



Società Italiana di Terapia Antinfettiva
Antibatterica Antivirale Antifungina

14° CONGRESSO NAZIONALE

GENOVA | 21-22 novembre 2024



Infezioni nel paziente trapiantato di polmone

Novità nella gestione e l'esperienza italiana

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Transplant Infectious Disease



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REVIEW ARTICLE

C. Corey Hardin, M.D., Ph.D., Editor

Lung Transplantation

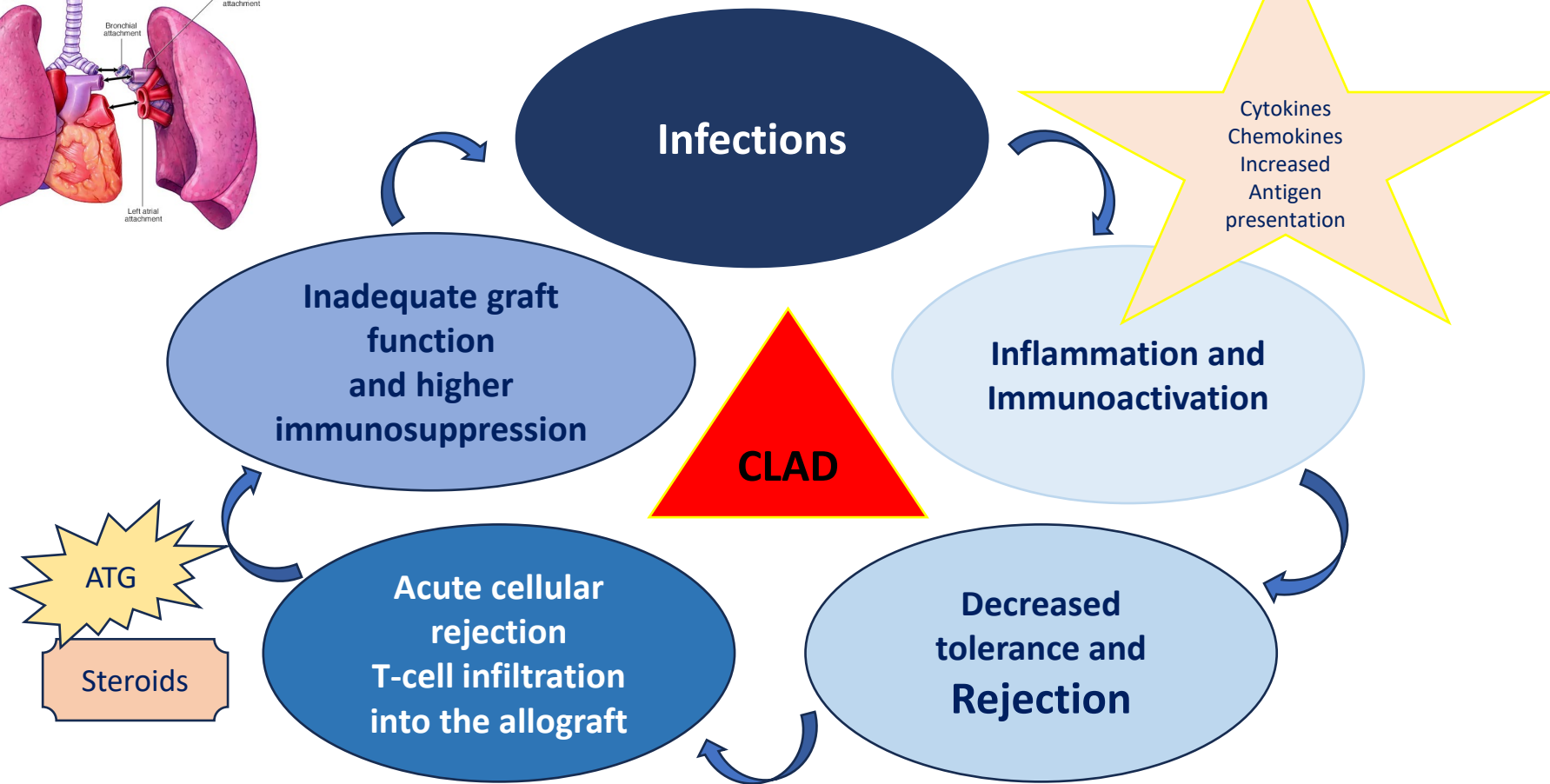
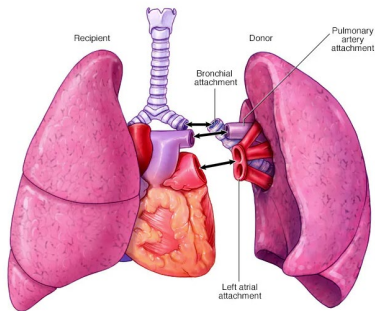
Jason D. Christie, M.D., Dirk Van Raemdonck, M.D., Ph.D.,
and Andrew J. Fisher, Ph.D., B.M., B.S.

