

Toronto
Lung
Transplant
Program

Advances in Lung Transplantation

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CONFLICTS OF INTERESTS DISCLOSURE

- Founder, Shareholder, Chief Scientific Officer – Traferox Technologies Inc
- Consultant for Lung Bioengineering (United Therapeutics): EVLP centers
- Consultant to Incyte Inc, Avivo
- Research Support United Therapeutics, Avivo, Incyte Inc, Beyond Air, Gilead

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Major Advances in Lung Transplantation

- Lung Preservation at 10C
- Ex Vivo Lung Perfusion/Repair
- Artificial Lung Devices
- Transplant Highly Sensitized Patients
- Minimal Invasive Lung Transplantation

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- November 1983:

The first successful lung transplantation was performed in Toronto



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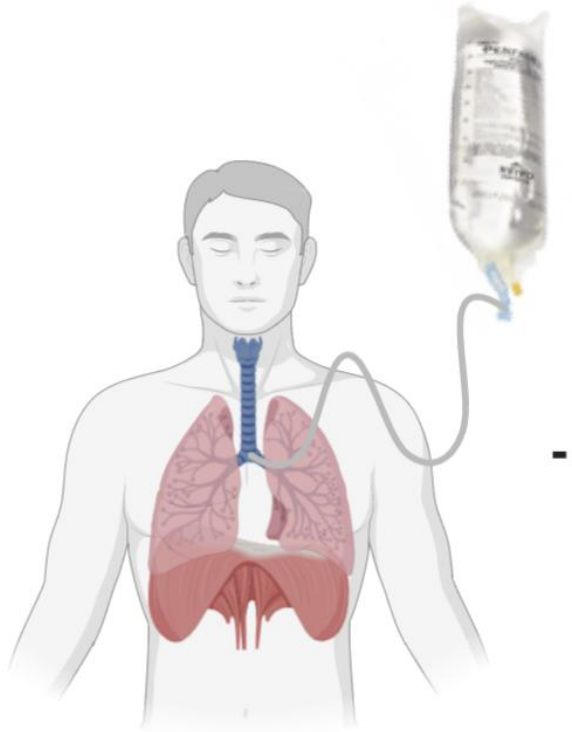
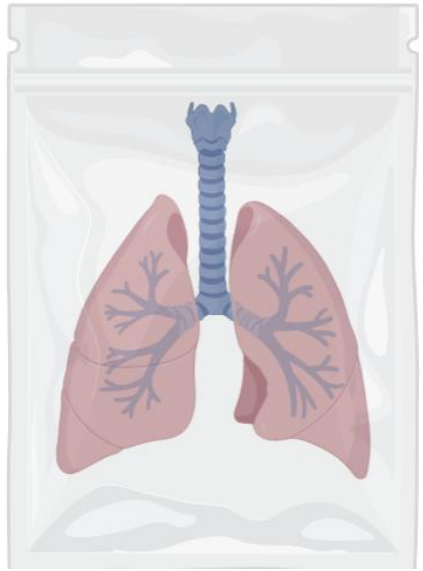
Gold standard technique in lung preservation (30+ years)



Low-Potassium Dextran Solution



Inflation
50% oxygen



Cold Static Preservation
(0-4ºC)

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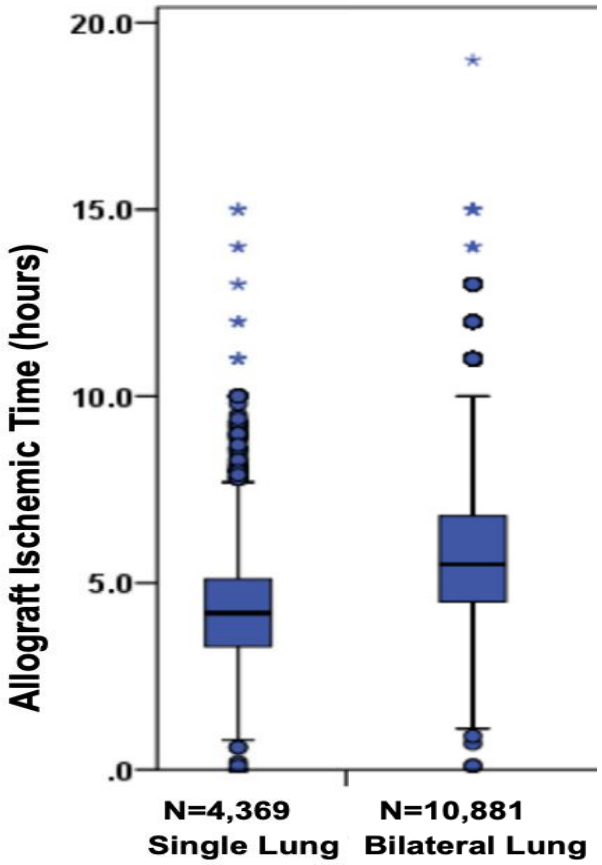
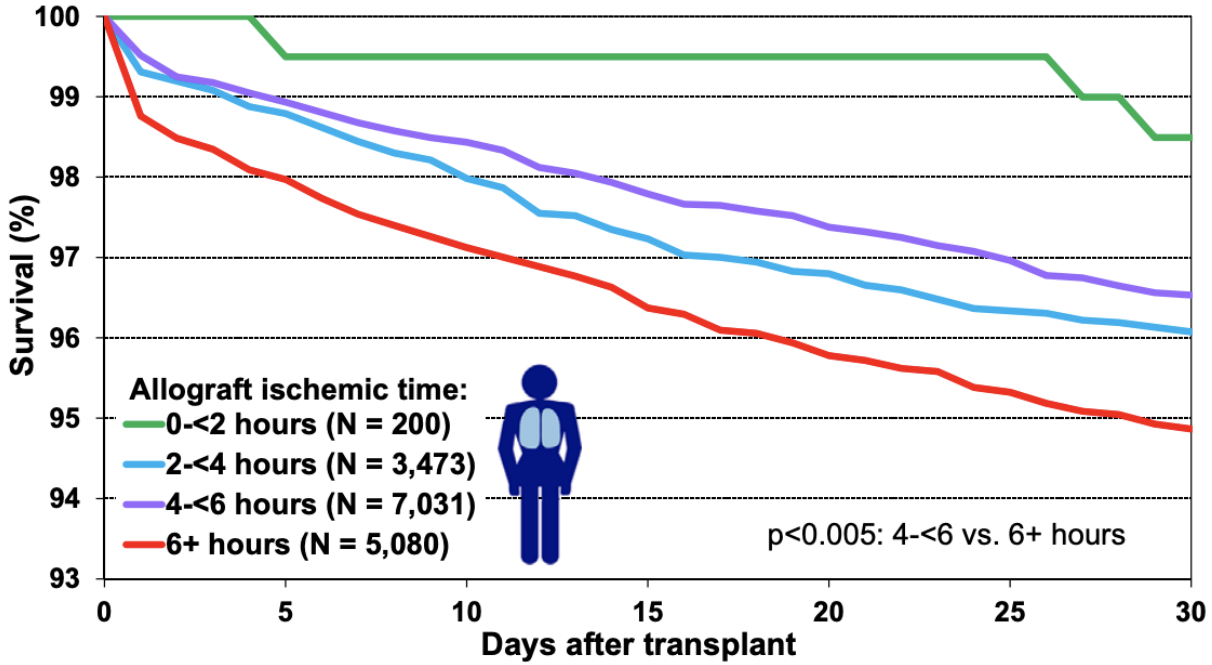
Cold Preservation is used conservatively





Chambers D *et al.* J Heart Lung Transplant. 2017 Oct;36(10):1047-1059.

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Implications of extended preservation



Overcoming Geographical Hurdles



Better Immunological Matching



Time-dependent therapeutics



Organ-banking Strategies



Semi-elective Transplantation

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The effect of ischemic time and temperature on lung preservation in a simple ex vivo rabbit model used for functional assessment

Liang-Shun Wang, MD,* Koichi Yoshikawa, MD, Shinichiro Miyoshi, MD, Kembu Nakamoto, MD, Chia-Ming Hsieh, MD, Fumio Yamazaki, MD, Paulo F. Guerreiro Cardoso, MD, Hans-Joachim Schaefers G., MD, Julio Brito, MD, Shafique H. Keshavjee, MD, Alexander Patterson, MD, FRCS(C), and Joel D. Cooper, MD, FRCS(C), *Toronto, Ontario, Canada*

4° C, 10° C, 15° C, 23° C, 34° C, 38° C



Oxygenation, Pulmonary Artery Pressure, Airway Pressures

10° C > 15° C > 4° C > 23° C> 34° C, > 38° C

J Thorac Cardiovasc Surg. 1989

In a canine model, lung preservation at 10° C is superior to that at 4° C

Hiroshi Date, MD,[a] Oriane Lima, MD, PhD,[a] Akihide Matsumura, MD,[a] Hiroharu Tsuji, MD,[a] D. André d'Avignon, PhD,[b] and Joel D. Cooper, MD, FRCS(C),[a] *St. Louis, Mo.*

18h CIT

- 4° C → P/F 243 mmHg
- **10° C** → P/F 451 mmHg

J Thorac Cardiovasc Surg. 1992

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A Study on Optimal Temperature for Isolated Lung Preservation

Kembu Nakamoto, MD, Masazumi Maeda, MD, Kiyohide Taniguchi, MD, Noriyuki Tsubota, MD, and Yasunaru Kawashima, MD

Second Department of Surgery, Kagawa Medical School, Kagawa, and First Department of Surgery, Osaka University School of Medicine, Osaka, J

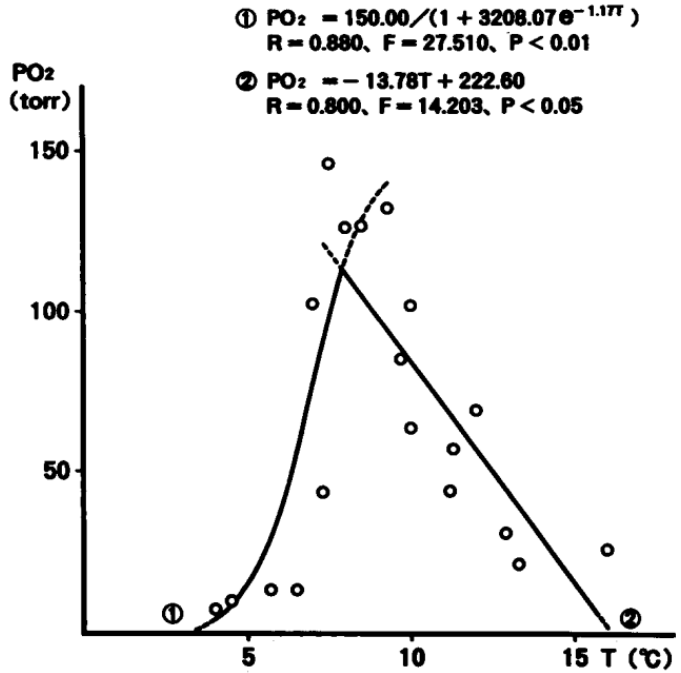

Fig 6. Regression line and curve between blood oxygen pressure (PO_2) during high-flow perfusion with ventilation and graft preservation temperature (T). Significant regression equations 1 and 2 intersected at the temperature of 7.9°C.

Annals of Thoracic Surgery 1992

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30 years of silence

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Founders of the new era in 10C Preservation/Implementation



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Science Translational Medicine

Current Issue First release papers

HOME > SCIENCE TRANSLATIONAL MEDICINE > VOL. 13, NO. 611 > STATIC LUNG STORAGE AT 10°C MAINTAINS MITOCHONDRIAL HEALTH AND PRESERVES…

TRANSPLANTATION

Static lung storage at 10°C maintains mitochondrial health and preserves donor organ function

Aadil Ali[1], Aizhou Wang[1], Rafaela V. P. Ribeiro[1], Erika L. Beroncal[2], Cristina Baciu[1], Marcos Galasso[1], Bruno Gomes[1], Andrea Mariscal[1], Olivia Hough[1], Edson Brambate[1], Etienne Abdelnour-Berchtold[1], Vinicius Michaelsen[1], Yu Zhang[1], Anajara Gazzalle[1], Eddy Fan[3], Laurent Brochard[3,4], Jonathan Yeung[1,5], Tom Waddell[1,5], Mingyao Liu[1], Ana C. Andreazza[2], Shaf Keshavjee[1,5], Marcelo Cypel[1,5]*

Ali A et al. *Sci Transl Med*. 2021 Sep 15;13(611).

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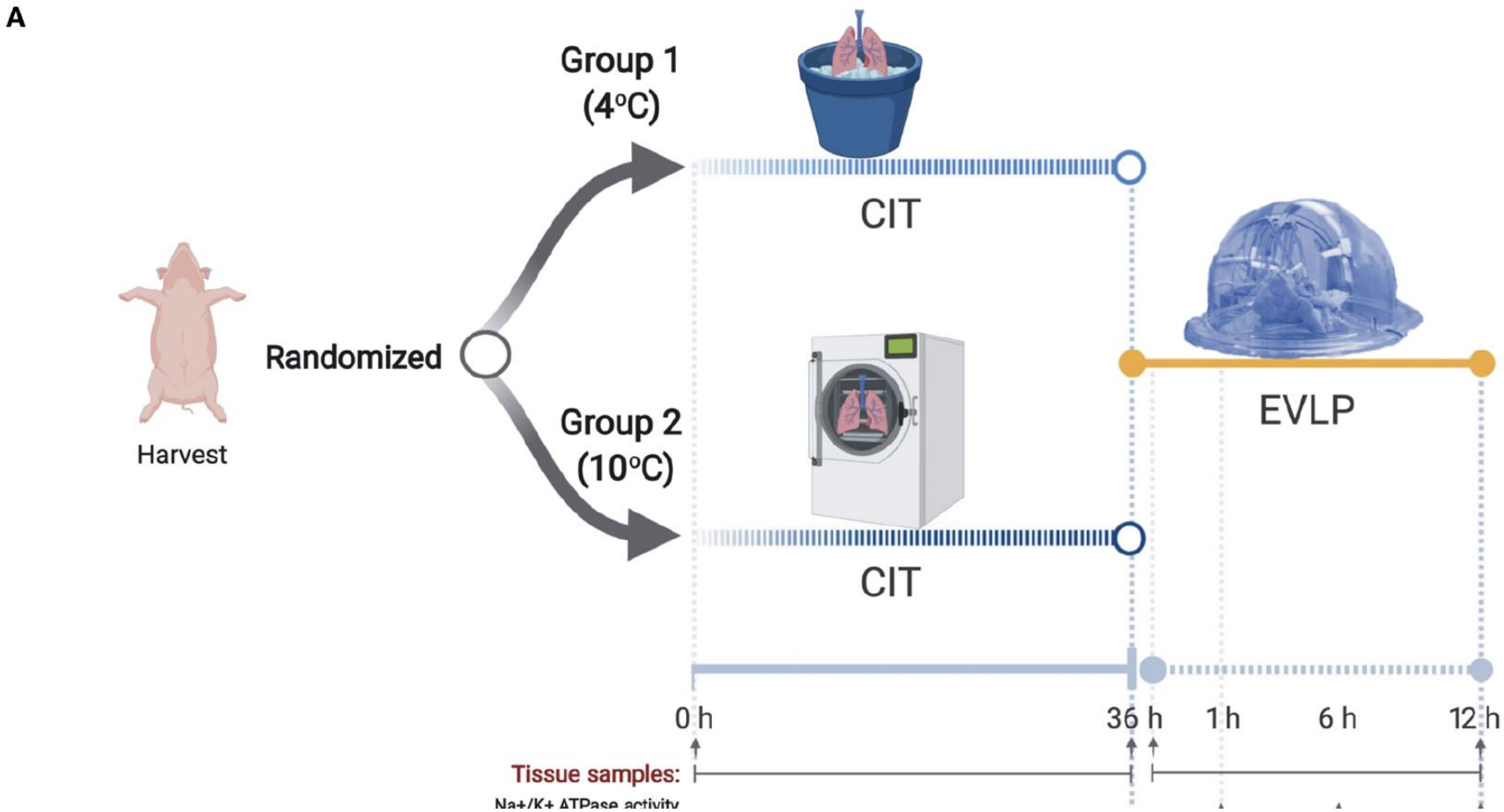

Ali A et al. *Sci Transl Med*. 2021 Sep 15;13(611).

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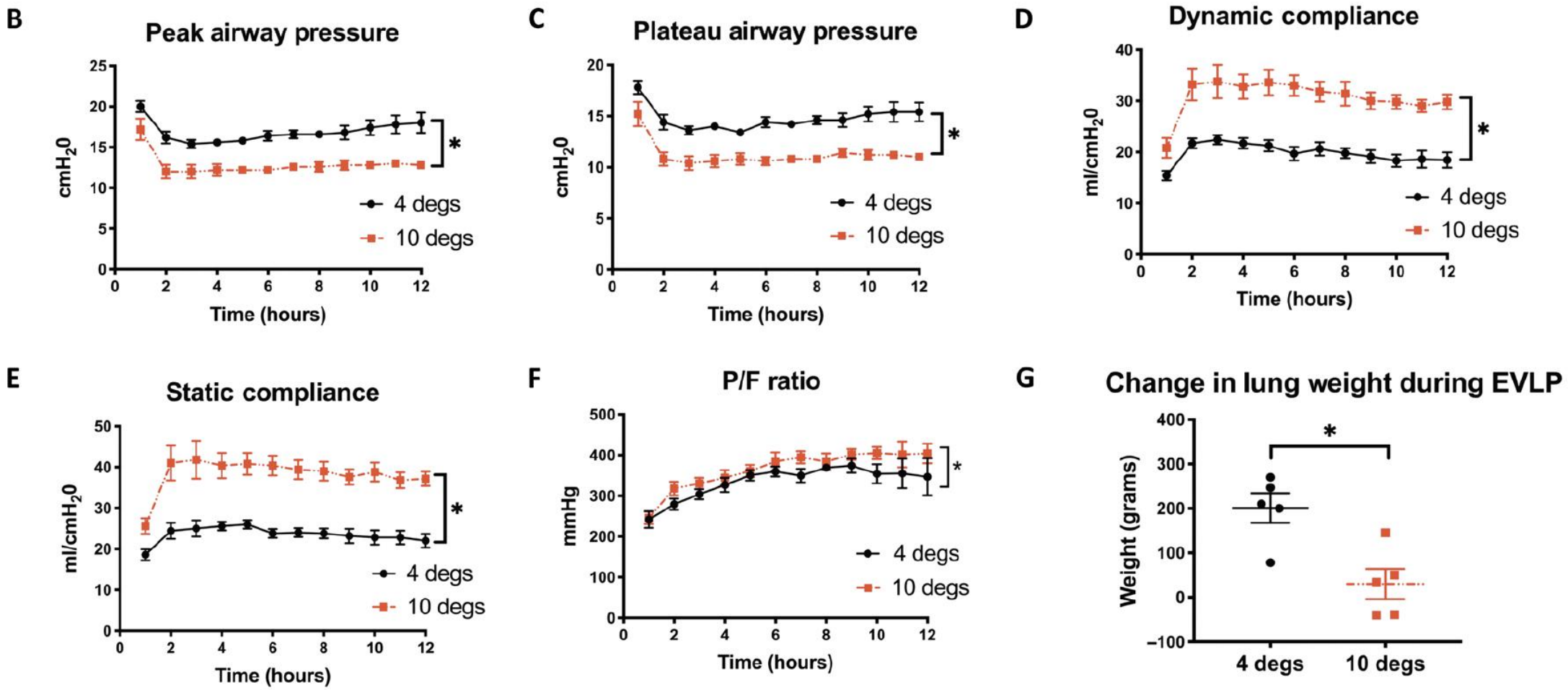

Ali A et al. *Sci Transl Med*. 2021 Sep 15;13(611).

