

APPENDIX

Safety and Efficacy of Non-Ischemic Hypothermic Machine Perfusion (NIHP) in Human Heart Transplantation With an Ischemic Time of 6-8 Hours

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Introduction: Despite improvements in circulatory support options, heart transplantation remains the gold-standard treatment for appropriate patients with advanced heart failure. The availability of donor hearts is significantly less than that required. Strategies to increase donor supply include donation after circulatory death and retrieval from remote locations. The safety and reliability of remote heart retrieval is impacted upon by the deleterious effects of long-ischemic times using the standard method of cold static storage. In particular, the risk of primary graft dysfunction and death risk increases exponentially beyond 3-4 hours. Experimental studies using a novel non-ischemic, hypothermic machine perfusion (NIHP) approach may be an appropriate means to safely extend ischemic time.

Objective: To demonstrate the safety, efficacy and clinical utility of NIHP in recipients of donor hearts with an ischemic time of 6-8 hours.

Methods: Patients listed for heart transplantation in 4 centres in Australia and New Zealand participated in this open label study. Donor hearts accepted for transplantation with a projected ischemic time of 6-8 hours were transported to the recipient hospital using an NIHP system (XVIVO, Sweden).

Results: To date 20 patients (age 48 ± 17 years) have undergone NIHP heart transplantation (ischemic time 411 ± 55 mins, perfusion time 327 ± 77 mins, donor age 37 ± 14 years). The longest donor heart ischemic time was 8 hrs 47 mins. Despite the prolonged ischemic time, only 1 episode of right ventricular primary graft dysfunction requiring temporary mechanical support has occurred, with no mortality.

Conclusion: Preservation of donor hearts with an ischemic time of 6-8 hours using NIHP is feasible and appears safe. NIHP has the potential to lead to a transformative shift in the management of longer ischemic time donor hearts and thus to increase the available donor pool and to enhance logistic planning for heart transplantation. With respect to Australia and New Zealand, with the commencement of this trial, there is no donor heart in either country that now cannot be transported to a transplant center, a previously unattainable goal with static cold storage.

Source: American Heart Association webpage for the AHA conference
<https://eppro02.ativ.me/src/EventPilot/php/express/web/planner.php?id=AHA22>