N ENGL J MED 391;19 NEJM.ORG NOVEMBER 14, 2024

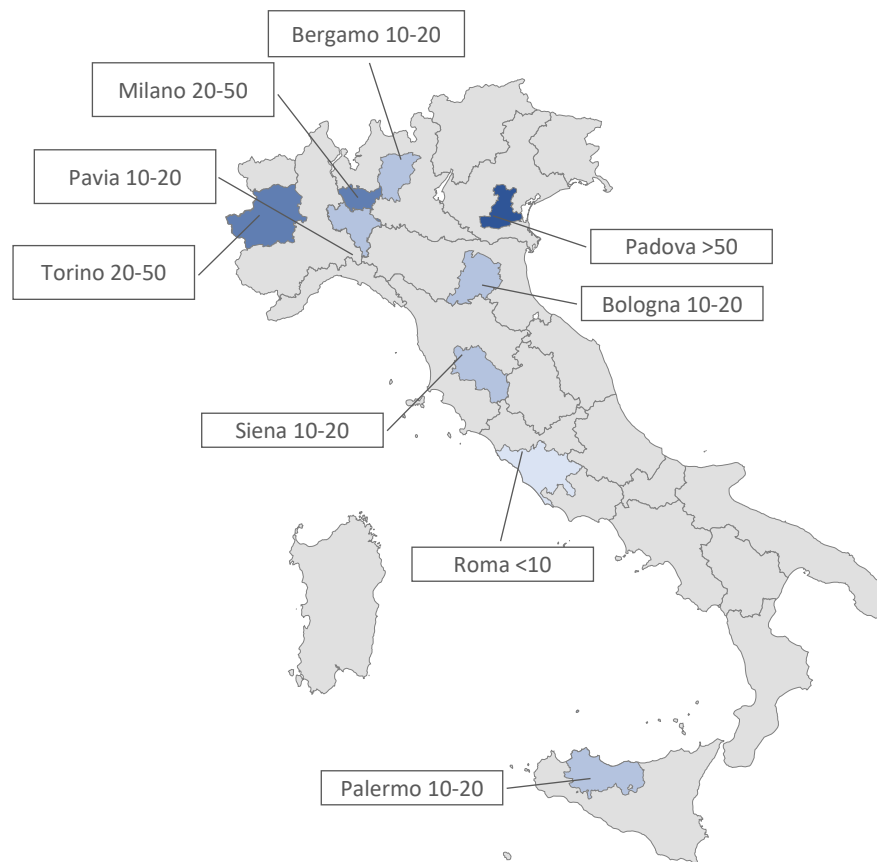
KEY POINTS

LUNG TRANSPLANTATION

- Lung transplantation is growing worldwide as a recognized treatment method for advanced lung diseases.
- Candidate selection for lung transplantation has evolved from the use of previously strict criteria to a more flexible assessment, with greater allowance for relative contraindications (for which the benefit of the procedure may outweigh the risk, as determined on a case-by-case basis) and active management to minimize their effects to facilitate the candidate's potential for recovery.
- Methods for donor-organ preservation are changing with the availability of emerging technological innovations, such as those enabling ex situ and in situ assessments, with the potential for preimplantation therapeutics to extend preservation time while potentially reducing the risk of primary graft dysfunction, which is the major cause of early complications and death.
- Maintaining graft function and the overall health of the recipient involves careful monitoring and striking a balance between the protective and adverse effects of long-term immunosuppression.
- Chronic lung allograft dysfunction remains the main obstacle to long-term survival, and further research into its mechanisms and multicenter clinical trials of preventive and therapeutic strategies are urgently needed.



Centres performing Lung Tx in Italy



FIRST STEP: Survey of current practices Dec 2023-Jan 2024 (52 Questions!!)

1. Information on management of infections among lung transplant candidates and recipients
2. Overview of the Italian scenario
3. Create a network of Infectious Disease specialists who work with Ltx and other SOT



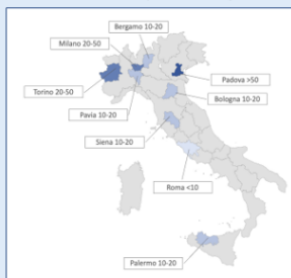
Infections management in the lung transplant setting in Italy: a web-survey

@TheTxIDJournal @AndreaLombardi3

Lombardi et al. *Transplant Infectious Diseases*. 2024.

Study design

52-question web-survey to assess infection management in lung transplant candidates and recipients in Italy.



Results



Pre-emptive therapy is the current strategy against CMV infection for D+/R- and R+ recipients in 3 (33%) and 4 (44%) centres, respectively.



Regarding antibiotic prophylaxis, most centres (6/9, 67%) utilise a regimen based on an anti-pseudomonal penicillin plus a glycopeptide. The two most common durations of antibiotic prophylaxis are 72 hours and 7 days, each reported by 2 centres (22%).



A minority of centres (4/9, 44%) employ pre-emptive therapy against fungal infections. Inhaled amphotericin B is the most common antifungal employed, used as pre-emptive therapy (2/4, 50%) and universal prophylaxis (2/5, 40%).

Conclusions

There is considerable heterogeneity in infection management among Italian LuTx centres. Establishing a shared platform for data collection and outcome evaluation is essential to improve infection management.

Candidate Assessment and Selection

- Allocate donor organs to candidates who are most likely to derive a net benefit from transplantation.
- Estimated risk of dying from their lung disease within 2 years of greater than 50% and a likelihood of being alive 5 years after transplantation of greater than 80%.