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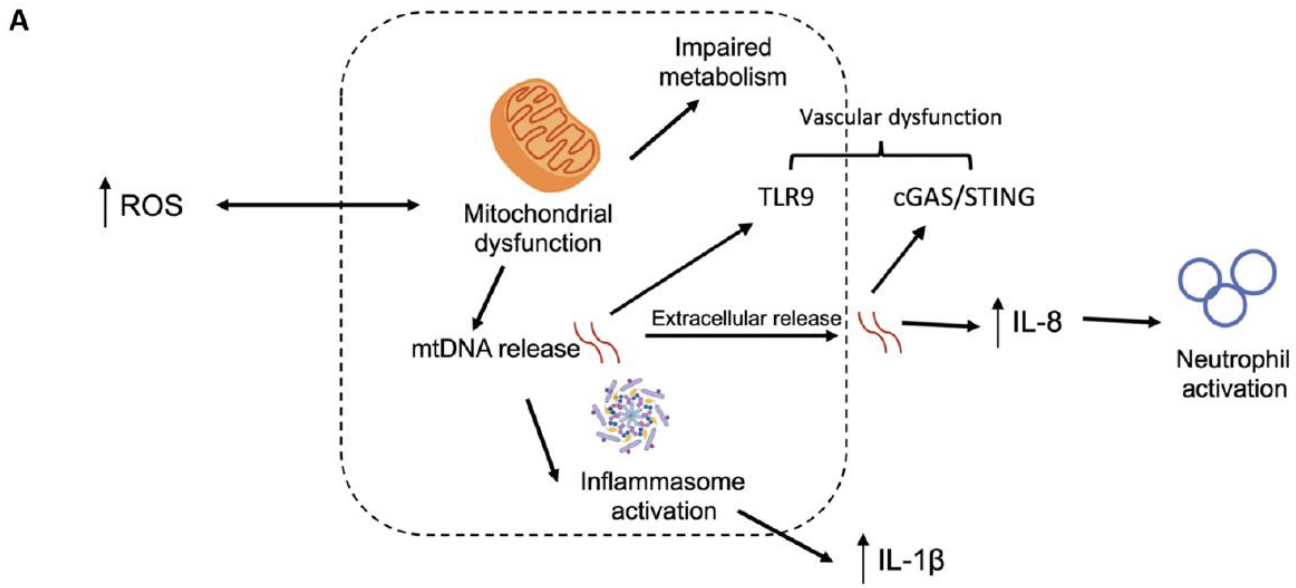

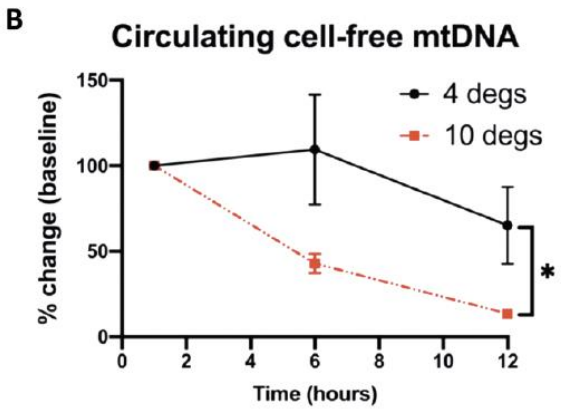

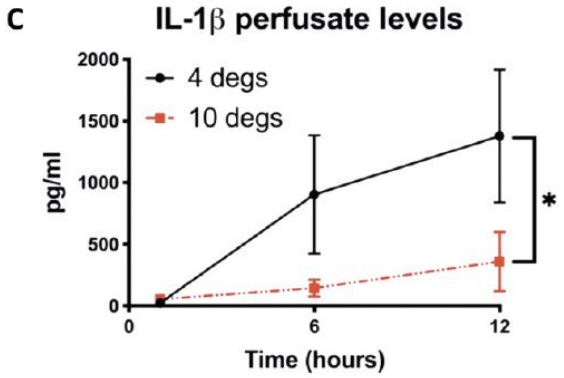

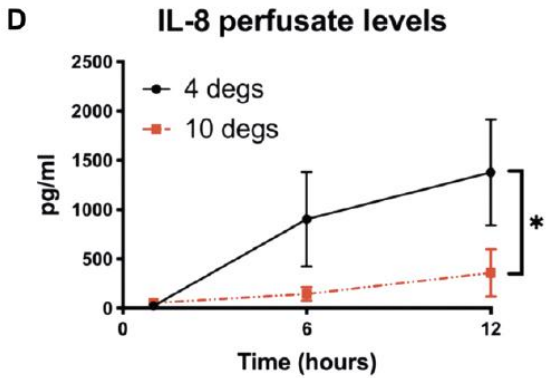

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Ali A et al. *Sci Transl Med*. 2021 Sep 15;13(611):eabf7601

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FULL LENGTH ARTICLE · Volume 41, Issue 12, P1679-1688, December 2022

Evaluation of 10°C as the optimal storage temperature for aspiration-injured donor lungs in a large animal transplant model

Etienne Abdelnour-Berchtold, MD [a,#] · Aadil Ali, PhD [a,#] · Cristina Baciu, PhD [a] · ... · Ana C. Andreazza, Pharm, PhD [b] · Shaf Keshavjee, MD, MSc [a,c] · Marcelo Cypel, MD, MSc [a,c] ... Show more

Affiliations & Notes Article Info

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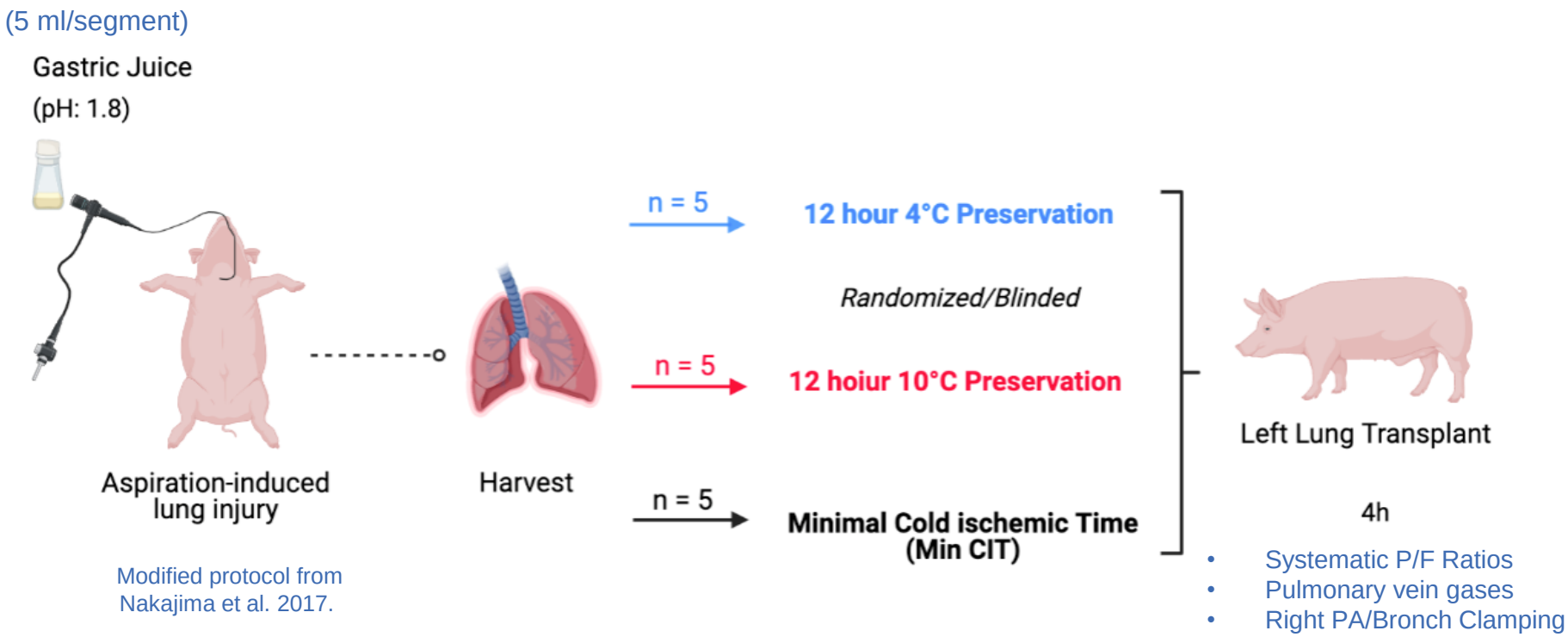

Modified protocol from Nakajima et al. 2017.

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Abdelnour-Berchtold et al. *JHLT.* 2022

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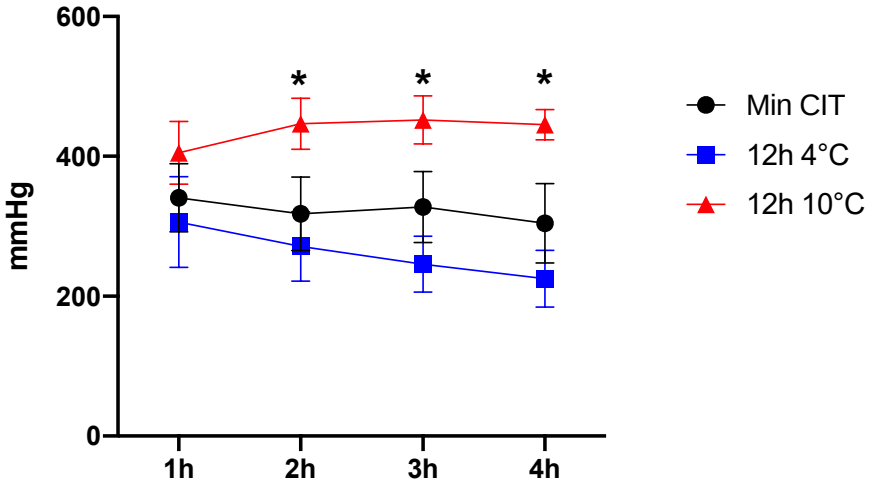
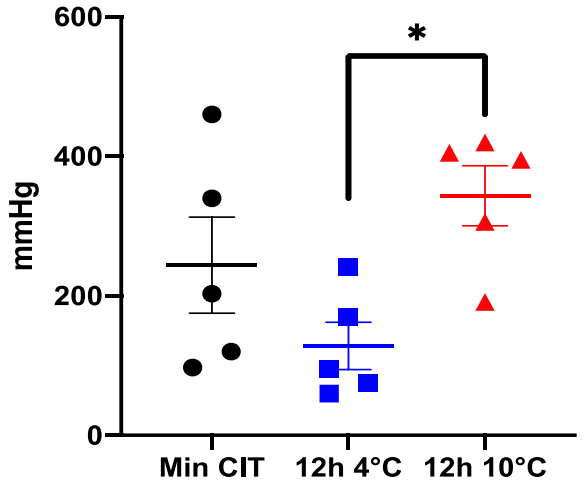
10ºC Preservation Results in Superior Post-Transplant Lung Function

Mean Graft Pulmonary Vein P/F Ratio



Systemic P/F Ratio after Right PA clamp



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Abdelnour-Berchtold et al. *JHLT.* 2022

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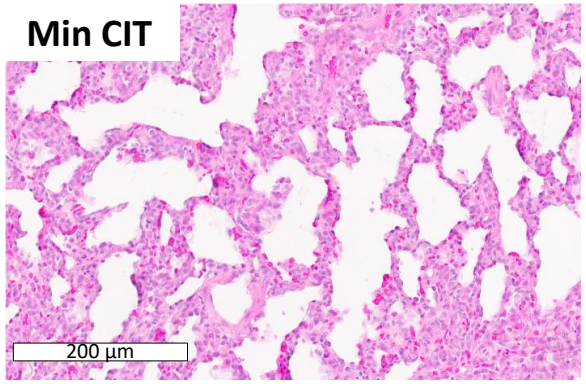
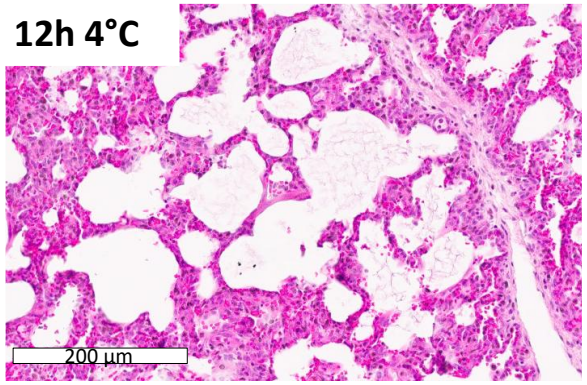
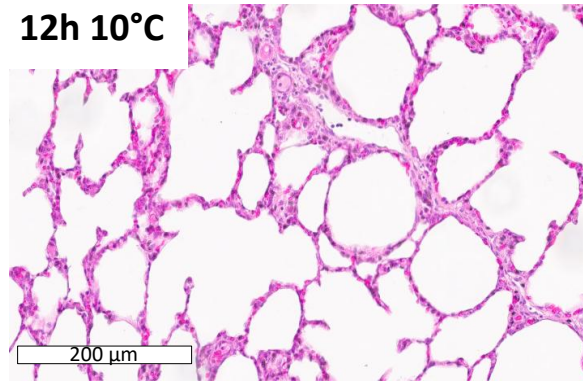
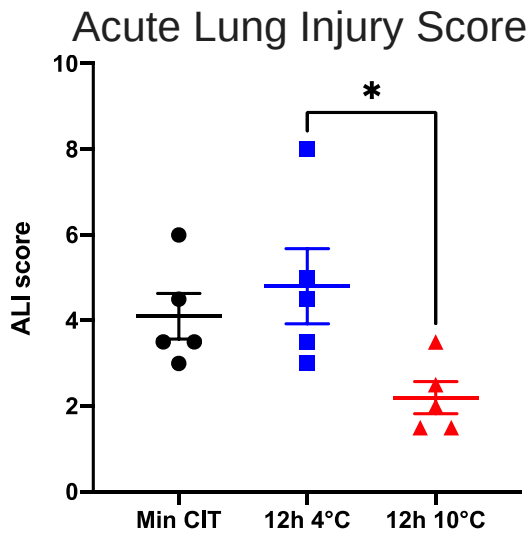
10ºC preservation preserves post-LTx Histology









Blindly graded based on:

- Interstitial edema
- Intra-alveolar edema
- Hemorrhage
- Cell infiltration
- Hyaline membrane formation

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Abdelnour-Berchtold et al. *JHLT.* 2022



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Change in Paradigm in Organ Preservation:

Can prolongation of ischemia (at the right temperature) improve organ quality?

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NEJM Evidence

Published April 20, 2023

DOI: 10.1056/EVIDoa2300008

ORIGINAL ARTICLE

Extension of Cold Static Donor Lung Preservation at 10°C

Aadil Ali, Ph.D.,[1] Konrad Hoetzenecker, M.D.,[2] Jose Luis Campo-Cañaveral de la Cruz, M.D.,[3] Stefan Schwarz, M.D.,[2] Mariana Gil Barturen, M.D.,[3] George Tomlinson, Ph.D.,[4] Jonathan Yeung, M.D.,[1] Laura Donahoe, M.D.,[1] Kazuhiro Yasufuku, M.D.,[1] Andrew Pierre, M.D.,[1] Marc de Perrot, M.D.,[1] Thomas K. Waddell, M.D.,[1] Shaf Keshavjee, M.D.,[1] and Marcelo Cypel, M.D.[1]

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Recipient Outcomes

Table 3. Posttransplant Outcomes.*	16h	7h	
Outcome	**Study Cohort (n=70)**	**Matched Controls (n=140)**	**Difference (95% CI)**
Incidence of PGD3 at 72 h — n (%)	4 (5.7)	13 (9.3)	−3.6 (−10.5 to 5.3)
Recipient vent time — h, median (IQR)	49 (29–82)	52 (27–89)	−3 (−15 to 7)
ICU LOS — d, median (IQR)	5 (3–9)	5 (3–12)	0 (−2 to 1)
Hospital LOS — d, median (IQR)	25 (20–40)	30 (20–54)	−5 (−8 to 2)
Post-LTx ECMO used — n (%)	5 (7.1)	13 (9.3)	−2.1 (−9.3 to 7.2)
30-d survival — n (%)	70 (100)	135 (96.4)	3.6 (−2.0 to 8.1)

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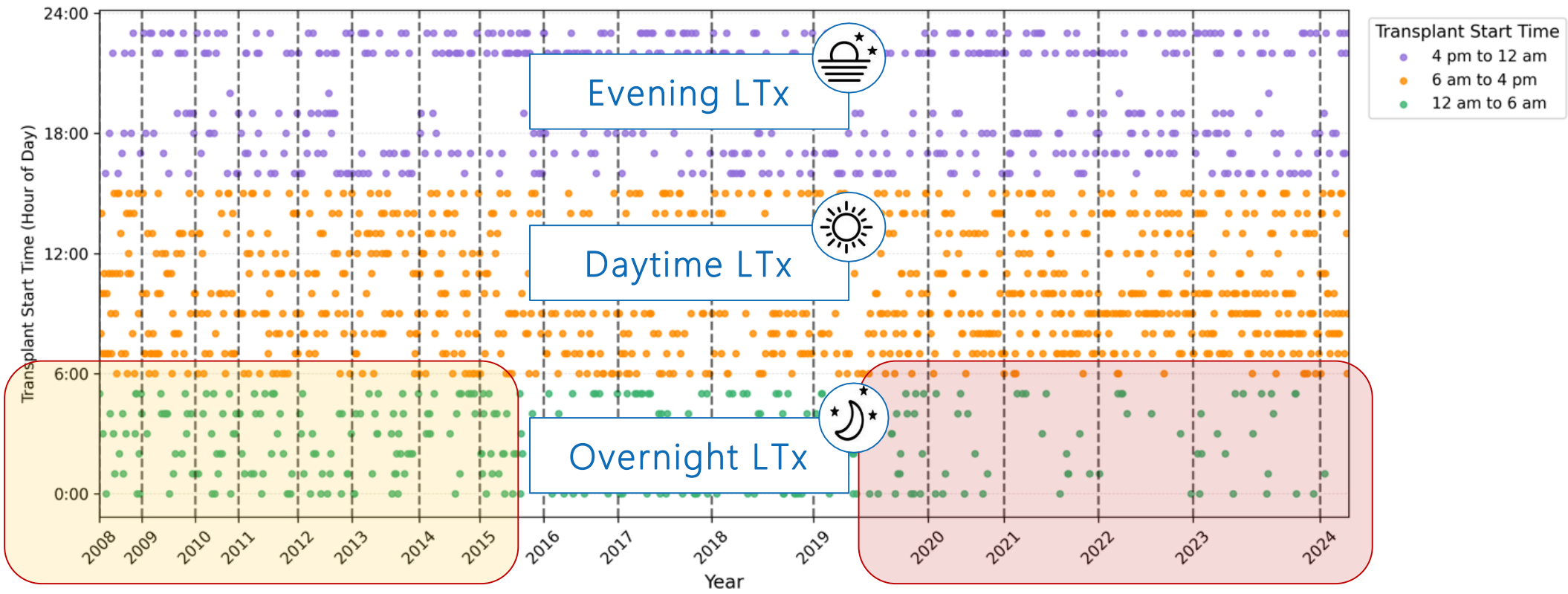
LTx more Practical and Manageable



