, France; www.ilca2015.org

Please visit us at booth No. 8.

ESOT, 17th Congress of the European Society for Organ Transplantation, September 13-16, 2015, Brussels, Belgium; <http://esot2015.esot.org>

Please visit us at booth No. 29.

About Humedics

Humedics has developed a breath test based diagnostic system (LiMAx test), which comprises a CE-marked medical device, breath masks and a diagnostic drug. More than 100 million people world-wide suffer from liver diseases (i.e. cirrhosis, hepatitis, fatty liver, metabolic disorders and liver tumors). The LiMAx test enables the clinician to quantitatively determine the individual liver function capacity for a patient within minutes. This allows for selection of treatment strategies that are 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 of liver failure) and assessment of diseases such as liver cirrhosis. The LiMAx test has been used about 14,000 times in clinical practice. Results have been published in highly respected scientific journals. For the approval of the LiMAx test Humedics is presently conducting a phase III multi-center clinical trial. Results are expected in Q IV 2015.

LiMAx Test

The underlying principle of the LiMAx test involves the following steps: Firstly, the diagnostic drug solution is administered intravenously and the drug is metabolized in the liver to paracetamol and ¹³CO₂. The latter is exhaled in the breath. The exhaled air is collected via a respiratory mask. Subsequent continuous measurement of ¹³CO₂ in the patients' breath using laser detection in the FLIP device provides a quantitative determination of the liver capacity and thus reflects the liver function.

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