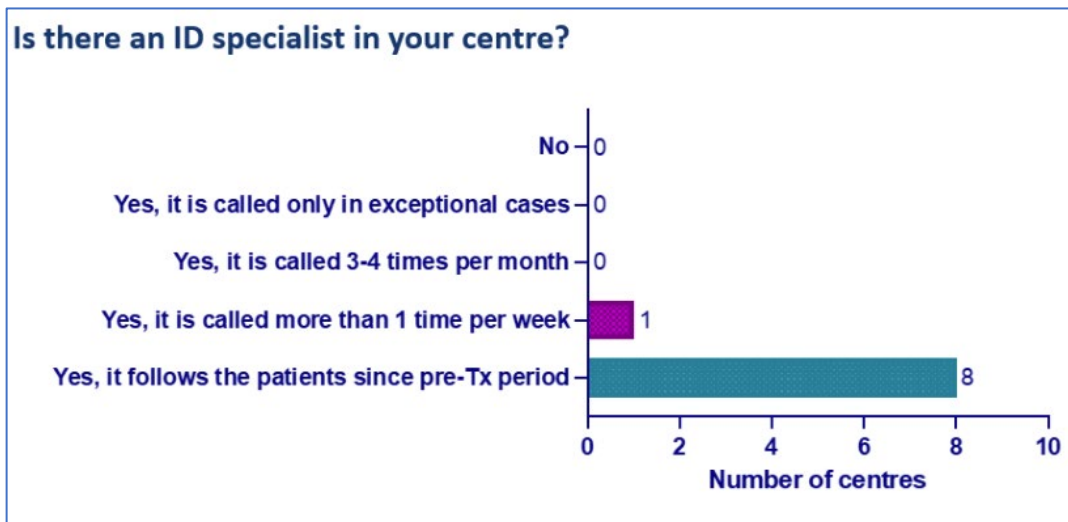


Table 1. Consensus-Based Contraindications to Lung Transplantation and Risk Factors for Poor Outcomes.^a

Contraindications and Risk Factors

Absolute contraindications

Lack of patient willingness or acceptance to undergo transplantation
 Malignant condition with a high risk of recurrence or death related to cancer
 Glomerular filtration rate of <40 ml/min/1.73 m² of body-surface area (unless being considered for multiorgan transplantation)
 Acute coronary syndrome or myocardial infarction in the past 30 days (excluding demand ischemia)
 Stroke in the past 30 days
 Liver cirrhosis with portal hypertension or synthetic dysfunction (unless being considered for multiorgan transplantation)
 Acute liver failure
 Acute kidney failure with a rising creatinine level or that is being treated by dialysis, with a low likelihood of recovery (unless being considered for multiorgan transplantation)
 Septic shock
 Active extrapulmonary or disseminated infection
 Active tuberculosis infection
 HIV infection with detectable viral load
 Limited functional status (e.g., nonambulatory) with poor potential for post-transplantation rehabilitation
 Progressive cognitive impairment
 Repeated episodes of nonadherence without evidence of improvement†
 Active substance use or dependence (e.g., current tobacco use, vaping, marijuana smoking, or intravenous drug use)
 Other severe uncontrolled medical condition expected to limit survival after transplantation

- These factors substantially increase the risk of an adverse outcome after transplantation and would make transplantation most likely harmful for a recipient.
- Exception under very exceptional circumstances

Traditional relative contraindications: factors associated with substantially increased risk

Age >70 years
 Severe coronary artery disease that warrants coronary-artery bypass grafting at transplantation
 Reduced left ventricular ejection fraction of <40%
 Substantial cerebrovascular disease
 Severe esophageal dysmotility
 Untreatable hematologic disorders (e.g., bleeding diathesis, thrombophilia, or severe bone marrow dysfunction)
 BMI >35
 BMI <16
 Limited functional status with potential for post-transplantation rehabilitation.
 Psychiatric, psychological, or cognitive conditions with potential to interfere with medical adherence without sufficient support systems
 Unreliable support system or caregiving plan
 Lack of understanding of disease or transplantation (or both) despite having been provided adequate education
Mycobacterium abscessus infection
Lomentospora prolificans infection
Burkholderia cenocepacia or *B. gladioli* infection
 Hepatitis B or C virus infection with detectable viral load and liver fibrosis
 Chest wall or spinal deformity expected to cause restriction after transplantation
 Extracorporeal life support
 Retransplantation <1 year after initial lung transplantation
 Retransplantation for restrictive CLAD
 Retransplantation for AMR as the cause of CLAD

- Candidates may be considered in centers with specific expertise.
- More than one of these risk factors present: possibly multiplicative in terms of increasing the risk of adverse outcomes.
- Modifiable conditions should be treated to mitigate risk when possible

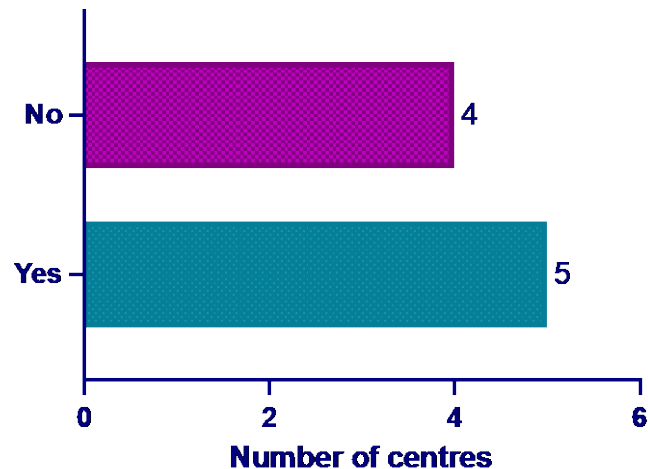
INFECTIONS IN LUNG TRANSPLANTATION:

