Assessing & Improving Organ Function *Ex Vivo*

*Is the Ice Age Melting?*

Richard S. Luskin
Disclosures

• I serve as a part-time consultant to TransMedics
• This presentation reflects my personal opinions and not the official statements of any of the companies or organizations manufacturing or using the devices described.
Organ Donation Communication Options
1988 – Radio Shack Computer
COMMUNICATION 2016
Some Kidneys Pumped
Kidney Pump Updated by the 90’s but....still on Ice

Livers, hearts, lungs, pancreas  all preserved on ice
Extra Renal Organs in Coolers on Ice
Organ Transporter or Beer Cooler?
Cold Static Preservation +/-

+ Relatively inexpensive and easy to do
- Preservation time remains limited
+ Damage to the organs is slowed
  - but not eliminated
- No ability to assess or treat the organ during the preservation period
- Ischemia- reperfusion injury
Implications of Limitations of Cold Static Preservation

• Limited ability to transplant extra renal organs from expanded criteria and DCD donors (controlled and uncontrolled)
• Geographic distribution of organs and timing of reimplantation operation limited by preservation times

... And the Wait List Keeps Growing
At last, Organ Preservation is Changing

IMHO:

It’s the NEXT BIG THING
ECRI 2016

TOP 10 HOSPITAL C-SUITE WATCH LIST

1. Mobile Stroke Units: Are They More Than a Concierge Ambulance Ride?
2. Medical Device Cybersecurity: When Will Your Pacemaker Be Hacked?
3. Wireless Wearable Sensors: Data Sense or Data Chaos?
5. Blue-violet LED Light Fixtures: Can the Flip of a Switch Help Prevent Healthcare-acquired Infections?
6. New High-cost Cardiovascular Drugs: Will They Help Readmission Rates?
7. Changing Landscape of Robotic Surgery: Is a Mainframe to Tablet-type Paradigm Change Coming?
8. Spectral Computed Tomography: What’s the New Hype About?
9. Injected Bioabsorbable Hydrogel (SpaceOAR): An End to Some Radiation Therapy Complications?
10. Warm Donor Organ Perfusion Systems: Will They Ease the Organ Supply Shortage?
Possible Outcomes w/o *ex vivo* pump

- Recover & TX organ
- Recover & discard organ
- Don’t recover organ
Possible Outcomes with *ex vivo* pump

- **Recover & TX organ**
  - Improve organ function & TX with better ST & LT function
  - Discard organ due to pump parameters

- **Recover & discard organ**
  - Improve organ function to permit TX of organ that would have been discarded

- **Don’t recover organ**
  - Improve organ function to permit TX of organ that would not have been recovered
The Potential of *ex vivo* Pumping

- Improved organ function
  - Reduce ST graft dysfunction & morbidity
    - Reduce post TX hospitalization
    - Reduce TX hospital costs
  - Reduce LT graft dysfunction & failure

- Allow transplantation of organs now considered not transplantable. Examples:
  - Expanded criteria donors
  - DCD lungs & hearts

- Allow for rational timing of transplant surgery
  - Surgeon sleep, less disruption of OR schedule
Organ Preservation Options

• Static Cold Storage recovery to TX
• Cold Perfusion recovery to TX
• Static Cold Storage → Warm Perfusion → Static Cold Storage → TX
• Warm Perfusion recovery to TX
Extra Renal Ex Vivo Perfusion
Initial static cold storage, followed by 2-6 hours on device at normothermia using proprietary pump solution, at the transplant center or the OPO.
Initial static cold storage, followed by 2-6 hours on device at normothermia using proprietary pump solution, at the Perfusix facility. Then put back in static cold storage for transport to transplant center for implantation.
Lung placed on device in recovery hospital operating room and perfused with blood and proprietary solution at normothermia for up to 11 hours. Transported to transplant hospital on device. Ground or air transport.
Lungs perfused with perfusate at temperatures from hypothermia to normothermia
Liver placed on device in recovery hospital operating room and perfused proprietary solution at hypothermia. Transported to transplant hospital on device.
Liver placed on device in recovery hospital operating room and perfused with blood and proprietary solution at normothermia. Transported to transplant hospital on device. OrganOx ground transport only, TransMedics ground & air transport
Liver perfused with either blood or perfusate, at temperatures from hypothermia to normothermia
Heart placed on device in recovery hospital operating room and perfused with blood/PRBC and proprietary solution at normothermia. Transported to transplant hospital on device.
1st DCD Heart - Sydney

31 DCD heart transplants to date
From 3 centers in the UK & Australia

TransMedics, Inc.
Key Points to Remember

1. In the coming years, static, hypothermic preservation, especially for extra renal organs, will gradually be replaced by *ex vivo*, dynamic, normothermic organ preservation, assessment and treatment.

2. Multiple devices, using varying protocols, are in clinical trials in the US. Some are in active clinical use in Canada, Europe (with CE mark) and other parts of the world.
Key Points to Remember (con’t.)

3. Use of these devices will expand the pool of transplantable extra-renal organs, especially from DCD and expanded criteria donors. As one example, more than 30 hearts from DCD donors have been transplanted in the past 18 months.

4. Use of these devices will impact the donation process, but mostly after cross clamp and before implantation.
Key Points to Remember (con’t.)

5. Further study is required, but much, if not all, of the cost of the devices and disposables should be off set by reduced post transplant complications and shorter post transplant hospitalization.

6. Issues remain about allocation when organs are maintained on these devices prior to identifying a recipient.
Any Questions?