Less 5% overnight transplants in 2024

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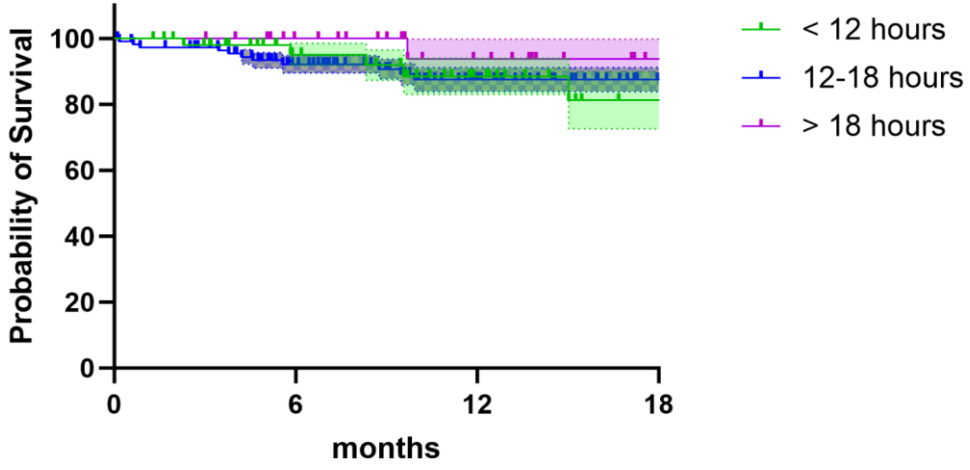
Retrospective, non-controlled

Prolonged Preservation of up to 24h at 10°C does not Impact Outcomes after Lung Transplantation

Hoetzenecker, Konrad MD PhD[*,†]; Ali, Aadil PhD[‡]; Campo-Cañaveral de la Cruz, Jose , MD[§]; Schwarz, Stefan MD PhD[*]; Crowley Carrasco, Silvana MD[§]; Romero Roman, Alexandra MD[§]; Aladaileh, Mohammed MD[‡]; Benazzo, Alberto MD PhD[*]; Jaksch, Peter MD[*]; Wakeam, Elliott MD[‡]; Aversa, Meghan MD[‡]; Keshavjee, Shaf MD PhD[‡]; Cypel, Marcelo MD MSc[‡]

ANNALS OF SURGERY

n=198 patients

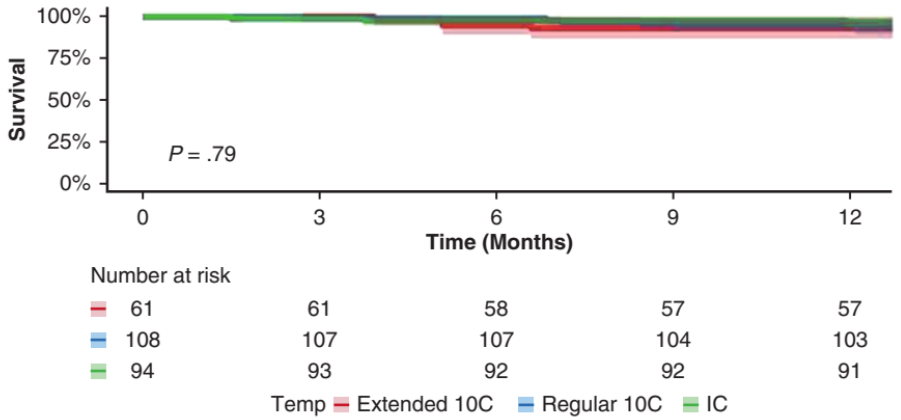


Lung transplant outcomes after implementation of a hospital-based 10 °C controlled hypothermic organ preservation unit

The Journal of Thoracic and Cardiovascular Surgery JTCVS AATS

Alexey Abramov, MD, MS,[a] Joseph Costa, DHSc, PA-C,[a] Jake Rosen, MD,[a] Richa Asija, DO, MS,[a] Luke Benvenuto, MD,[b] Gabriela Magda, MD,[b] Lori Shah, MD,[b] Harpreet S. Grewal, MD,[b] Angela DiMango, MD,[b] Hilary Robbins, MD,[b] Selim Arcasoy, MD,[b] Bryan P. Stanifer, MD, MPH,[a] Philippe Lemaitre, MD, PhD,[b] Joshua Sonett, MD,[b] and Frank D'Ovidio, MD, PhD[b]

n=169 patients



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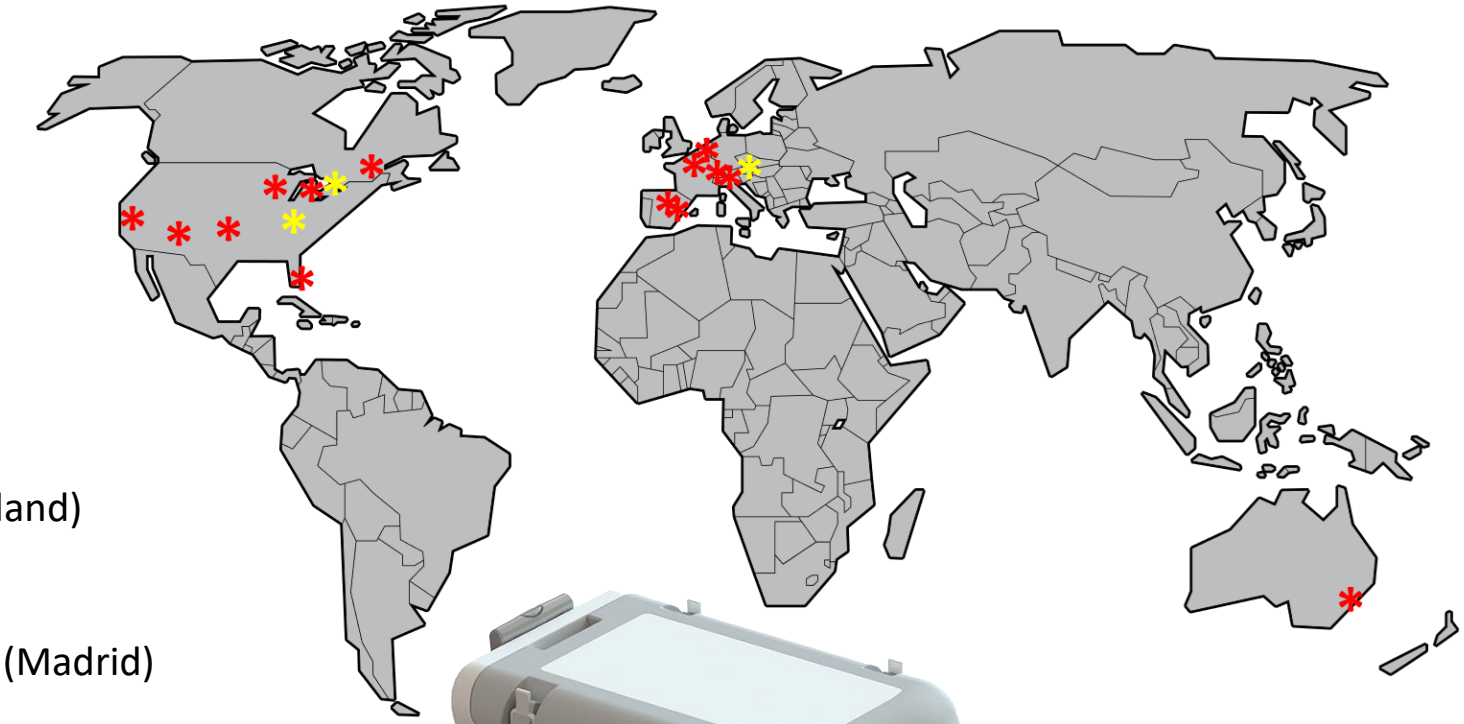
The 10°C vs ice preservation RCT (CIHR sponsored)

University Health Network (Canada)
Medical University of Vienna (Austria)
Vanderbilt University (US)
Puerto de Hierro (Madrid)
UCSF (US)
CHUV (Switzerland)
Leuven University (Belgium)
Mayo Clinic Rochester (US)
St Vincent Hospital (Australia)
UT Southwestern (US)
CHUM (Canada)
Spectrum Health, Michigan (US)
Medical University of Zurich (Switzerland)
University of Miami (US)
Marie Lannelonge Hospital (France)
Hospital Universitario 12 de Octubre (Madrid)
Norton - St. Joseph's Hospital (US)
Northwestern Chicago

18 participating centers





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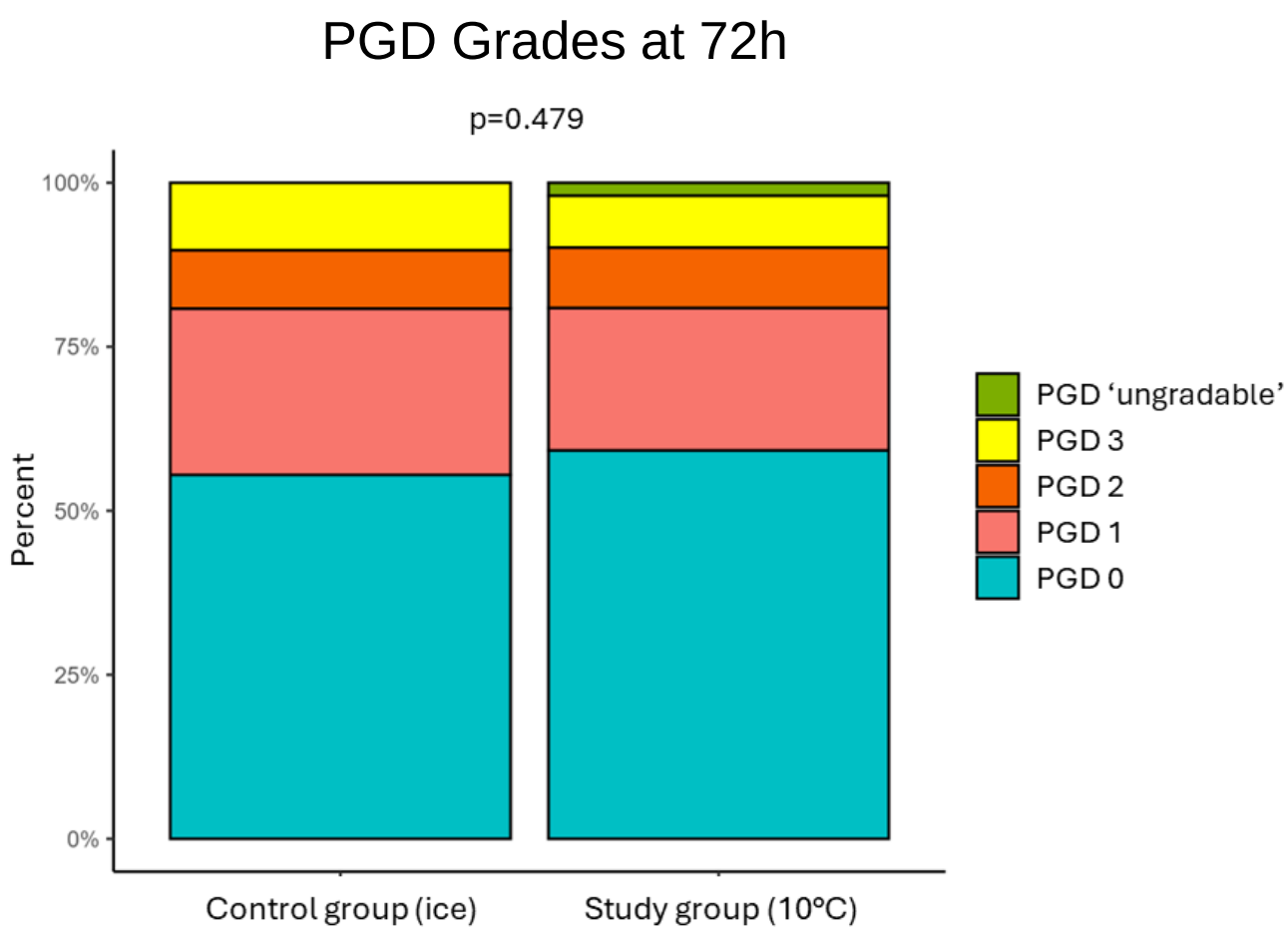
Primary endpoint





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Major Advances in Lung Transplantation

- Lung Preservation at 10C
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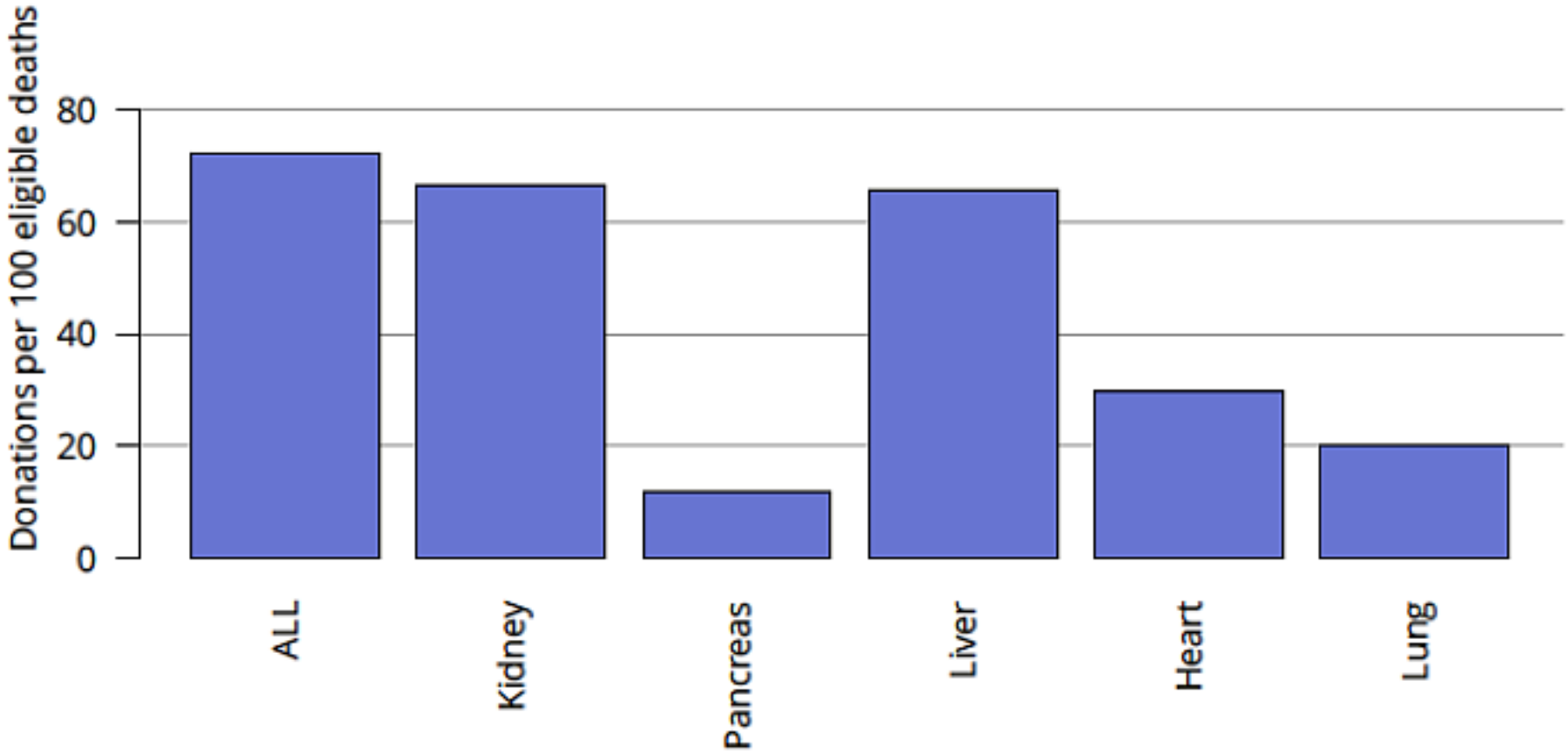
Donor lung utilization is low



OPTN/SRTR Annual Data Report

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Toronto Lung Transplant Program

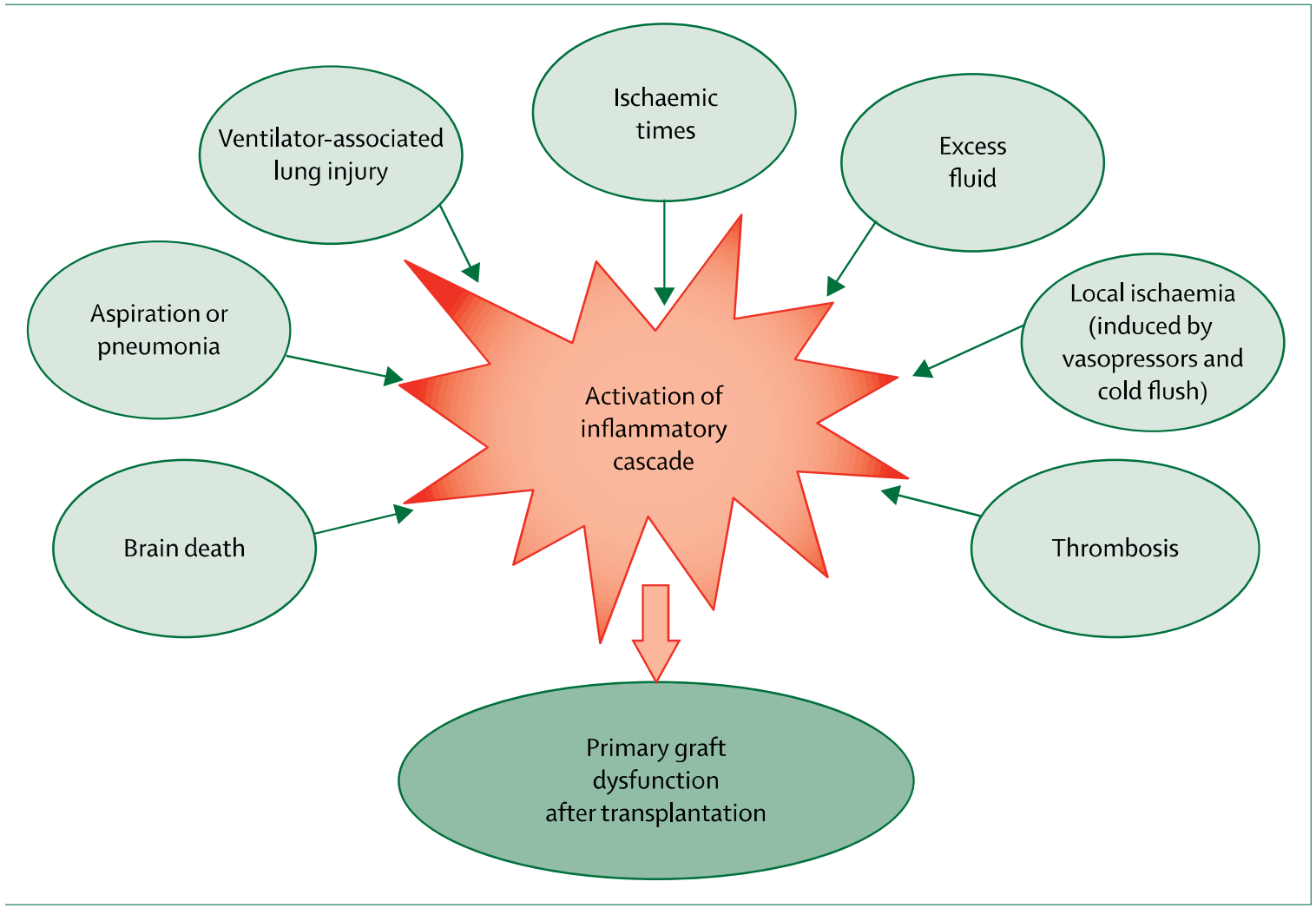

Figure 1: **Injuries to donor lungs in potential multiorgan donors**

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Ex vivo Lung Perfusion (TorEx EVLP)