A network to meet the challenge

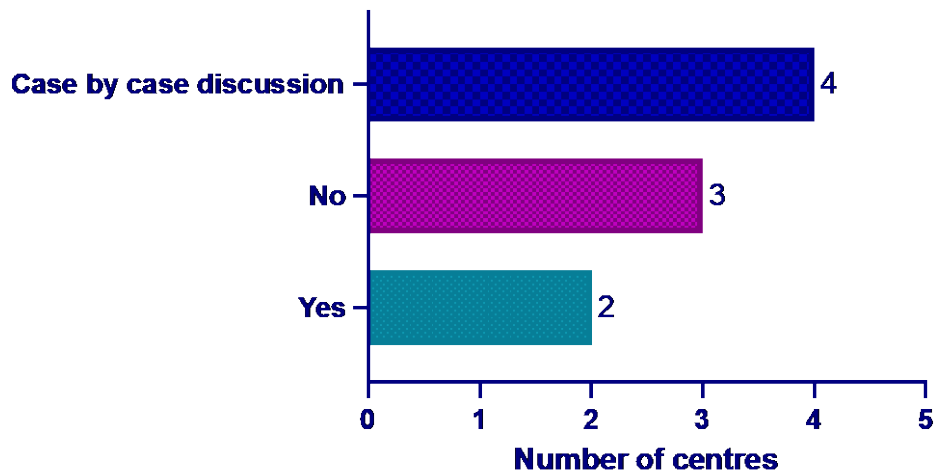
.....



The patient colonized by *Mycobacterium abscessus*: excluded from LuTx?



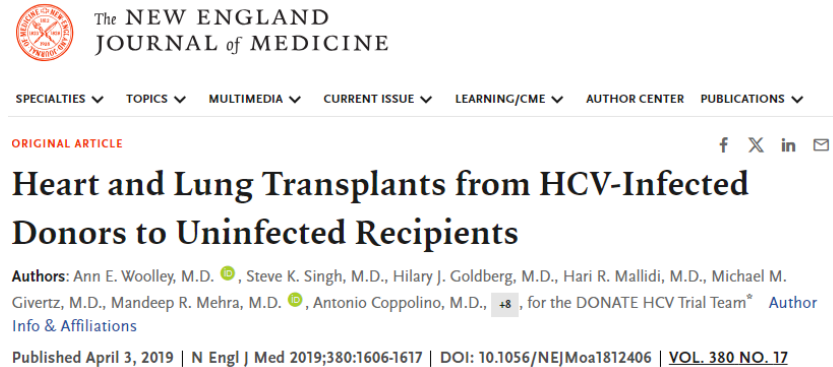
The patient colonized by *B. cenocepacia*/ genomavar III: excluded from LuTx?



Courtesy of Andrea Lombardi MD

Past Contraindications: HCV

- Traditionally, transplantation of organs from donors infected with transmissible viruses has been avoided in uninfected recipients
- Direct-acting antiviral agents against hepatitis C virus (HCV) have enabled safe transplantation of HCV-positive donor lungs into recipients who are negative for HCV.

