

Press Release Humedics

Use of LiMAx test leads to reduction in post-hepatectomy liver failure and related mortality

Retrospective analysis of 1170 patients shows improved outcomes of partial liver resections after the determination of the patient's individual operative risk with the LiMAx test.

Berlin, Germany, January 07, 2016 – 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 retrospective study investigating the impact of the LiMAx test on clinical patient outcome after hepatectomy. Study results showed that the use of the LiMAx test led to reductions in post-operative liver failure and to a decrease of liver failure related mortality.

Post-operative liver failure is a severe complication after partial liver resections. Pre-existing hepatic dysfunction therefore remains a major concern when considering patients for liver resection. We need selection criteria that accurately identify patients in whom a surgical intervention can be safely performed. Humedics' LiMAx test has been demonstrated to accurately and reliably assess liver function in both healthy subjects and patients with cirrhosis. It furthermore has been shown to be unaffected by age, gender or obesity.

In a retrospective study at the Department of General, Visceral and Transplantation Surgery, Charité – Universitätsmedizin Berlin, Campus Virchow Hospital, 1170 patients undergoing elective hepatectomy between January 2006 and December 2011 were analyzed. The aim of this study was to investigate the impact of the LiMAx test on patient selection and outcome. Propensity score matching was used to compare the effects on morbidity and mortality of the integration of the LiMAx algorithm into clinical practice.

Study results showed that even with more cirrhotic patients were selected to undergo liver surgery (6.9% in 2006 to 11.3% in 2011), the post-operative liver failure rate were dramatically decreased by 54.4% after the full implementation of LiMAx algorithm. Besides, the liver failure-related mortality dropped from 4% to 0.9% regardless of the increase in complex hepatectomy cases (including extended right hepatectomies and resections with concomitant biliary and/or vascular reconstruction).

The analysis of data for the propensity score-matched cohort suggests that the integration of the LiMAx algorithm was a major factor contributing to the improved outcomes. In conclusion, the integration of the LiMAx algorithm seems to have played an important role in optimizing risk assessment prior to hepatic surgery.

Investigator PD Dr. Martin Stockmann said: "We saw an increasing number of complex hepatectomies over the study period and at the same time a decline in postoperative liver failure and in particular a reduction in the number of postoperative liver failure related deaths. In my opinion the improved outcomes are associated with the integration of the LiMAx test in our routine work-up."

A major strength of this study is that the analysis is based on all consecutive and unselected patients over 6 years that received partial hepatic resection of one or more segments in an attempt to overcome a potential selection bias.

Erwin de Buijzer, CEO of Humedics GmbH, stated: "We are very pleased that this retrospective study demonstrates once more the usefulness of our LiMAx test and its benefits for patients considered for liver surgery. For us, this study is especially interesting because the long study period covers the time of the introduction of the LiMAx test into the work routine at the Charité and clearly demonstrates the improvements in clinical outcomes over six years."

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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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 15,000 times in clinical practice. Results have been published in highly respected scientific journals. The phase III multi-center clinical trial required for marketing authorization of the LiMAx test has been closed successfully.

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 $^{13}\text{CO}_2$. The latter is exhaled in the breath. The exhaled air is collected via a respiratory mask. Subsequent continuous measurement of $^{13}\text{CO}_2$ 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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