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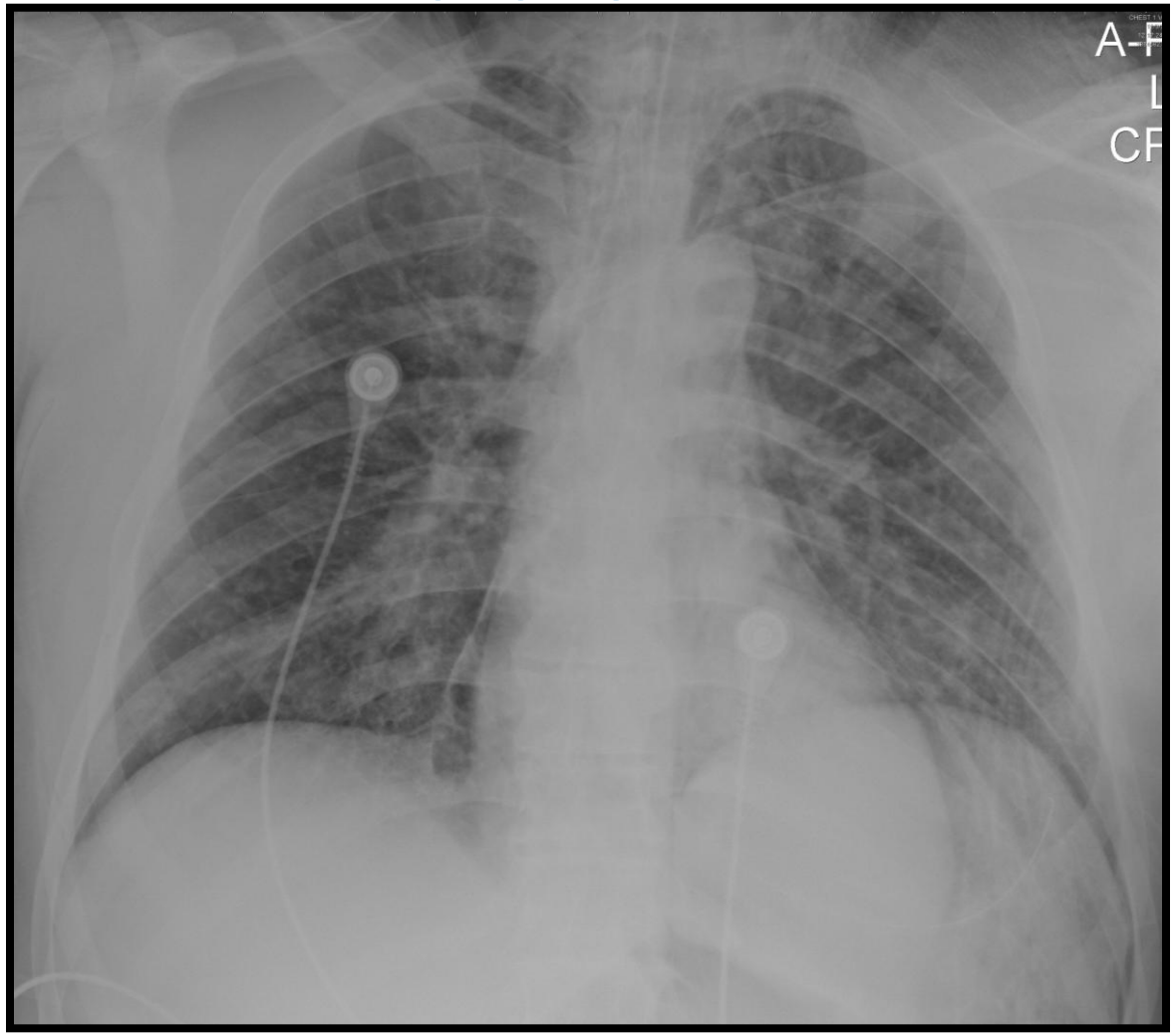
Donor CXR



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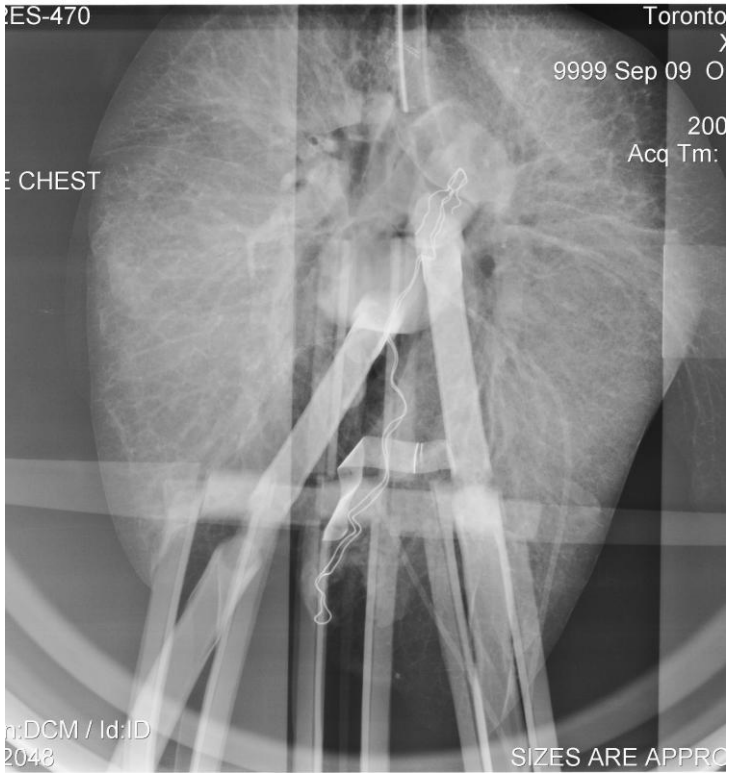
EVLP Xrays



1h EVLP P/F 250mmHg



3h EVLP P/F 460mmHg

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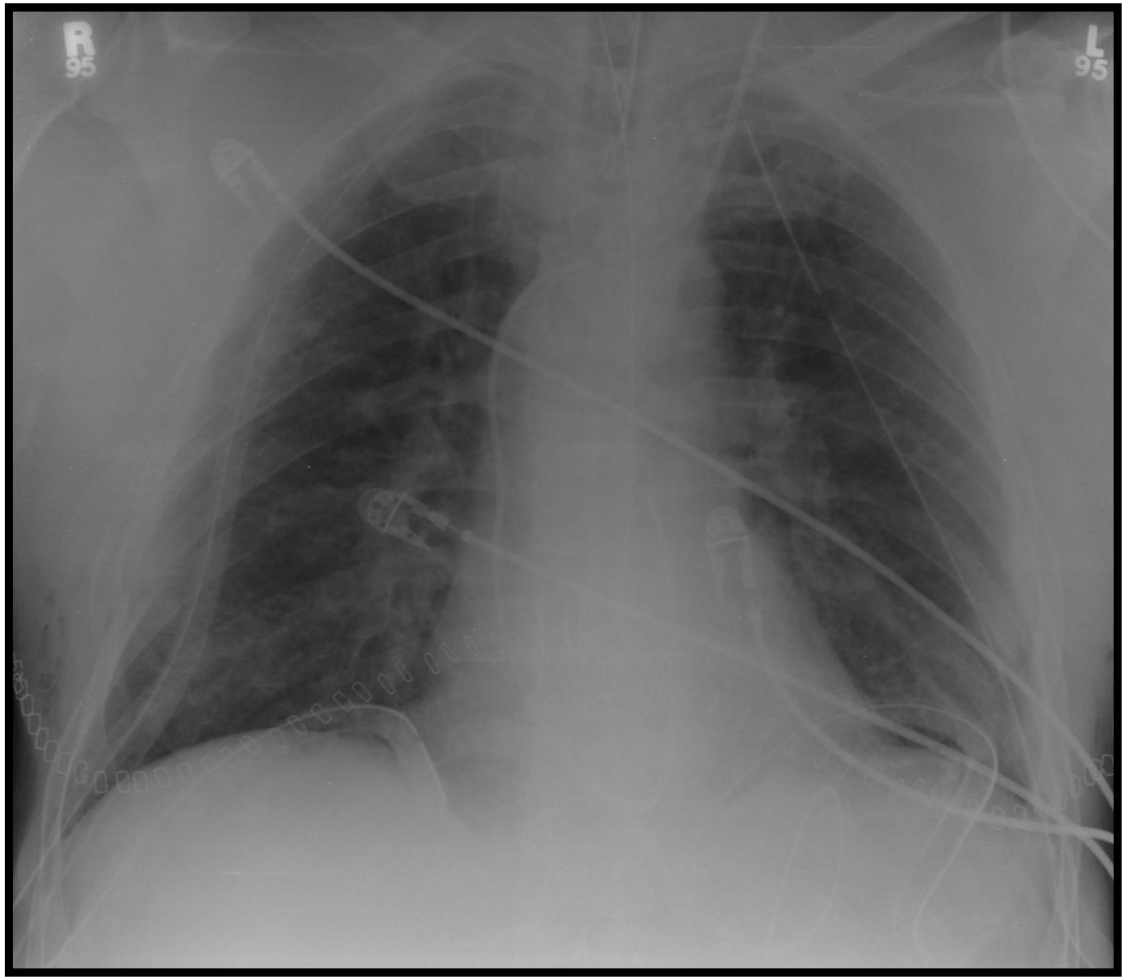
Recipient CXR on ICU Arrival



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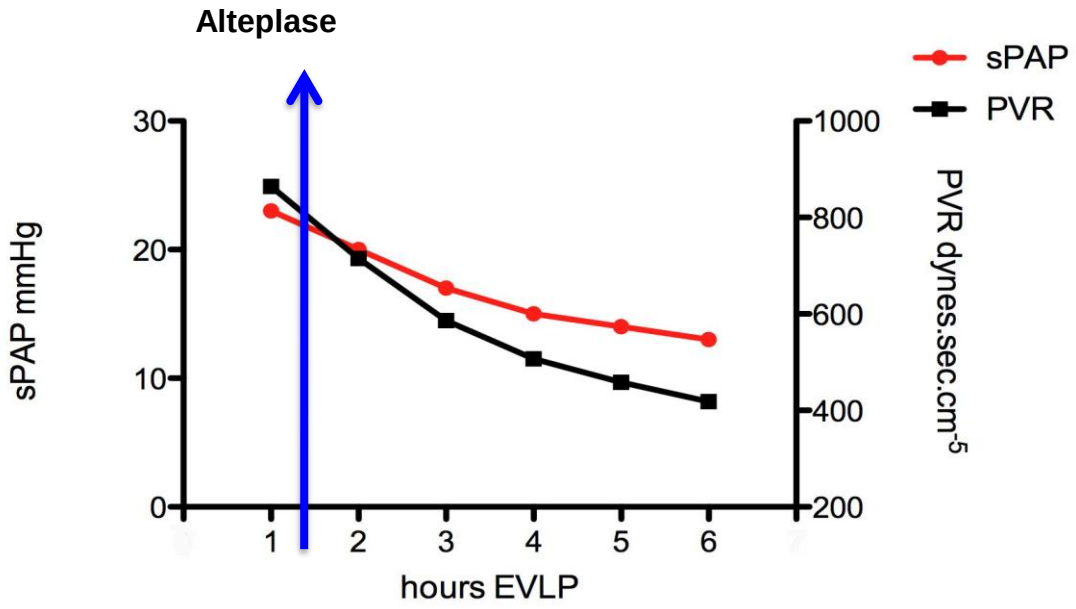
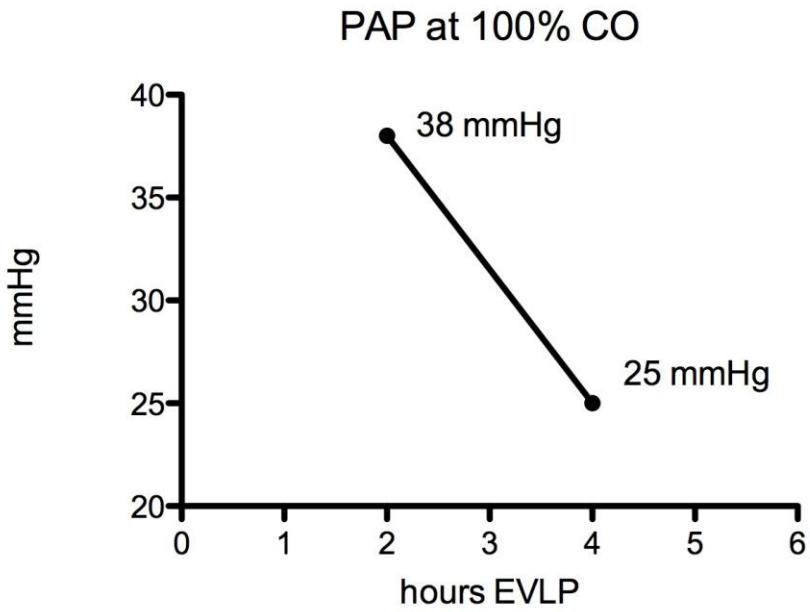
Massive Pulmonary Embolism





diagnosis

treatment

Machuca et al. Am J Respir Crit Care Med. 2013 Oct 1;188(7):878-80.

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EVLP Eras

Era 1: Better Organ Assessment: ~100% increase in volumes

DONE!

Era 2: Simple Established Personalized Therapies: i.e. antibiotics, thrombolytics, anti-inflammatory drugs

DONE!

Era 3: Advanced Therapies: Improving patient outcomes

COMING!

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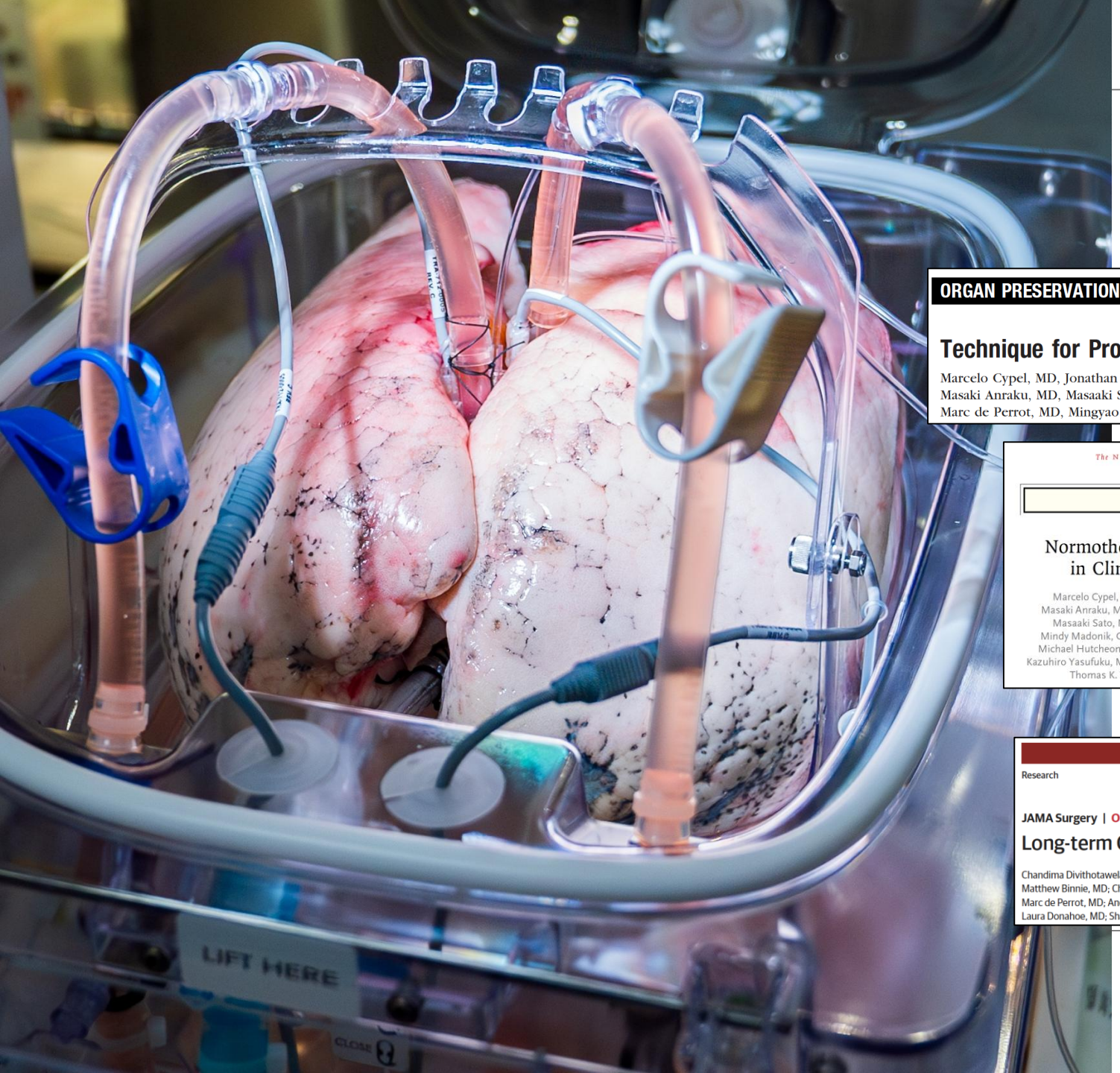
EVLP has Transformed Lung Transplantation



ORGAN PRESERVATION

Technique for Prolonged Normothermic Ex Vivo Lung Perfusion

Marcelo Cypel, MD, Jonathan C. Yeung, MD, Shin Hirayama, MD, Matthew Rubacha, MD, Stefan Fischer, MD, Masaki Anraku, MD, Masaaki Sato, MD, Stephen Harwood, MD, Andrew Pierre, MD, Thomas K. Waddell, MD, Marc de Perrot, MD, Mingyao Liu, MD, and Shaf Keshavjee, MD

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Normothermic Ex Vivo Lung Perfusion in Clinical Lung Transplantation

Marcelo Cypel, M.D., Jonathan C. Yeung, M.D., Mingyao Liu, M.D., Masaki Anraku, M.D., Fengshi Chen, M.D., Ph.D., Wojtek Karolak, M.D., Masaaki Sato, M.D., Ph.D., Jane Laratta, R.N., Sassan Azad, C.R.A., Mindy Madonik, C.C.P., Chung-Wai Chow, M.D., Cecilia Chaparro, M.D., Michael Hutcheon, M.D., Lianne G. Singer, M.D., Arthur S. Slutsky, M.D., Kazuhiro Yasufuku, M.D., Ph.D., Marc de Perrot, M.D., Andrew F. Pierre, M.D., Thomas K. Waddell, M.D., Ph.D., and Shaf Keshavjee, M.D.

