Press Release Humedics

Safer liver resection: Perioperative assessment of liver function with the LiMAx® test shortens hospital stay and reduces complications after liver surgery

Clinical phase III trial at 6 specialized liver centers demonstrates impressive benefits of the LiMAx® test

Berlin, Germany, July 25, 2018 – Humedics GmbH, a specialist in real-time measurement of liver function capacity, announced results of a multicenter randomized controlled clinical trial that clearly shows the benefits of the LiMAx® test in liver surgery. Perioperative use of the LiMAx® test shortens hospital stay by 3 days and significantly reduces the incidence of severe complications after liver surgery.

Liver resection is a common treatment for patients with liver tumors. However, liver surgery bears a high risk of postoperative liver failure and death. Due to the lack of accurate diagnostic tests to predict the individual patient outcome, the current conservative standard of care proposes a postoperative transfer of patients to the intensive care unit (ICU). With the LiMAx® test, Humedics provides a solution that bridges the existing diagnostic gap as the test allows for real-time quantification of the liver function and thus for optimized surgery planning and patient management.

Humedics executed a randomized controlled phase III clinical trial to evaluate the clinical impact of perioperative liver function assessment with the LiMAx® test on early postoperative patient outcome and patient management after liver resection. Study results clearly demonstrate that the LiMAx® test shortens the length of stay in the ICU and the hospital overall, and it reduces the incidence of severe complications after liver surgery. In contrast to the currently common and cost-intensive practice of a mandatory stay in the ICU, 62 percent of the patients in the LiMAx® group (58 patients in total) did not require a stay in the ICU after surgery because postoperative LiMAx® indicated the presence of sufficient functional liver capacity to enable rapid recovery without complications. 10 percent of the LiMAx® group were transferred to an intensive care unit due to critically low LiMAx® values (150 µg per kg per h or less) and another 28 percent due to non-liver related complications. In the control group, only one out of 60 patients (2 percent) was immediately referred to a general ward. Postoperative severe complications were significantly lower in the LiMAx® group as well, with 14 percent, versus 28 percent in the control group. Both, the length of ICU stay and the length of the overall hospital stay, were significantly shorter in the LiMAx® group compared to the control group.

Karsten Damgaard-Iversen, CEO of Humedics GmbH, stated: “Following a retrospective analysis of our early experience with the LiMAx® test in liver surgery, which already showed a striking decrease in postoperative liver failure when the LiMAx® test was used, we initiated this clinical trial to further evaluate and document the impact of the LiMAx® test on postoperative patient outcome, as well as on safe and cost-effective patient management. The results of this clinical trial have clearly demonstrated the unique benefits of the LiMAx® liver function capacity test in this setting, but in addition, we are also confident that these results will help us convince clinicians and hospital

administrators to adopt a broader utilization of our test. Not only in the context of liver surgery, but across the space of liver disease management and diagnosis in oncology and hepatology."

Erwin de Buijzer, COO of Humedics, further commented: "The unparalleled results show the impact of the LiMAx® test in clinical routine. Whenever the LiMAx® system is implemented, the liver surgeons and hepatologists realize the unprecedented value of the test for their clinical decision making. It is evident that the health economic benefits of using the test as a result of the complication reduction and shorter length of stay contribute significantly to cost containment in the healthcare environment."

Study details

The primary endpoint of the study was the direct transfer of patients from the recovery room to a general ward (instead of transfer to intensive care unit and regular discharge from hospital maximally 30 days after surgery). Secondary study endpoints included the development of postoperative liver failure and severe complications.

A total of 148 patients with liver tumors scheduled for open liver resection were recruited at six German academic centers specialized in complex liver surgery. Patients were randomized equally in two study arms, either to the intervention arm (LiMAx® group) or to the standard-care arm (control group). In the intervention group, two LiMAx® test assessments were performed in patients: The first one the day before surgery – for individual surgical planning. The second one was done within 6 h after surgery – to determine the individual patient's postoperative management. In the control group, perioperative management followed standard clinical care without performing a LiMAx® test. A total of 118 patients, 58 in the LiMAx® group and 60 in the control group, were eligible for analysis.

Reference:
https://onlinelibrary.wiley.com/doi/full/10.1002/bjs5.81

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About Humedics

Humedics has developed a breath test based *in vivo* diagnostic system (the LiMAx® test), which comprises a CE-marked medical device, breathing masks and a diagnostic drug. The LiMAx® test enables the clinician to quantitatively determine the individual liver function capacity of a patient within minutes. This allows for selection of treatment strategies and disease monitoring optimally adapted to the individual patients' liver status. Current clinical applications, studies of which have already been published in highly respected peer-reviewed scientific journals, 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 acute liver failure) and assessment of diseases such as liver fibrosis and cirrhosis. Over 20 trials in new indications such as the diagnosis of chronic liver diseases like non-alcoholic steatohepatitis (NASH) and the improvement of treatment decisions in liver oncology are ongoing. These investigator initiated trials impressively demonstrate the further potential of the LiMAx® test. The LiMAx® test is already being used in over 30 top-tier university clinics across Europe and more than 20,000 tests have already been performed. The LiMAx® test is commercially available in Germany, Austria and the UK.

LiMAx® Test

Based on the specific metabolic action of the liver enzyme CYP1A2, which is expressed in all functioning hepatocytes, performing the LiMAx® test is a simple procedure. The diagnostic drug solution is administered intravenously, and the liver immediately starts to metabolize the drug into low dose paracetamol and $^{13}CO_2$ (non-radioactive). The latter is exhaled in the breath, collected via a respiratory mask and guided to the LiMAx® system where, within 1-2 minutes following the injection, the LiMAx® IR laser spectroscopy system allows real-time and very precise quantification of the increase in $^{13}CO_2$

content. The resulting LiMAx® value, measured in micrograms per kilo body weight per hour, is a reliable and repeatable measure of the maximum functional capacity of the liver.

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