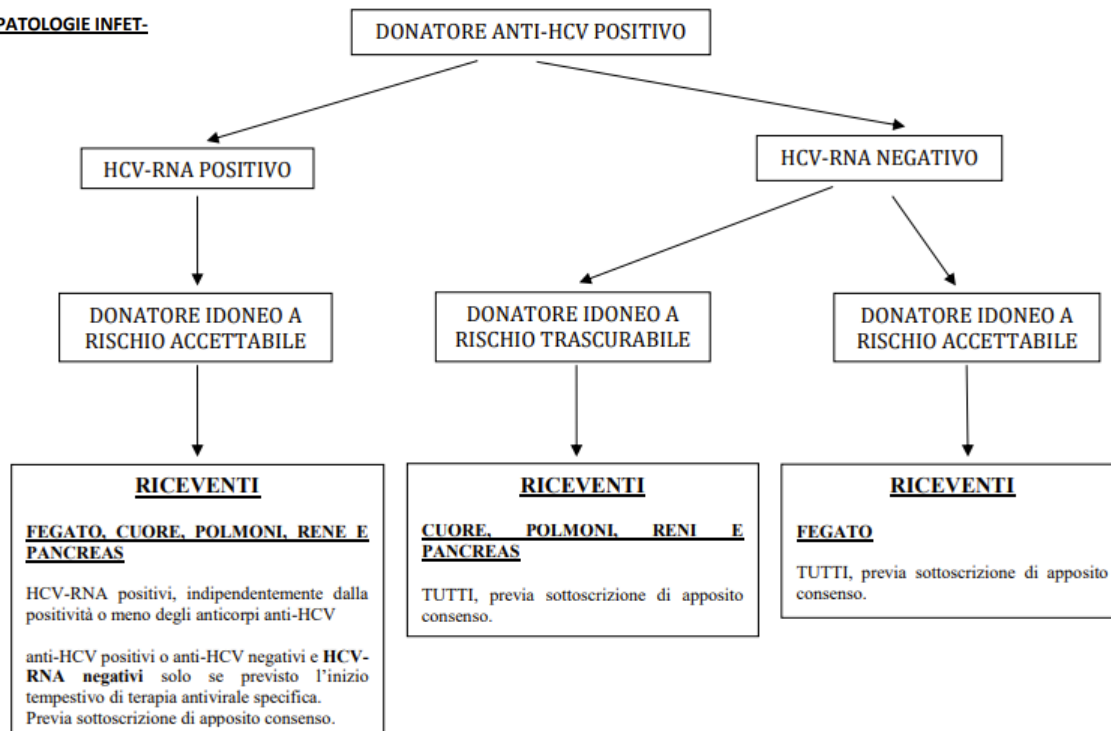


Woolley AE, Singh SK, Goldberg HJ, et al. Heart and lung transplants from HCV-infected donors to uninfected recipients. N Engl J Med 2019;380:1606-

FLOW-CHART DONATORE HCV POSITIVO

3 VALUTAZIONE DELL'IDONEITÀ DEL DONATORE IN RELAZIONE A PATOLOGIE INFETTIVE

Trapianto da Donatore con Infezione da HCV



Past Contraindications: HIV

HIV positive donor lungs can be transplanted into recipients who are positive for HIV

The **HIV Organ Policy Equity Act** (the **HOPE Act**) is a law that modifies rules regarding [organ donation](#) between HIV-positive individuals. The law authorizes clinical research and the revision of rules about organ donation and transportation as a result of the research. Organs from HIV donors would only be going to individuals who are already HIV positive, but could lead to 600 additional organ transplants a year.^[1] The use of HIV-positive organs was previously a federal crime.^[2] This bill passed the [United States Senate](#) during the [113th United States Congress](#),^[3] and also passed the [United States House of Representatives](#). It was signed into law as PL 113-51 by President [Barack Obama](#) on November 21, 2013.

HOPE
IN ACTION →

Received: 3 May 2024 | Revised: 18 September 2024 | Accepted: 1 October 2024
DOI: 10.1111/doi.14298

ORIGINAL ARTICLE

Perspective on donor-derived infections in Italy

Paolo Antonio Grossi¹ | Letizia Lombardini² | Raffaele Donadio³ | Daniela Peritore⁴ | Giuseppe Feltrin⁵



CASE REPORT · Volume 9, Issue 9, P2190-2195, September 2009 · [Open Archive](#)

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Successful Lung Transplantation in an HIV- and HBV-Positive Patient with Cystic Fibrosis

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FULL LENGTH ARTICLE · Volume 38, Issue 12, P1296-1305, December 2019

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Heart or lung transplant outcomes in HIV-infected recipients

[Christine E. Koval, MD](#)¹ | [Maryjane Farr, MD](#)² | [Jill Krisl, PharmD](#)³ | [Ghady Haidar, MD](#)⁴ | [Marcus R. Pereira, MD](#)⁵ | [Nabin Shrestha, MD](#)⁶ | [Maricar F. Malinis, MD](#)⁷ | [Nicolas J. Mueller, MD](#)^{8,9} | [Margaret M. Hannan, MD](#)¹ | [Paolo Grossi, MD](#)¹ | [Shirish Huprikar, MD](#)¹⁰ [Show less](#)

- Donor followed by an infectious disease facility.
- If the donor is receiving antiretroviral therapy, documented efficacy of the therapy (undetectable HIV-RNA).
- Absence of opportunistic and neoplastic pathologies.
- If possible, the suitability of the organ is documented by histological findings.
- No a priori restrictions for CD4+ lymphocyte counts.
- Possibility for the infectious disease team to identify an appropriate treatment regimen antiretroviral (cART) to be initiated in the recipient, based on the clinical and pharmacological history of the donor and the recipient.

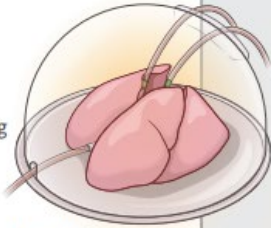
The donor with HIV infection, who meets the criteria listed above, is considered at standard risk for HIV-infected recipients unless other conditions coexist.

At the end of 2023, a total of 15 transplants from HIV-positive donors were performed in Italy (nine livers and six kidneys) with outcomes comparable to HIV-positive recipients of organs from HIV-negative donors (unpublished data).

Interim Care and Preparation

Ex Vivo Lung Perfusion

- Evaluation
- Reconditioning
- Preservation

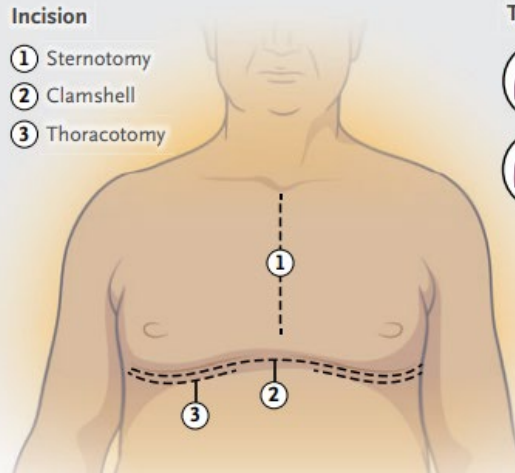


Bridging to Transplantation with Extracorporeal Life Support

Use in select candidates whose condition deteriorates dramatically

Incision

- ① Sternotomy
- ② Clamshell
- ③ Thoracotomy



Type of Transplantation



Extracorporeal Lung Support


- Off-pump
- ECMO (vein-artery, vein-vein-artery, or vein-vein)
- Cardiopulmonary bypass