ELSEVIER

The Journal of Heart and Lung Transplantation

Functional outcomes and quality of life after normothermic ex vivo lung perfusion lung transplantation

Jussi M. Tikkanen, MD, PhD, Marcelo Cypel, MD, Tiago N. Machuca, MD, Sassan Azad, CRA, Matthew Binnie, MD, Chung-Wai Chow, MD, Cecilia Chaparro, MD, Michael Hutcheon, MD, Kazuhiro Yasufuku, MD, Marc de Perrot, MD, Andrew F. Pierre, MD, Thomas K. Waddell, MD, Shaf Keshavjee, MD, and Lianne G. Singer, MD

AATS

Clinical Outcomes of over 500 Lung Transplants using Ex vivo Lung Perfusion: A Large Volume Single Center Retrospective Analysis

Research

JAMA Surgery | Original Investigation

Long-term Outcomes of Lung Transplant With Ex Vivo Lung Perfusion

Chandima Divithotawela, MD; Marcelo Cypel, MD; Tereza Martinu, MD; Lianne G. Singer, MD; Matthew Binnie, MD; Chung-Wai Chow, MD; Cecilia Chaparro, MD; Thomas K. Waddell, MD; Marc de Perrot, MD; Andrew Pierre, MD; Kazuhiro Yasufuku, MD; Jonathan C. Yeung, MD; Laura Donahoe, MD; Shaf Keshavjee, MD; Jussi M. Tikkanen, MD

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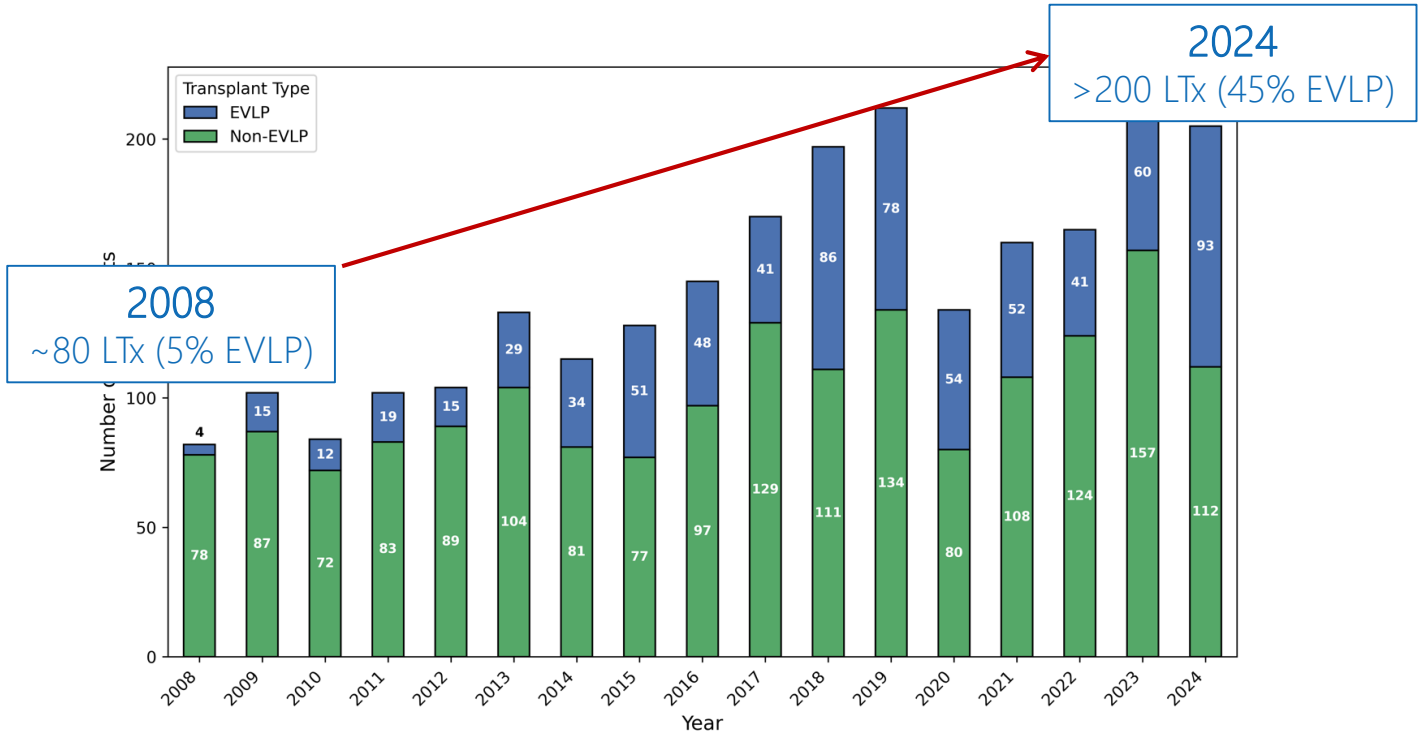
Toronto Lung Transplant Program

The TLTP Program has Expanded in the EVLP Era



Indications for 1,000 EVLPs

DCD Donor	49%
Bronchoscopic Concerns	23%
Pulmonary Edema	22%
PaO_2 <300mmHg	15%
Retrieval by a Non-Toronto Team	13%
Clinical Trial	7%
Infiltrates on CXR	6%
Donor Pulmonary Embolism	5%
High-Risk Donor History	5%
Logistic Issues	3%

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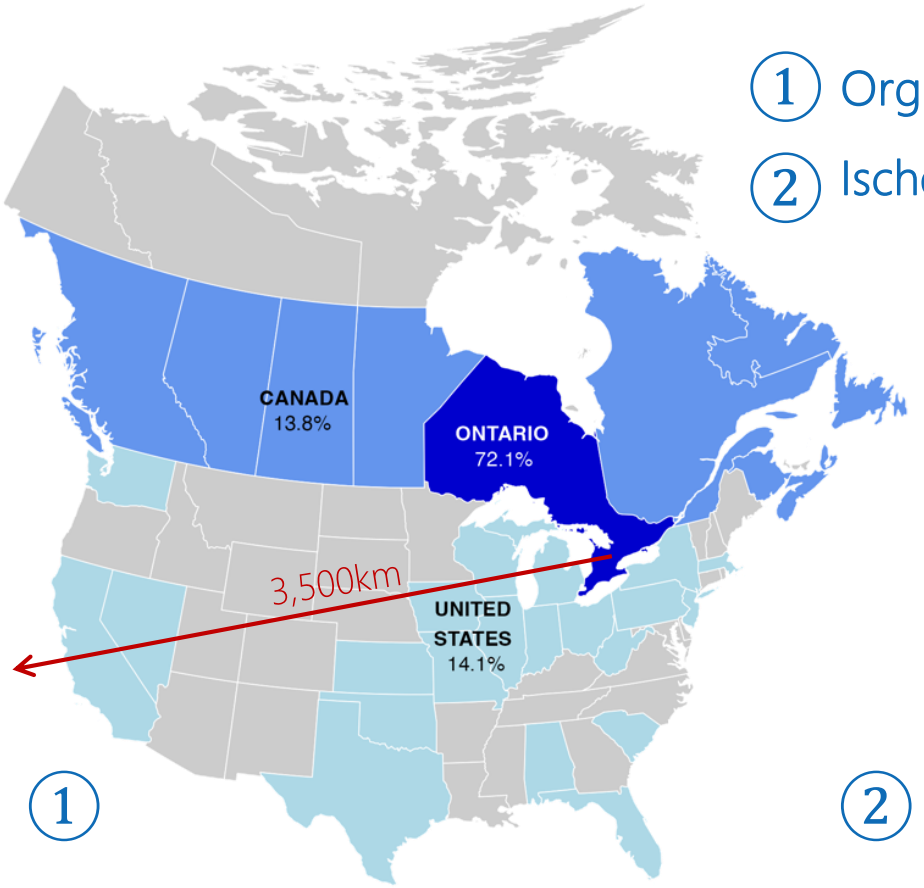
EVLP has Pushed the Boundaries of Donor Organ Recovery

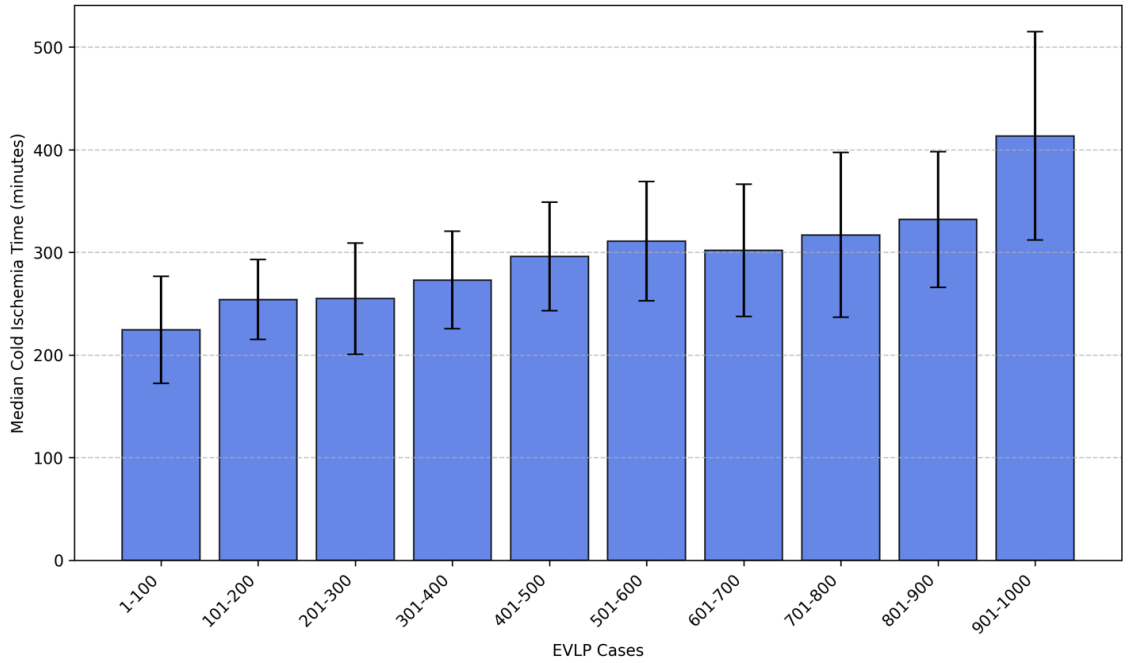




1

1. Organ Retrieval >3,500km
2. Ischemic Time Increased by >80%

2



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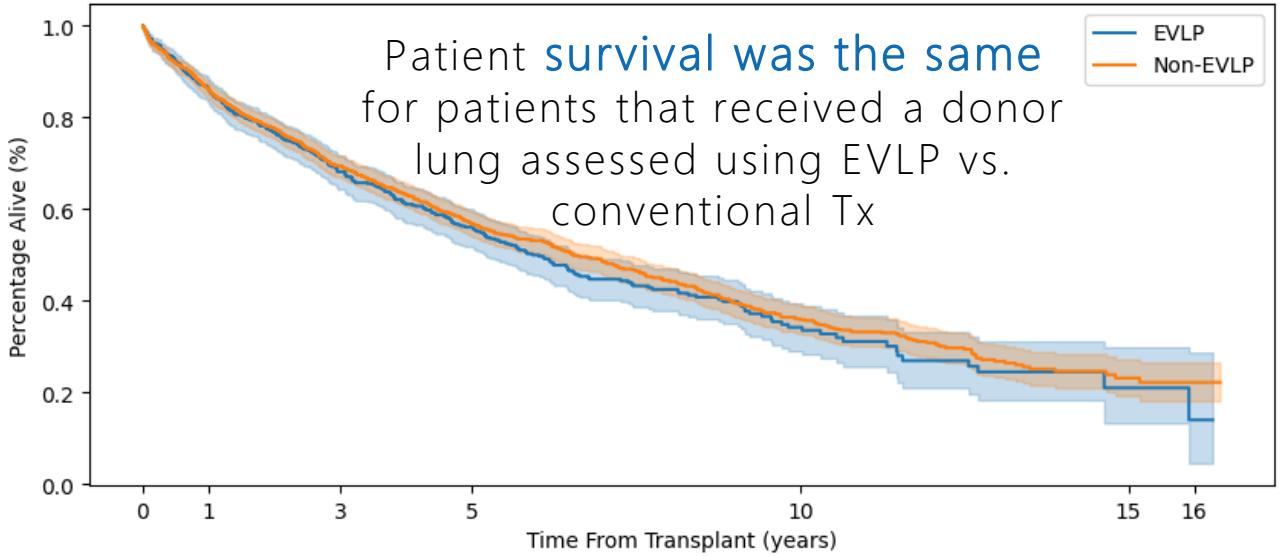
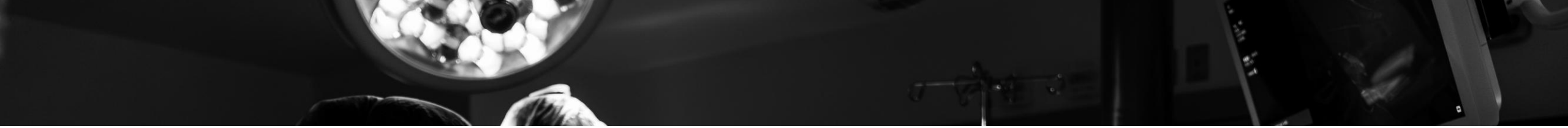
EVLP Continues to be a Safe and Effective Strategy to Expand the Donor Pool



LTx Outcomes (Median [IQR])	EVLP Group (n=659)	Non-EVLP group (n=1556)	P-Value
Time to Extubation (Hrs)	50 [27 – 113]	49 [26 – 122]	0.99
PGD Grade 3 (%)	12.8%	10.9%	0.91
ICU Length of Stay (Days)	4 [3–10]	5 [2 – 13]	0.17
Hospital Length of Stay (Days)	22 [16 – 42]	25 [17 – 45]	<0.01



How can we continue to innovate with EVLP?



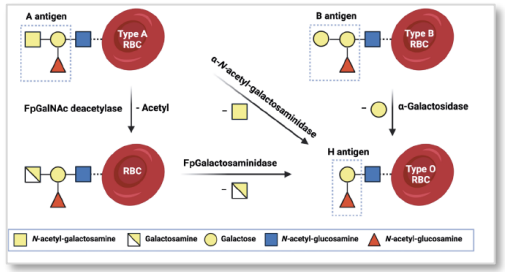
Universal Blood Type Donors

SCIENCE TRANSLATIONAL MEDICINE | RESEARCH ARTICLE

TRANSPLANTATION

Ex vivo enzymatic treatment converts blood type A donor lungs into universal blood type lungs

Aizhou Wang[1], Rafaela V. P. Ribeiro[1], Aadil Ali[1], Edson Brambate[1], Etienne Abdelnour-Berchtold[1], Vinicius Michaelsen[1], Yu Zhang[1], Peter Rahfeld[2], Haisle Moon[3], Hemant Gokhale[1], Anajara Gazzalle[1], Prodipto Pal[4], Mingyao Liu[1,5], Thomas K. Waddell[1,6], Christine Cserti-Gazdewich[7], Kathryn Tinckam[4,8], Jayachandran N. Kizhakkedathu[3,9], Lori West[10,11], Shaf Keshavjee[1,6], Stephen G. Withers[2], Marcelo Cypel[1,6]*



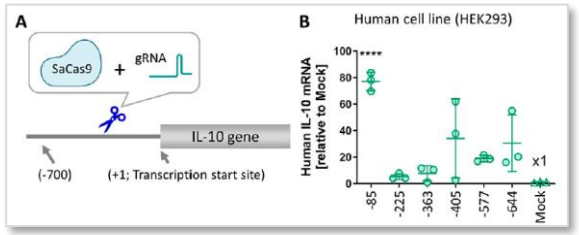
Artificial Intelligence



CRISPR-Cas Genome Editing

CRISPR-Cas Genome Editing in *Ex Vivo* Human Lungs to Rewire the Translational Path of Genome-Targeting Therapeutics

Kumi Mesaki,[1,2] Haruchika Yamamoto,[1] Stephen Juvet,[1-3] Jonathan Yeung,[1,2,4] Zehong Guan,[1] Akhi Akhter,[1] Yan Yao,[1] Cameron Dickie,[1] Henna Mangat,[1] Aizhou Wang,[1] Gavin W. Wilson,[1,5] Andrea Mariscal,[1] Jim Hu,[6,7] Alan R. Davidson,[8,9] Benjamin P. Kleinstiver,[10-12] Marcelo Cypel,[1,2] Mingyao Liu,[1,2,4] and Shaf Keshavjee[1,2,4,*]



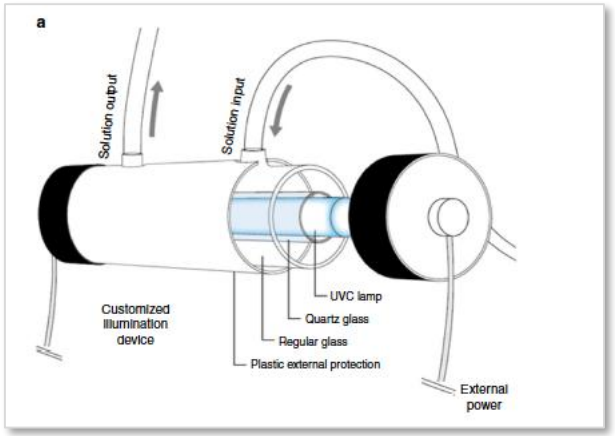
Donor Lung Treatment

ARTICLE

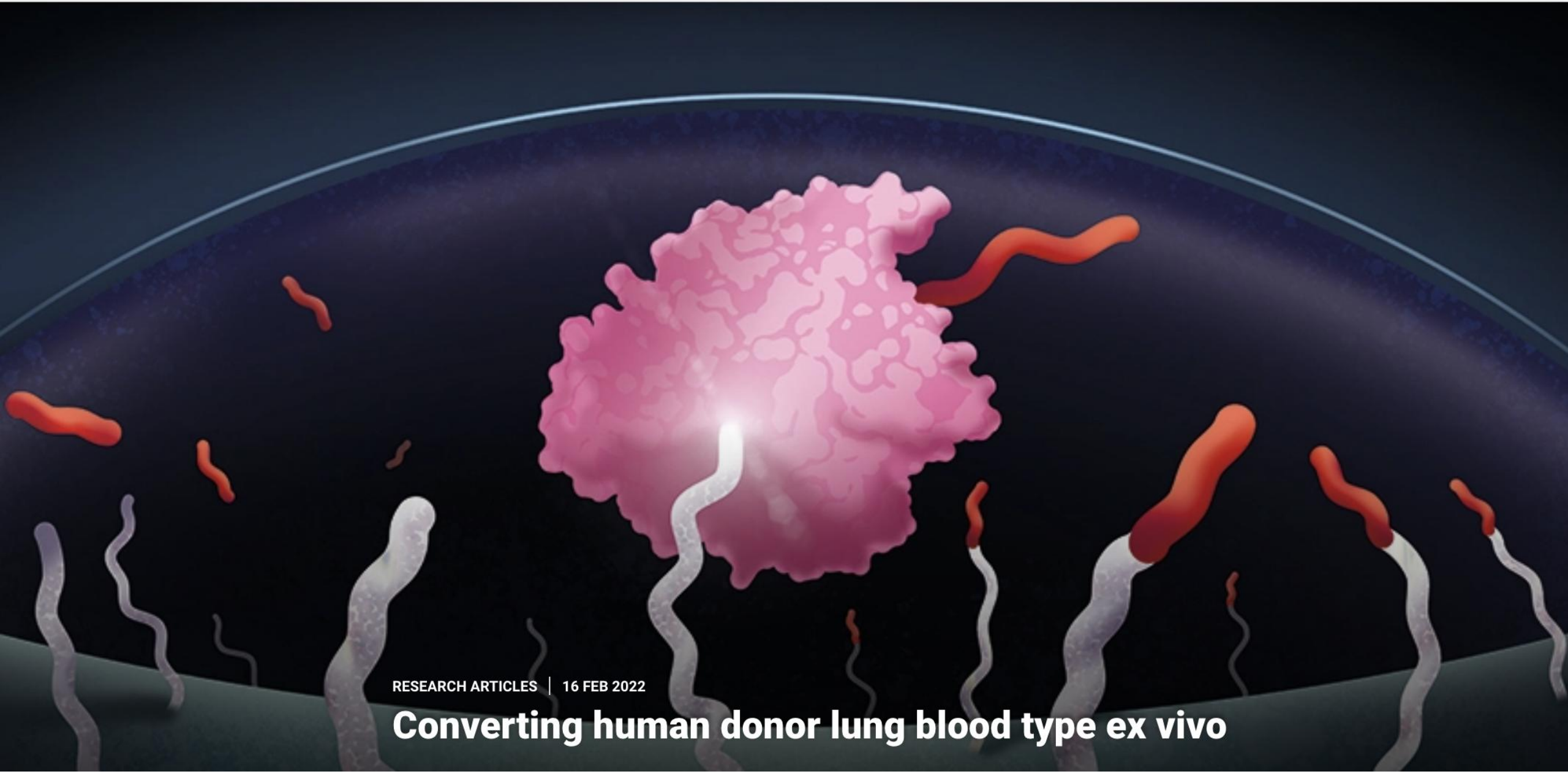
https://doi.org/10.1038/s41467-018-06261-z OPEN

