PRESS RELEASE
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Gothenburg

Results from European randomized controlled study using XVIVO's heart technology published in The Lancet

Today, the results of the European randomized controlled clinical trial investigating the use of XVIVO's heart technology were published in the prestigious scientific journal The Lancet[1]. The trial compared outcomes for patients who received a donor heart preserved either on ice, the current standard method, or using XVIVO's Heart Assist Transport device. The primary outcome demonstrated a clinically important 44% lower risk of severe complications after transplantation, driven by a 61% reduction in primary graft dysfunction (PGD) when XVIVO's heart technology was implemented.

Ice-based storage is still used during transport of the vast majority of donor hearts before transplantation. The static, cold environment leaves the donor heart without oxygen and blood supply. When the heart is restarted during transplantation, injury caused by the stress of ice storage may lead to heart dysfunction, resulting in severe complications for the patient. XVIVO's heart technology, including the XVIVO Heart Assist Transport device and a perfusion solution, provides an alternative to static ice storage. The device pumps an oxygenated perfusion solution, specifically tailored for this purpose, through the organ at low pressure and at 8 degrees Celsius, thereby preserving the heart in a controlled, low metabolic, resting state. This principle, which has been extensively proven successful in liver and kidney transplantation, is referred to as hypothermic oxygenated perfusion (HOPE).

The European randomized controlled clinical trial, now published in The Lancet, includes 204 patients across 15 trial sites in 8 European countries. The patients were randomly assigned to receive a transplant with a donor heart preserved on ice or preserved using HOPE with the XVIVO Heart Assist Transport device.

The study's primary endpoint, a composite of severe transplant complications within the first 30 days after transplant, was registered in 30% of patients receiving a donor heart preserved on ice and only in 19% of patients when the heart was preserved using the XVIVO Heart Assist Transport device. The clinically significant 44% reduction in risk was within a statistically significant confidence interval and accompanied by a p-value of 0.059, indicating that the study was slightly underpowered.

The improved patient outcome was driven by a significant 61% risk reduction for primary graft dysfunction, which is the leading cause of early mortality after heart transplantation, in patients whose donor hearts were preserved using XVIVO's heart technology.

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The authors, led by the principal investigator Professor Filip Rega from UZ Leuven, Belgium, concludes that “the study provides evidence of the safety and effectiveness of HOPE and is the first randomized controlled trial to demonstrate a reduction in primary graft dysfunction after heart transplantation. The results support the concept of HOPE mitigating graft injury and support the use of HOPE as a method for donor heart preservation in clinical heart transplantation”.

“This is the first-ever randomized controlled trial of any device for donor heart preservation to demonstrate a reduction in severe complications after heart transplantation. When the results were first presented at the most recent ISHLT congress in April, they were received with great interest and enthusiasm by the thoracic transplant community. This publication in The Lancet further underscores the importance of the study's findings. We exist for the patients and it is now proven that our heart technology brings us closer to our vision that ‘nobody should die waiting for a new organ’", says Christoffer Rosenblad, CEO of XVIVO.

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Christoffer Rosenblad, CEO
XVIVO Perfusion AB (publ)

[1] **https://doi.org/10.1016/S0140-6736(24)01078-X**

Link to an interview with Professor Filip Rega:
https://vimeo.com/998579901/5f354b1b24?share=copy

Link to an animation of the study results:
https://vimeo.com/999487529/2043d56a5f

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About Us

Founded in 1998, XVIVO is the only medical technology company dedicated to extending the life of all major organs - so transplant teams around the world can save more lives. Our solutions allow leading clinicians and researchers to push the boundaries of transplantation medicine. XVIVO is headquartered in Gothenburg, Sweden, and has offices and research sites on two continents. The company is listed on Nasdaq and has the ticker symbol XVIVO. More information can be found on the website www.xvivogroup.com.

Image Attachments

XVIVO Heart Assist Transport Blue01 Background Hires
XVIVO Heart Assist Transport White Background Hires
XVIVO Heart Assist Transport High Res

Attachments

Results from European randomized controlled study using XVIVO’s heart technology published in The Lancet
XVIVO Scientific Summary Hypothermic Oxygenated Perfusion Of The Donor Heart In Heart Transplantation The Short Term Outcome From A Randomised, Controlled, Open Label, Multicentre Clinical Trial