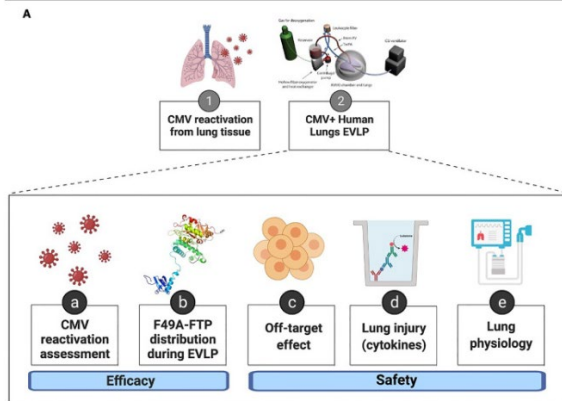
EVLP

Ex Vivo Lung Perfusion



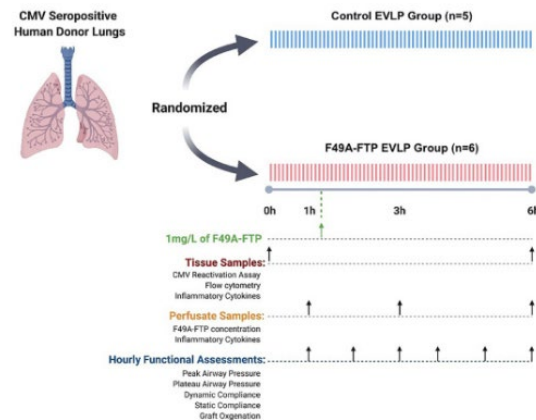
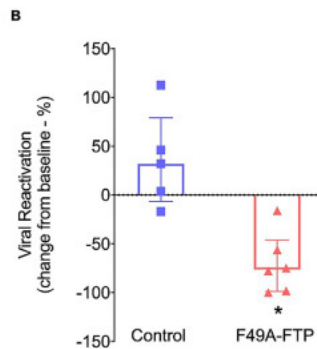
Ex vivo treatment of cytomegalovirus in human donor lungs using a novel chemokine-based immunotoxin

Rafaela V.P. Ribeiro MD^a, Terrance Ku MSc^b, Aizhou Wang PhD^a, Layla Pires PhD^a,
 Victor H. Ferreira PhD^b, Vinicius Michalosen PhD^a, Aodh All PhD^a, Marcos Galasso MD^a,
 Sajad Moshkelgosha PhD^a, Anajara Gazzalle MD^a, Mads G. Jeppesen PhD^a,
 Mette M. Rosenkilde PhD^{a,d}, Mingyao Liu MD^a, Lianne G. Singer MD^a, Deepali Kumar MD, MSc^a,
 Shaf Keshavjee MD, MSc^{a,b}, John Sinclair PhD^a, Thomas N. Kiedal PhD^a, Atul Humar MD, MSc^{a,b},
 Marcelo Cypel MD, MSc^{a,b}  



Immunotoxin (F49A-FTP) kills latent HCMV for reducing the HCMV reservoir from donor lungs using EVLP

CMV pos human lungs placed on EVLP alone or EVLP + 1mg/L of F49AFTP for 6 hours Lung function on EVLP and inflammatory cytokine production were evaluated as safety endpoints.

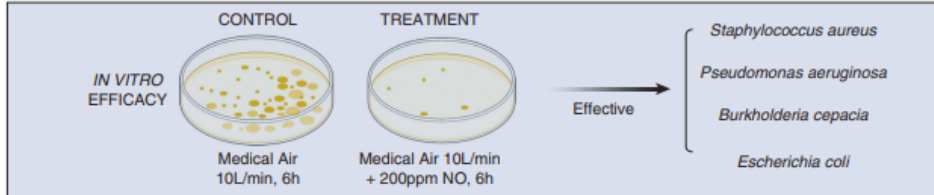


- Lungs treated ex-vivo with F49A-FTP had a significant reduction in HCMV reactivation compared to controls (76% median reduction in F49A-FTP vs 15% increase in controls, $p = 0.0087$).
- Ex-vivo lung function was stable over 6 hours and no differences in key inflammatory cytokines were observed demonstrating safety of this novel treatment

