

Press Release November 20, 2020 Gothenburg

Publication in The Lancet shows better survival of transplanted kidneys after cold machine perfusion with oxygen

An article published in the scientific journal The Lancet today, shows that oxygenated perfusion of kidneys before transplantation has a significant impact on the first-year result after transplantation: less graft failure, better function and lower rejection of the kidney when compared to cold perfusion alone. The randomized trial, with kidneys aged 50 years or older, donated after circulatory death was done in 19 European transplant centers and included 212 patients. The Kidney Assist Transport device, used in the trial described in the Lancet article, is CE-marked and XVIVO intends to submit an application to the FDA during 2021 for the device.

It has previously been shown that the best practice for transport of a kidney from donor to recipient is use of a machine that continuously pumps a cold preservation solution through the kidney. Today The Lancet publishes the results from a study that investigated the benefit of adding oxygen during machine perfusion of donor kidneys. The device used to perfuse the kidneys in this study, Kidney Assist Transport, was developed and provided by Organ Assist, XVIVO's recent acquisition. The study was carried out in Belgium, the Netherlands and the United Kingdom within the large international clinical COMPARE trial in kidney transplantation performed by the Consortium for Organ Preservation in Europe (COPE).

Kidneys from 106 high risk donors (DCD or Donation after Circulatory Death) were included in the study. Since a donor has two kidneys which are given to two different recipients, one kidney could be randomized to oxygenated perfusion and the other one to perfusion without oxygen. The 212 recipients were followed for 12 months after transplantation and kidney function, episodes of rejection and complete loss of kidney function were registered.

During the follow-up period the risk of acute rejection was 48 percent lower in patients with kidneys perfused with oxygen. The researchers also found that in the group with oxygenated perfusion, significantly fewer patients lost kidney function completely, only 3%, compared to 10% in the group that had not received oxygen. In the primary analysis no difference in estimated kidney function was detected but when the patients with complete loss of kidney function was included in the analysis, kidney function was significantly better in recipient of oxygenated kidneys.

Oxygen deprivation in the kidney during transport initiates a complex reaction with a distinct inflammatory response and impaired function after transplantation. This inflammation alerts the immune system and renders the organ more susceptible to rejection. In turn, this causes scarring of the tissue, with a decline of function, which may eventually lead to the kidney stop working entirely. The results of this study confirm that oxygen deficiency during transport causes damage and that this injury can be reduced with oxygenated perfusion using the Kidney Assist Transport device.

XVIVO Perfusion AB, Box 530 15, SE-400 14 Göteborg. Corporate identity number 556561-0424. Tel: +46 31 788 21 50. Fax: +46 31 788 21 69. E-mail: info@xvivoperfusion.com. Website: www.xvivoperfusion.com

Wilfred den Hartog, Sales Director Organ Assist comments: "This result is a testimony of years of research and development by our team and partners. We are proud to have been part of the consortium and are confident that these results will lead to a transformation in kidney transplantation. Our technology will in the end lead to better organs and thereby improve patient's well-being and quality of life".

"The Kidney Assist Transport device strengthens its unique competitive position with the results presented in The Lancet, showing the benefits of oxygenated perfusion on kidneys. This is a major achievement for XVIVO, since the acquisition of Organ Assist earlier this year, 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:

http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32411-9/fulltext

November 20, 2020 Gothenburg Dag Andersson, CEO XVIVO Perfusion AB (publ)

For further information please contact:

Dag Andersson, CEO, +46 76 643 30 31, e-post: <u>dag.andersson@xvivoperfusion.com</u> Christoffer Rosenblad, CFO, +46 73 519 21 59 e-post: christoffer.rosenblad@xvivoperfusion.com

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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