Inactivating hepatitis C virus in donor lungs using light therapies during normothermic ex vivo lung perfusion

Marcos Galasso[1], Jordan J. Feld[2], Yui Watanabe[1], Mauricio Pipkin[1], Cara Summers[1], Aadil Ali[1], Robert Qaqish[1], Manyin Chen[1], Rafaela V.P. Ribeiro[1], Khaled Ramadan[1], Layla Pires[1], Vanderlei S. Bagnato[3], Cristina Kurachi[3], Vera Cherepanov[2], Gray Moonen[1], Anajara Gazzalle[1], Thomas K. Waddell[1], Mingyao Liu[1], Shaf Keshavjee[1], Brian C. Wilson[4], Atul Humar[5] & Marcelo Cypel[1,5]



Science Translational Medicine



RESEARCH ARTICLES | 16 FEB 2022

Converting human donor lung blood type ex vivo

Mitochondrial enhancement strategies

Toronto Lung Transplant Program

1

Modulating endogenous mitochondrial immunometabolism





2

Providing exogenous mitochondrial replacement



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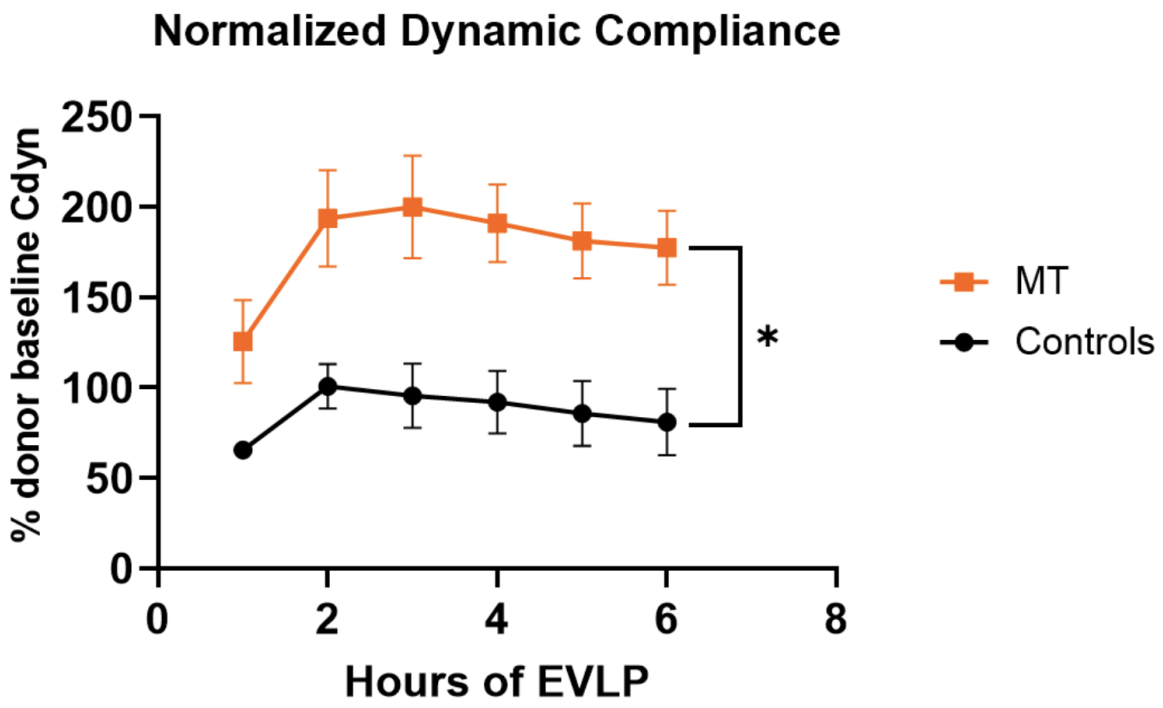
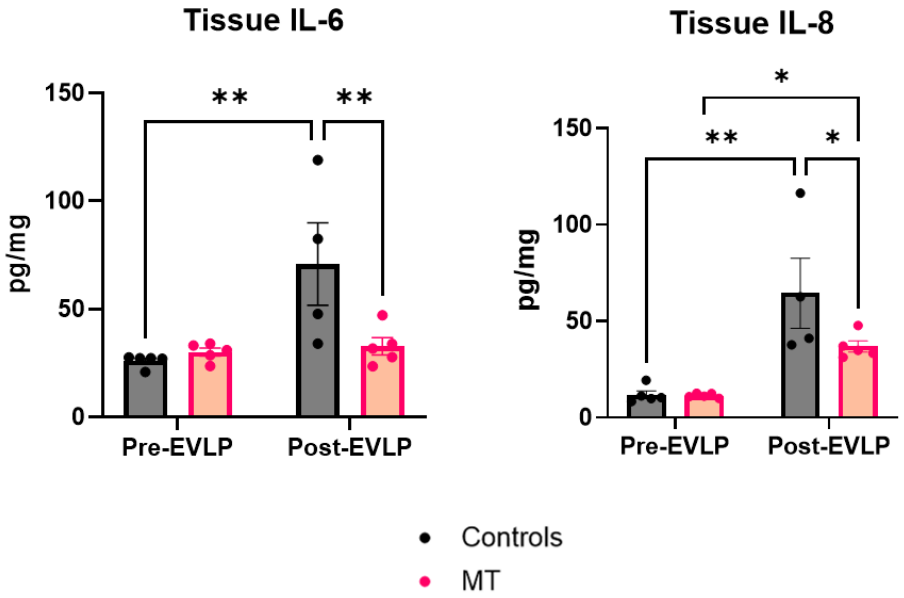
Results: MT improves **lung mechanics** on EVLP





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Major Advances in Lung Transplantation

- Lung Preservation at 10C
- Ex Vivo Lung Perfusion/Repair
- Artificial Lung Devices
- Transplant Highly Sensitized Patients
- Minimal Invasive Lung Transplantation

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Evolution in Practice

VV

VV



VV





VV



VA

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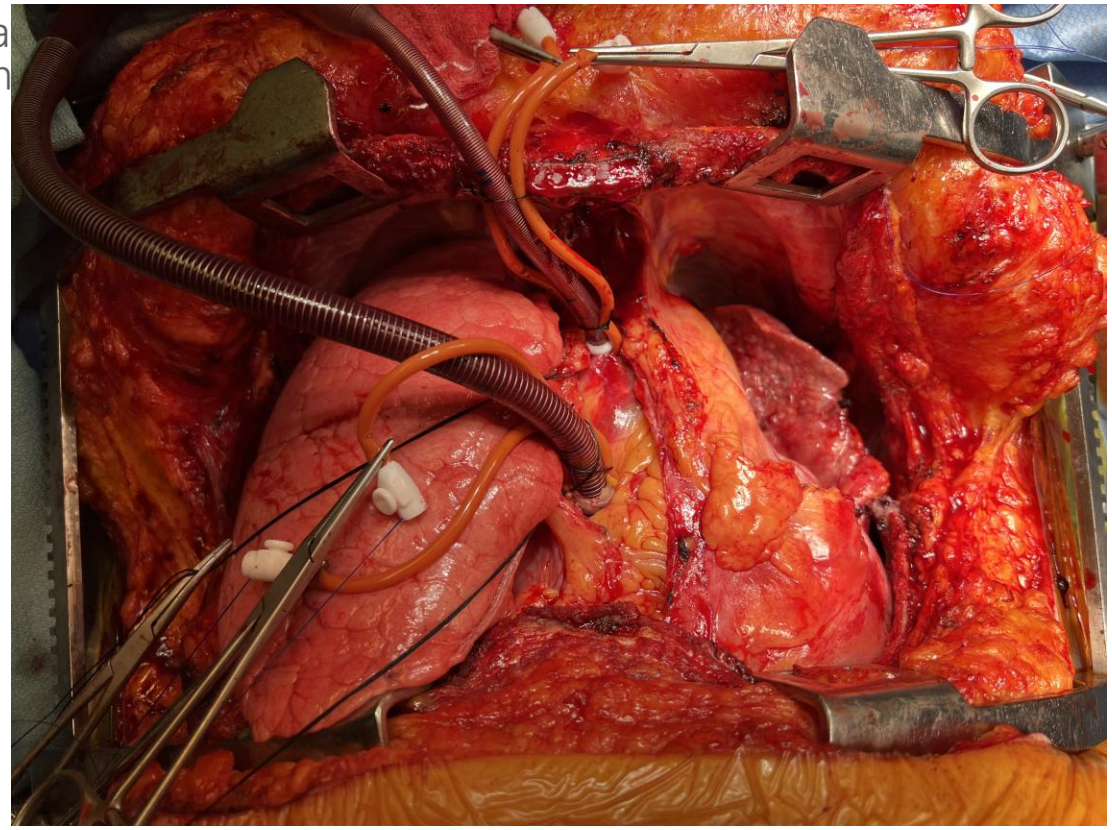
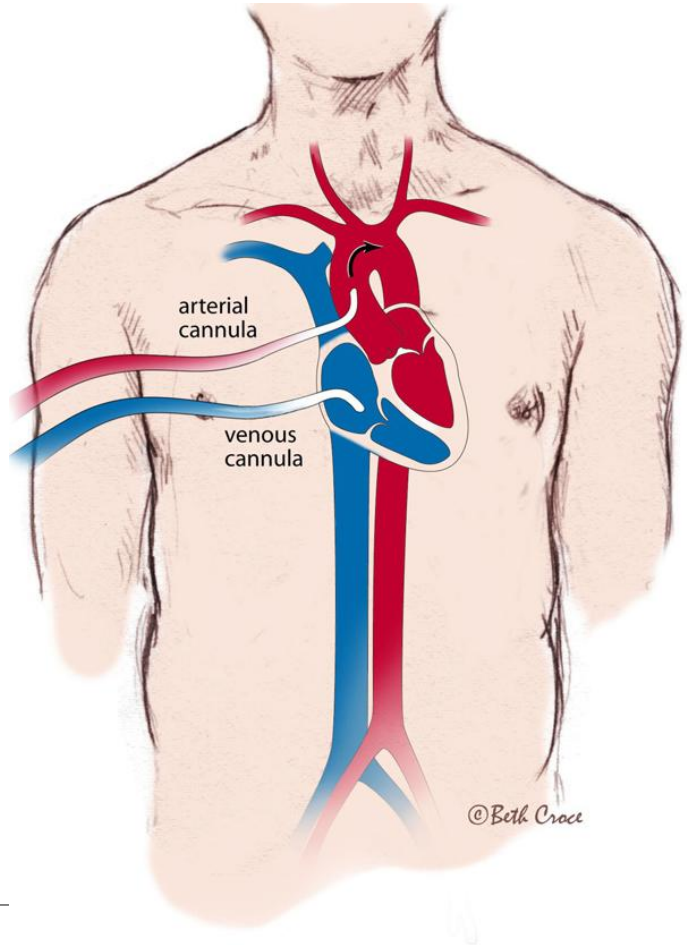
Toronto Lung Transplant Program

Intra-operative VA made lung transplantation easier and safer





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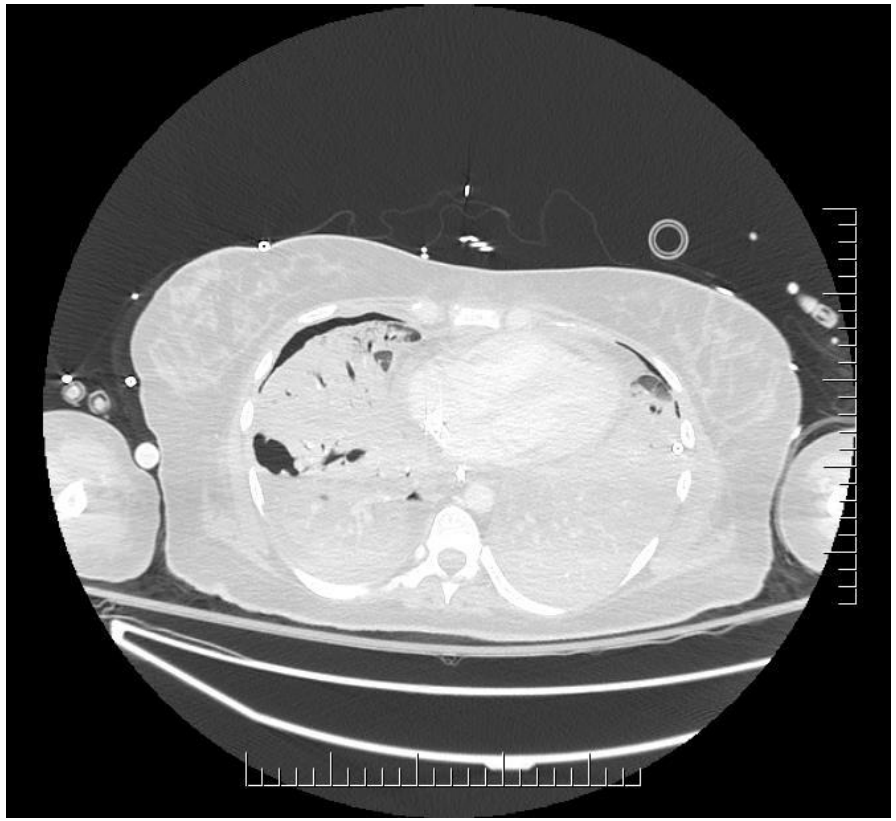
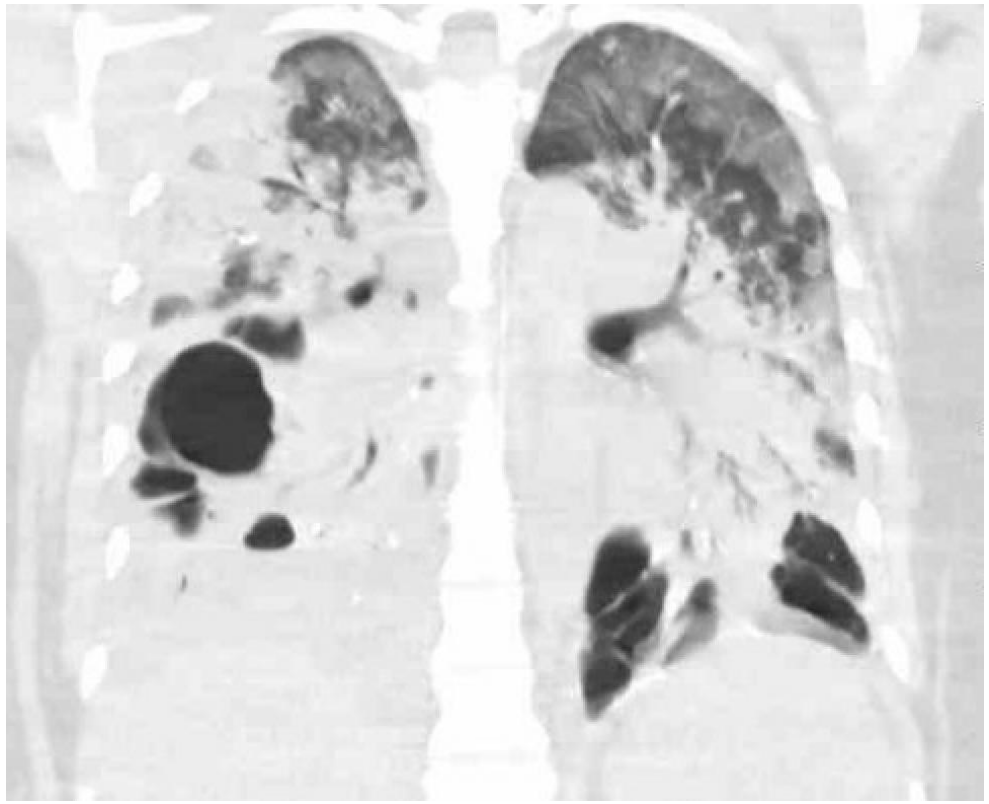
Bilateral necrotizing MRSA pneumonias and Septic Shock (Lactate 16, max pressors)





