Press Release
February 26, 2021
Gothenburg

Publication in The New England Journal of Medicine shows complications after liver transplantation significantly reduced with cold, oxygenated machine perfusion.

An article published in the scientific journal The New England Journal of Medicine, shows that oxygenated perfusion of the donated liver before transplantation has a significant positive impact on the outcomes after transplantation. The study demonstrates two thirds lower rates of biliary complications, less hemodynamic compromise and that the incidence of early graft dysfunction is reduced by nearly half with oxygenated perfusion. The randomized trial, with livers donated after circulatory death, was performed in a large international consortium of liver transplant centers and included 156 patients. The Liver Assist device that was used for oxygenated perfusion in the trial, is CE-marked. XVIVO intends to submit an application for regulatory approval of the device to the FDA during 2021.

During a transplant procedure, it is inevitable that the donated liver is exposed to a period without blood flow. The liver's bile ducts are vulnerable and absent blood flow may cause ischemic injury to the tissue. If the small blood vessels leading to the bile ducts and liver tissue are injured, this increases the risk of biliary complications after the transplant. This may require advanced treatment, and, in some cases, the complications can only be remedied by a second transplant. Biliary complications are the leading reason why transplanted livers are lost.

The New England Journal of Medicine published the results from a study that investigated the benefit of cold, oxygenated machine perfusion of donor livers before transplant. The device used to perfuse the livers in this study, the Liver Assist, was developed by Organ Assist, XVIVO's recent acquisition. The study was led by Professor Robert Porte, liver surgeon at the University Medical Center Groningen in the Netherlands and carried out in The Netherlands, Belgium and the United Kingdom.

Livers from 156 high risk donors (Donation after Circulatory Death) were included in the study and randomized to either the current treatment regime, static cold storage or to 2 hours of cold oxygenated machine perfusion after static cold storage. Biliary complications within 6 months after the transplant were registered as the primary endpoint of the trial.

This study demonstrated a significant benefit when oxygenated machine perfusion was used. During the follow-up period only 6 percent of the patients that received a machine perfused liver developed biliary complications, compared to 18 percent in the static cold storage group. Furthermore, recipients of a machine perfused liver were less likely to develop compromised hemodynamics after graft reperfusion (so called post-reperfusion syndrome) and had the incidence of early graft dysfunction reduced by nearly half.

The risk of complications for patients that are transplanted with a liver donated after circulatory arrest are

greater than if the liver comes from a donation after brain death. Because of this, many transplant centres are hesitant to accept donor livers of this kind. This is especially true in the USA where few livers are used from donors after circulatory death compared to in countries such as the Netherlands, Belgium and the UK. The machine perfusion technology used in the trial prevents complications after transplant and has the potential to increase the number of transplanted patients by allowing liver surgeons to accept more donor livers that have been procured after circulatory arrest.

Wilfred den Hartog, Sales Director Organ Assist comments: "We have always persisted in our concept of cold and oxygenated perfusion, and these results are the final evidence of what we always believed in. These study results will lead to a transformation in liver transplantation, leading to better and more organs and thereby improve patient's well-being and quality of life".

"The Liver Assist device has a unique leading position being the only device for dual oxygenated cold perfusion of donor livers in the market. Even more, the same device can also be used for normothermic evaluation of livers whose quality is unsure. This is a major achievement for XVIVO, and an important step in the committed all-organ strategy," says Dag Andersson XVIVO Perfusion's CEO.

Please follow the link below for the article in full:
https://www.nejm.org/doi/full/10.1056/NEJMoa2031532

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About Us

XVIVO Perfusion AB is a medical technology company which develops solutions and systems for assessing and preserving organs outside the body and for selecting usable organs and maintaining them in optimal condition pending transplantation. The company is headquartered in Gothenburg, Sweden, and has one office in Lund, Sweden, one office in Groningen, the Netherlands and one office in Denver, USA. The XVIVO share is listed on Nasdaq Stockholm and has the ticker symbol XVIVO. More information can be found on the website www.xvivoperfusion.com.

Attachments

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