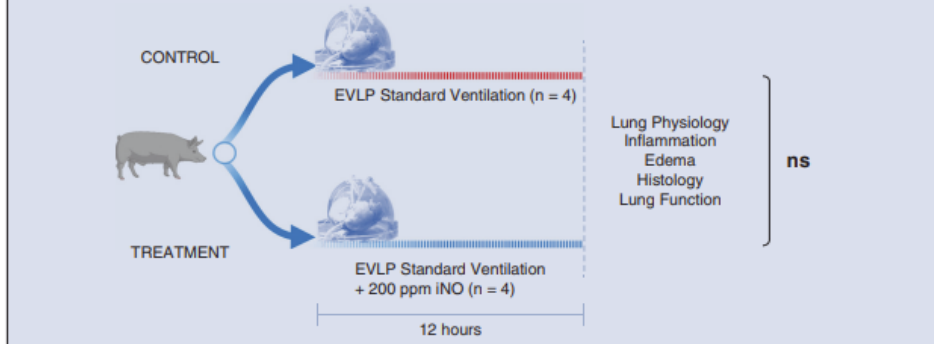
Safety of continuous 12-hour delivery of antimicrobial doses of inhaled nitric oxide during ex vivo lung perfusion

Vinicius S. Michaelsen, PhD, Rafaela V. P. Ribeiro, MD, Aadil Ali, BSc, Aizhou Wang, PhD
Anajara Gazzalle, MD, Shaf Keshavjee, MSc, MD, and Marcelo Cypel, MSc, MD

SAFE DELIVERY OF CONTINUOUS HIGH-DOSE NITRIC OXIDE DURING EVLP



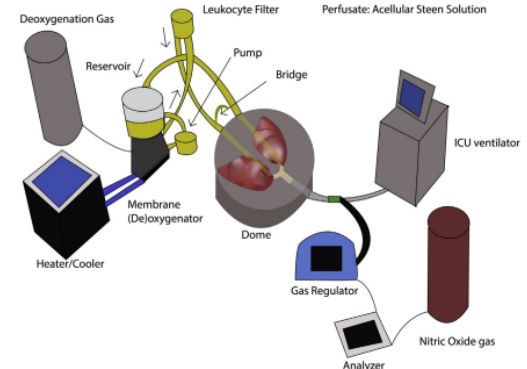
EX VIVO SAFETY AND FEASIBILITY OF CONTINUOUS HIGH-DOSE OF NITRIC OXIDE



NO = Nitric Oxide iNO = Inhalation of Nitric Oxide ppm = parts per million
EVLP = *ex vivo* lung perfusion; ns = not significantly different

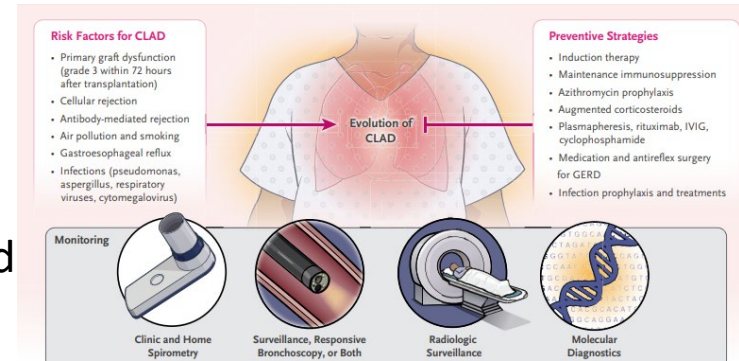


Inhaled nitric oxide delivery setup during ex vivo lung perfusion.