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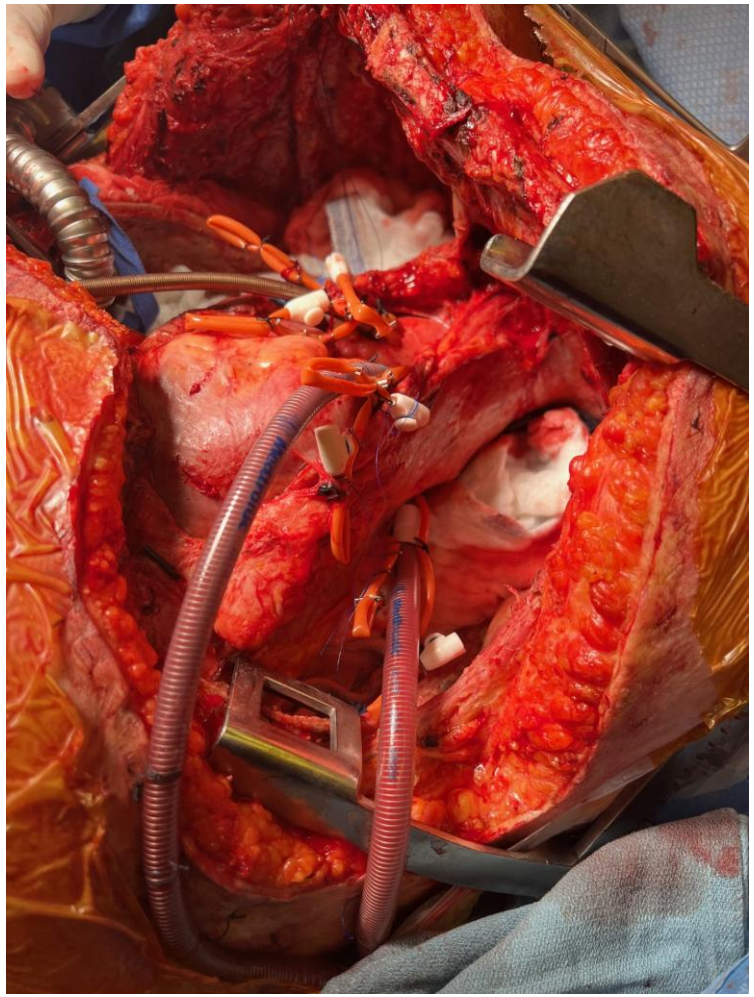
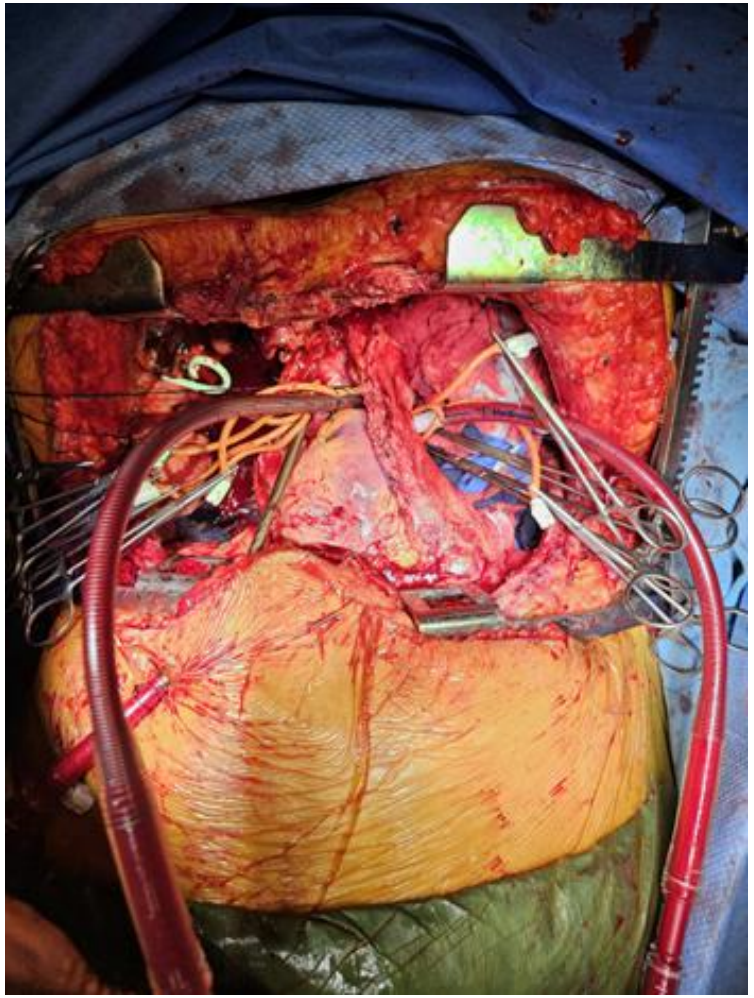
VA ECMO plus PA-LA Novalung (pumpless)





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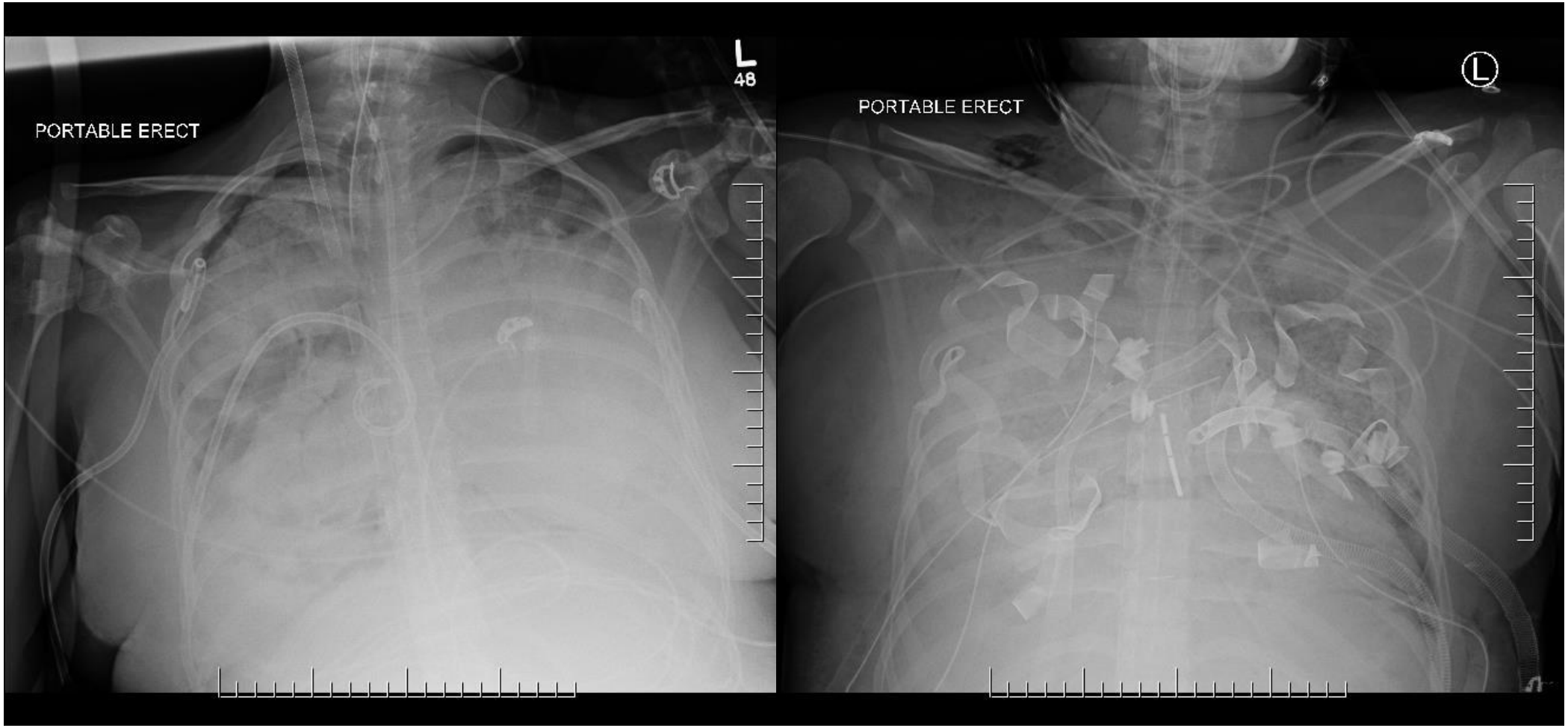
Pre- and Post-Pneumonectomy



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Explanted lungs – extensive necrotizing pneumonia





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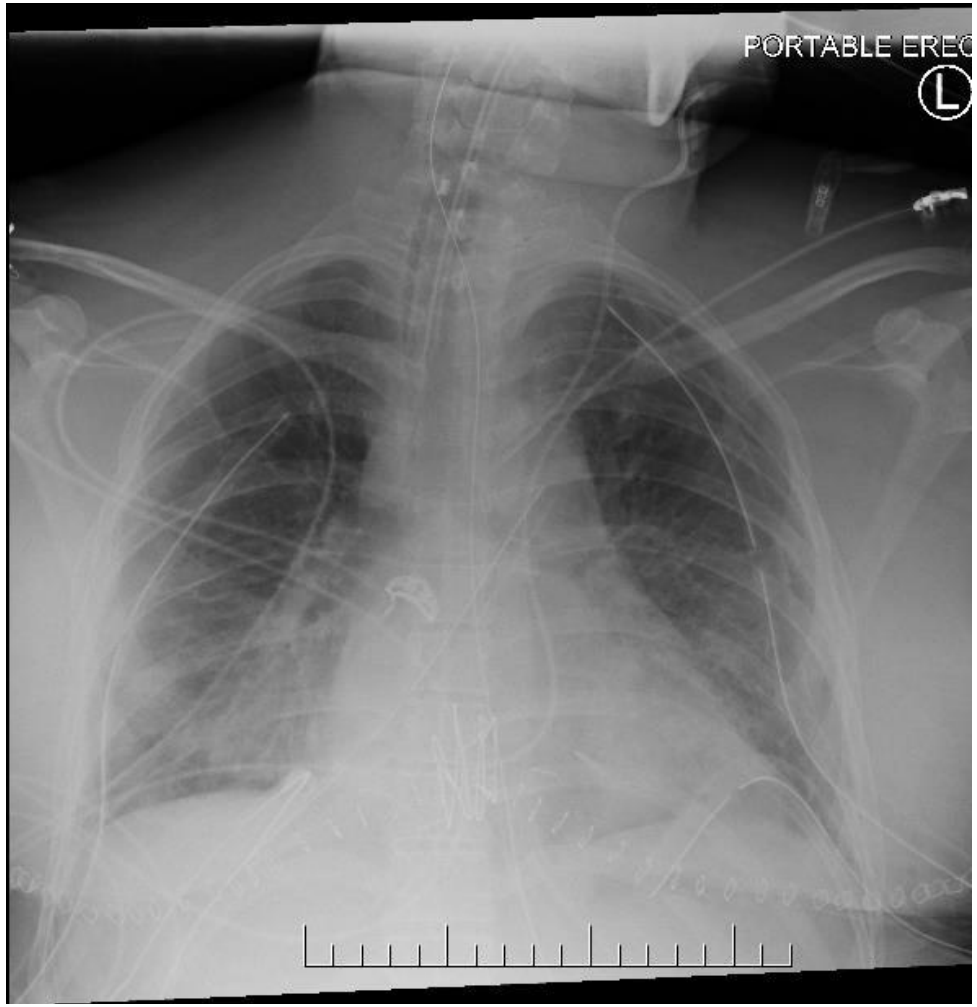
Bilateral lung transplant 2023



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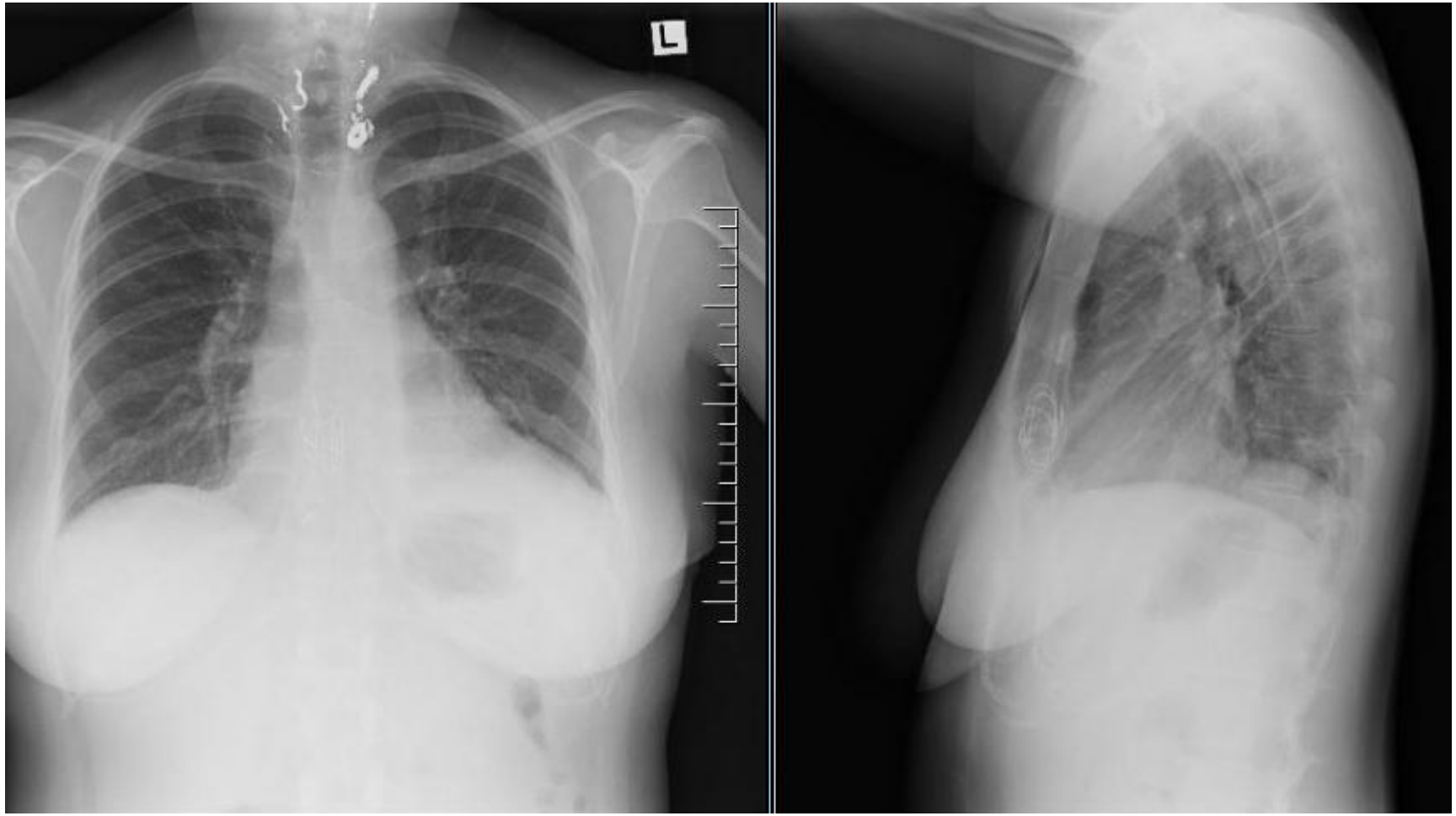
Current CXR



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April 2026



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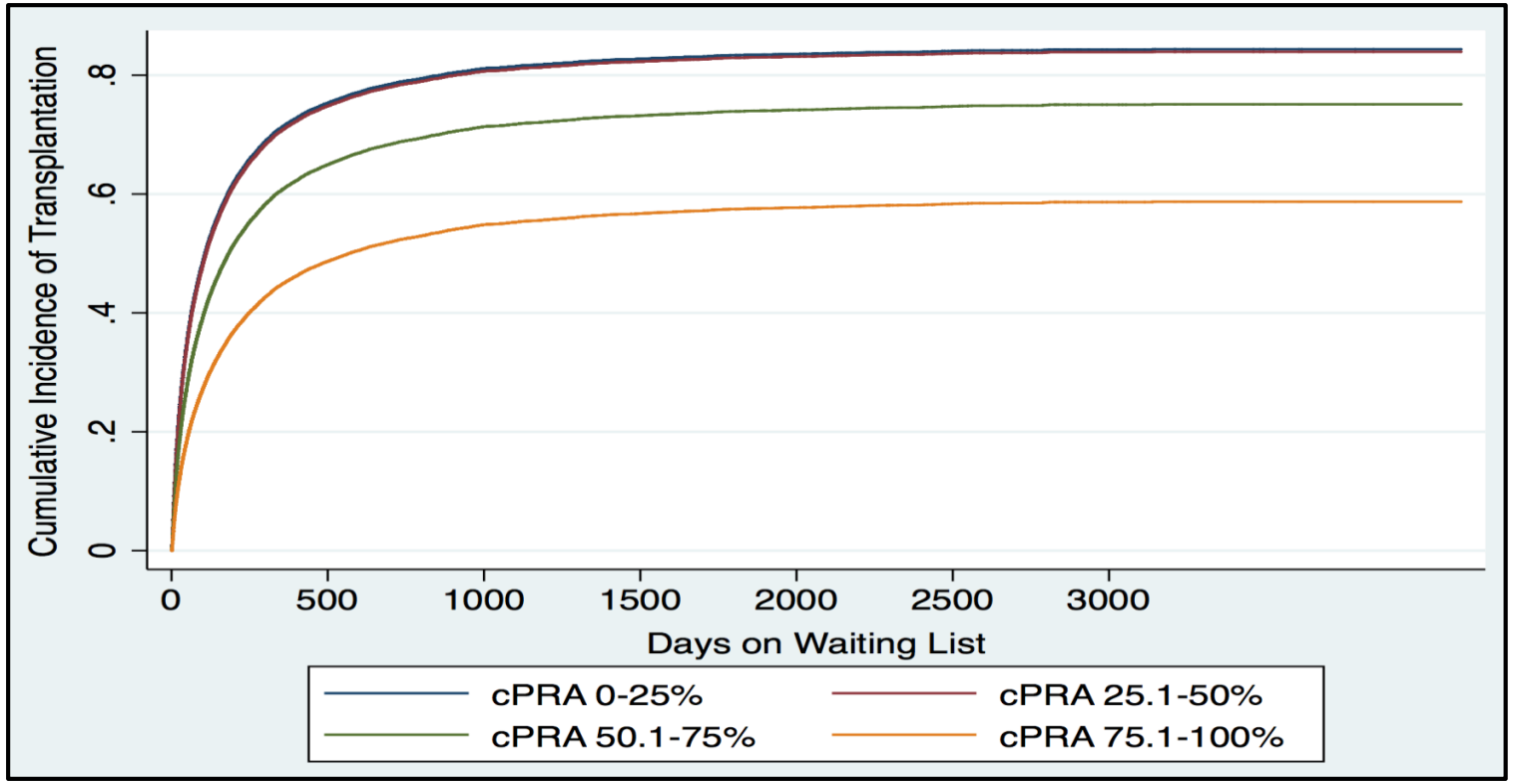
The Impact of Sensitization on Lung Transplant

cPRA Score	sHR For Lung Transplant	95% CI	p-value
0-25%	Reference	Reference	Reference
25.1-50%	0.99	0.91-1.06	0.707
50.1-75%	0.75	0.68-0.82	<0.001
75.1-100%	0.48	0.43-0.53	<0.001



Aversa M, Benvenuto L, Kim H, et al. Effect of calculated panel reactive antibody value on waitlist outcomes for lung transplant candidates. *Ann Transplant*. 2019;24:383-392.

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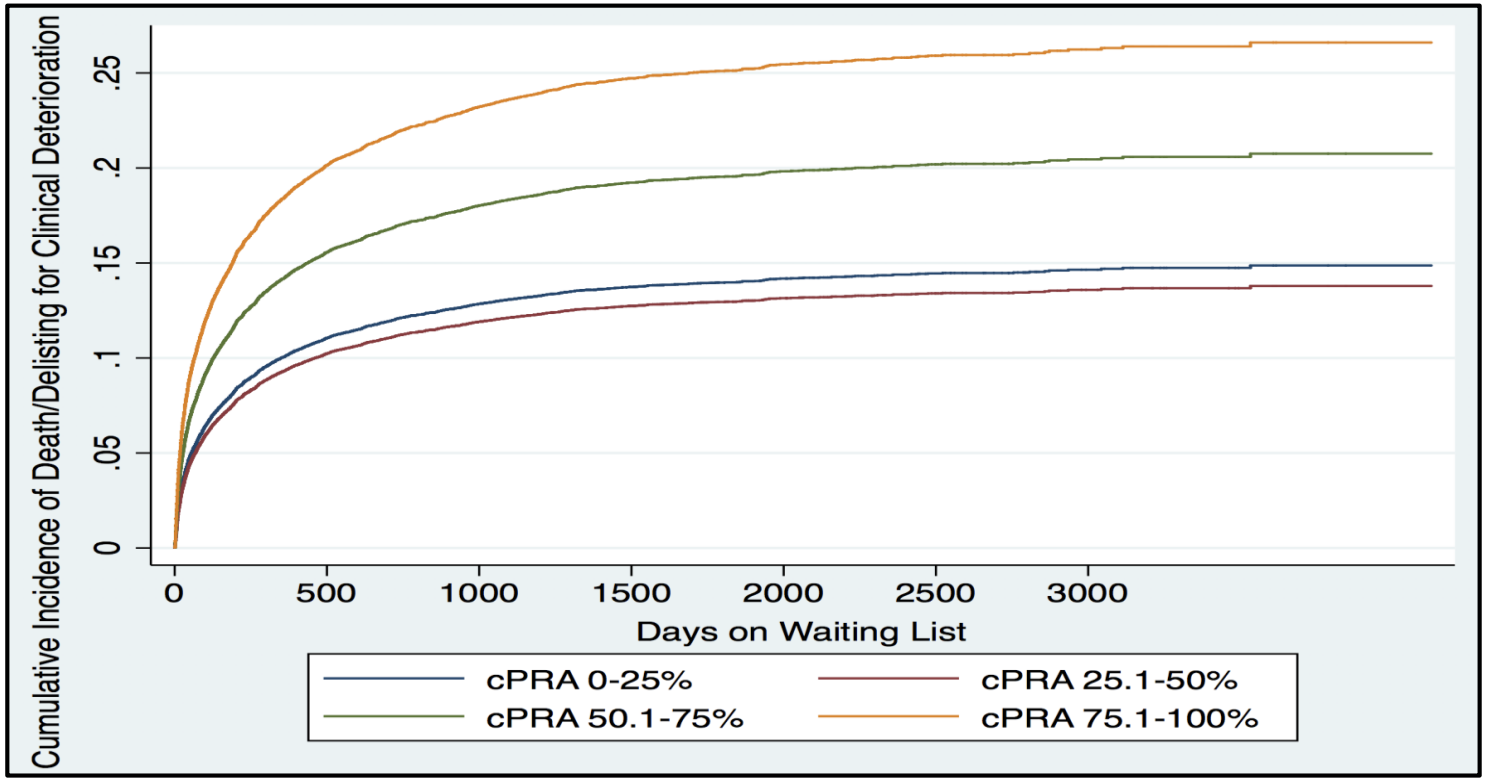
The Impact of Sensitization on Death/Delisting

cPRA Score	sHR For Death/Delisting	95% CI	p-value
0-25%	Reference	Reference	Reference
25.1-50%	0.92	0.77-1.10	0.363
50.1-75%	1.44	1.22-1.71	<0.001
75.1-100%	1.92	1.64-2.24	<0.001



Aversa M, Benvenuto L, Kim H, et al. Effect of calculated panel reactive antibody value on waitlist outcomes for lung transplant candidates. *Ann Transplant*. 2019;24:383-392.

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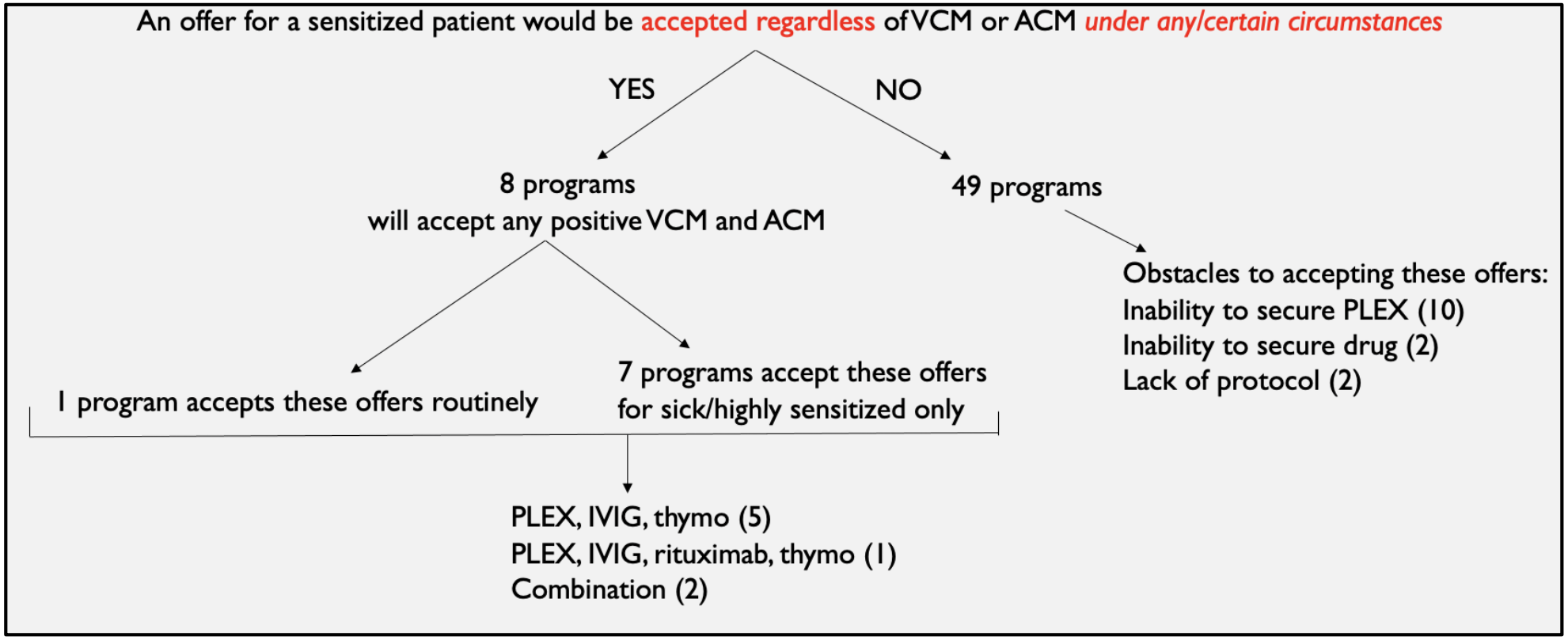
Management of Sensitized Lung Transplant Candidates: An International Survey



Aversa M, Darley D, Hirji A, et al. Approaches to the management of sensitized lung transplant candidates: findings from an international survey. *J Heart Lung Transplant.* 2020;39(4):S315.

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Toronto Lung Transplant Desensitization Protocol

- Intra-op PLEX x 3 PV (2 albumin, 1 FFP)
- Post-operative PLEX
- IVIG 1 g/kg over 2 days
- ATG 3 mg/kg if FCXM neg, 5 mg/kg if FCXM pos

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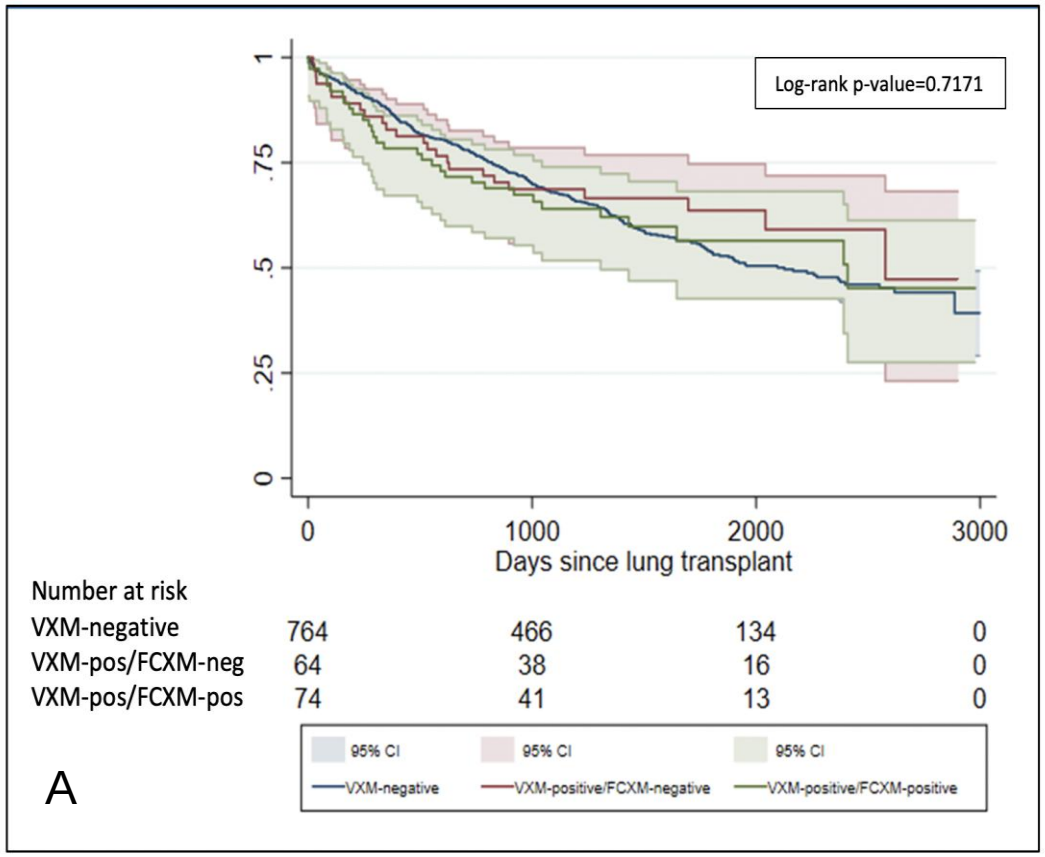
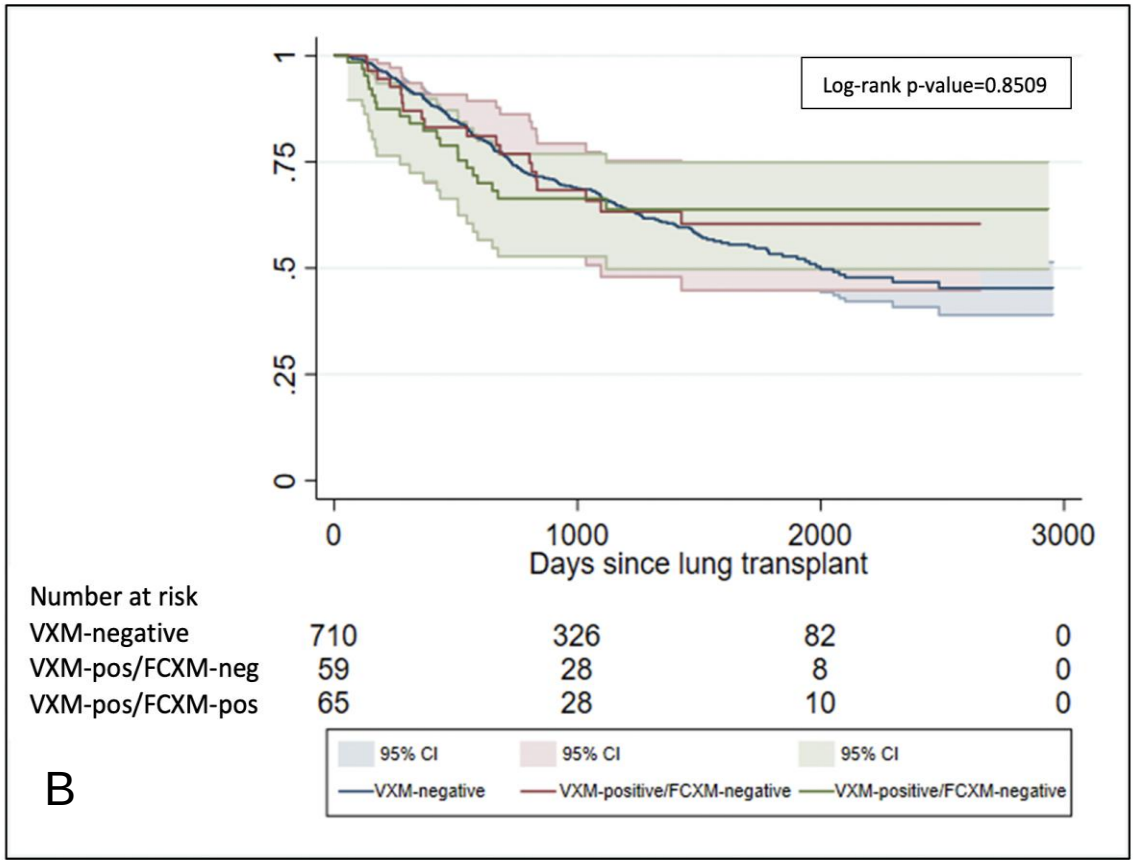
TLTP Desensitization Protocol: Allograft Survival (A) and CLAD-Free Survival (B) by FCXM status





Unpublished data

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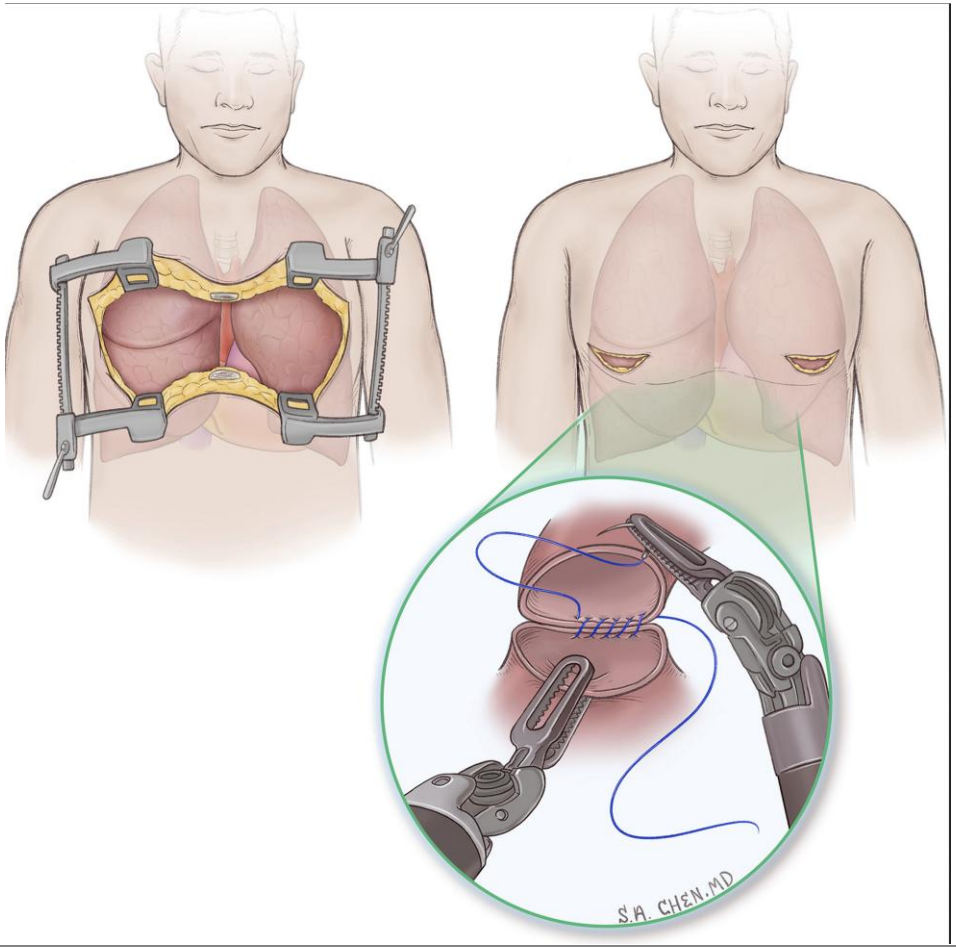
Robotic Lung Transplantation



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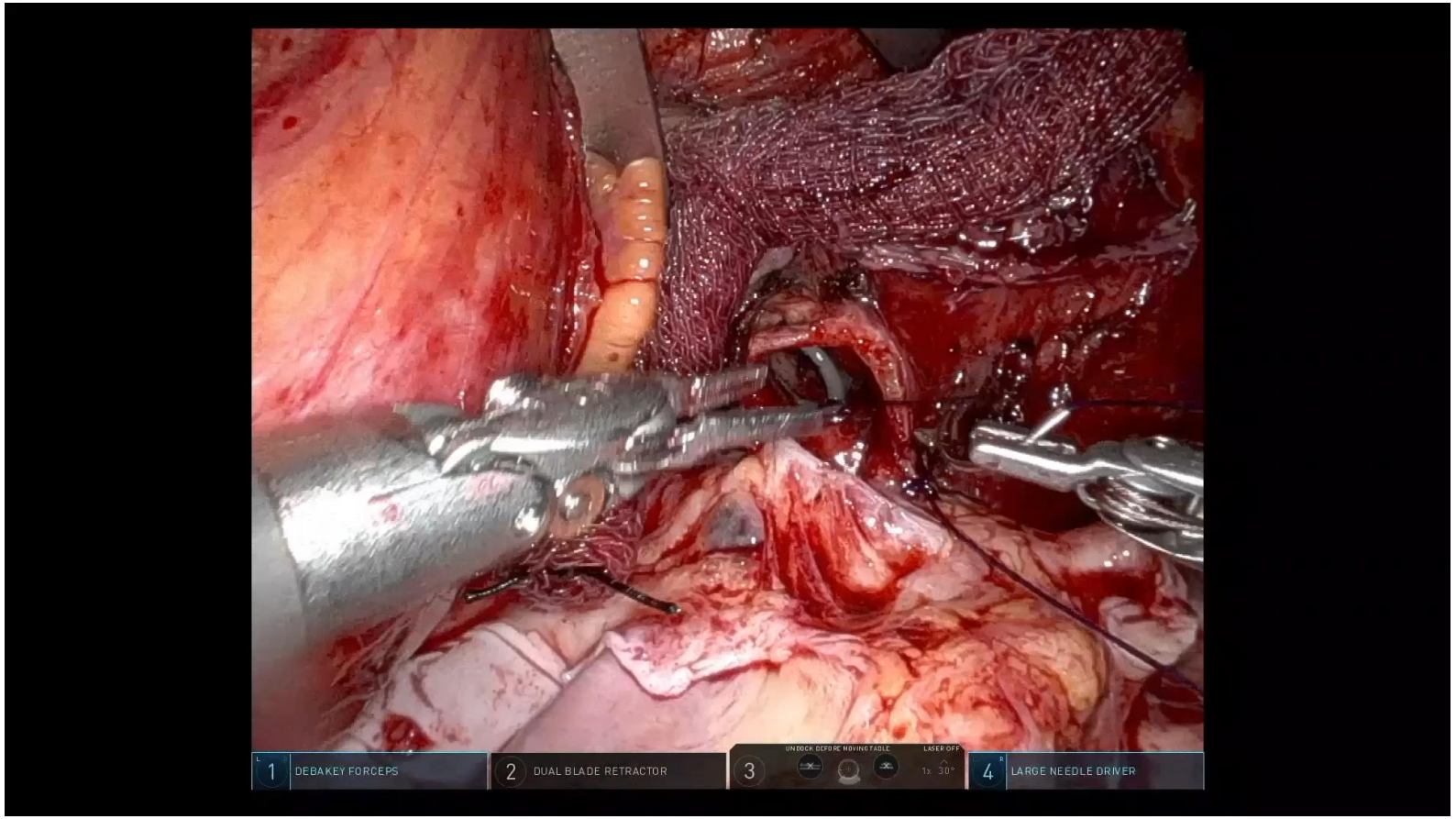
Robotic Lung Transplantation



Courtesy of Stephanie Chang, NYU

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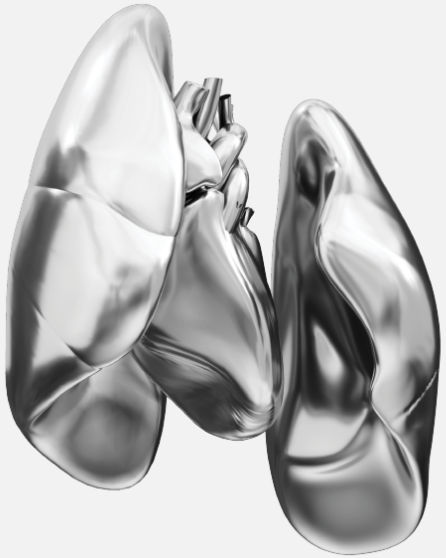

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