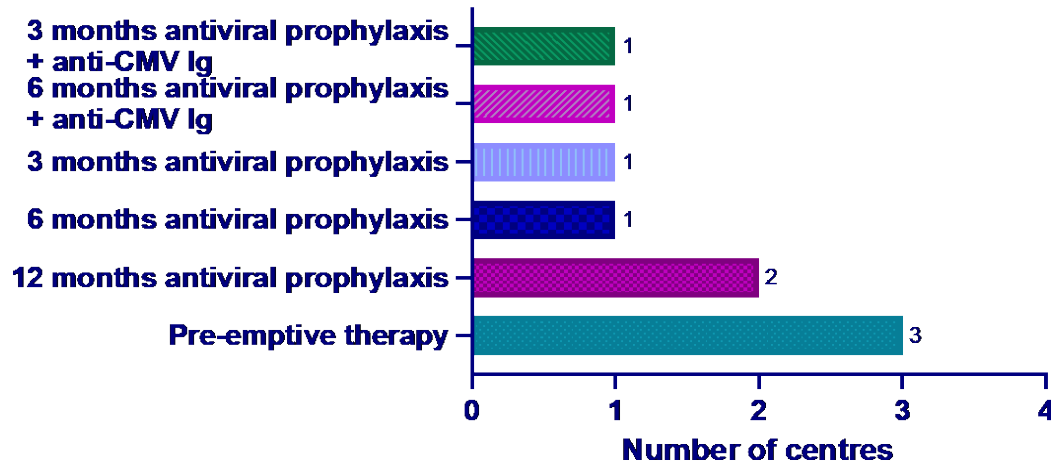


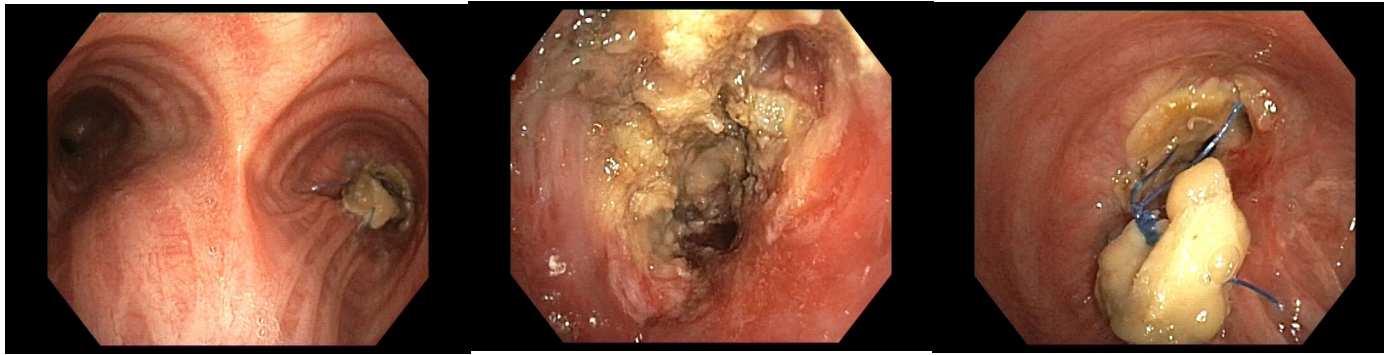
CMV infection

Primary infection with or reactivation of CMV is common and leads to systemic illness, graft injury, and an increased risk of CLAD.



Prevention of CMV in D+/R-: which strategy in Italy?

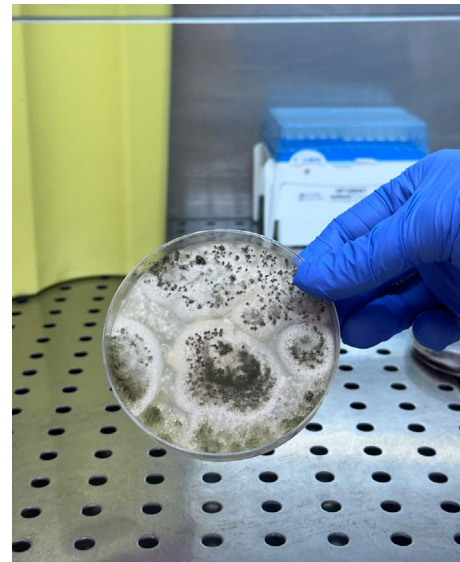
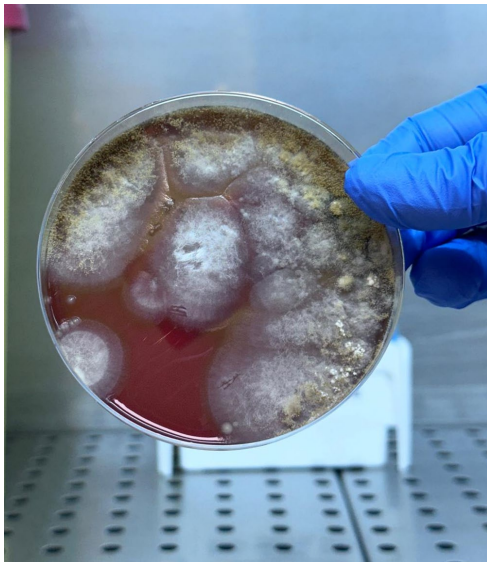




Technical Problems



Infections



Recipient

Surgical Complications

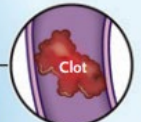
Airway Problems
(ischemia, necrosis, dehiscence, fistula, bleeding, stenosis)



Wound Problems
(infection, dehiscence, herniation)



Nerve Problems
(phrenic, vagus, recurrent laryngeal, brachial plexus)



Arterial or Atrial Problems
(kinking, thrombosis, infarction, dehiscence, stenosis)

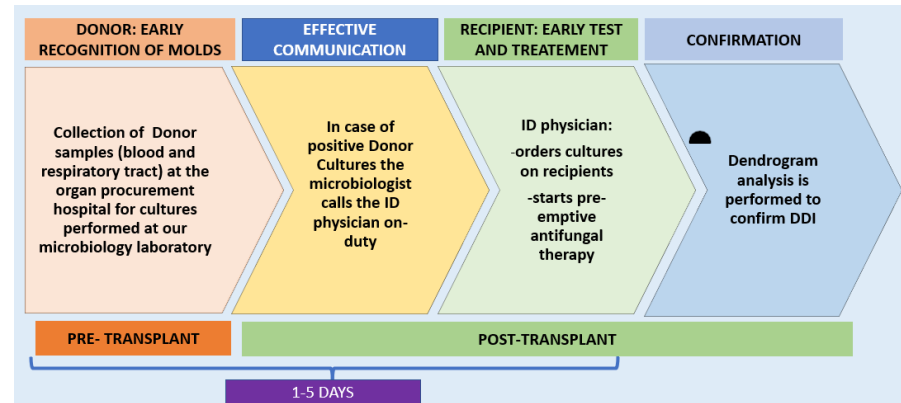


Postoperative Bleeding

Unexpected **donor-derived fungal infections:** rare but potentially fatal complication in **lung transplant (Tx) recipients**

Prospective cohort study
Study period: 2015-2022
82 lung Tx were performed from 80 donors

Our Local Active Surveillance System



Prevalence of DONORS with “unexpected - unknown” mold isolation from the respiratory tract was 3.75%

Isolated molds were: ***Aspergillus niger***, ***Rhizopus oryzae*** and ***Aspergillus flavus***

Donor-derived mold infections in lung transplant recipients: The importance of active surveillance

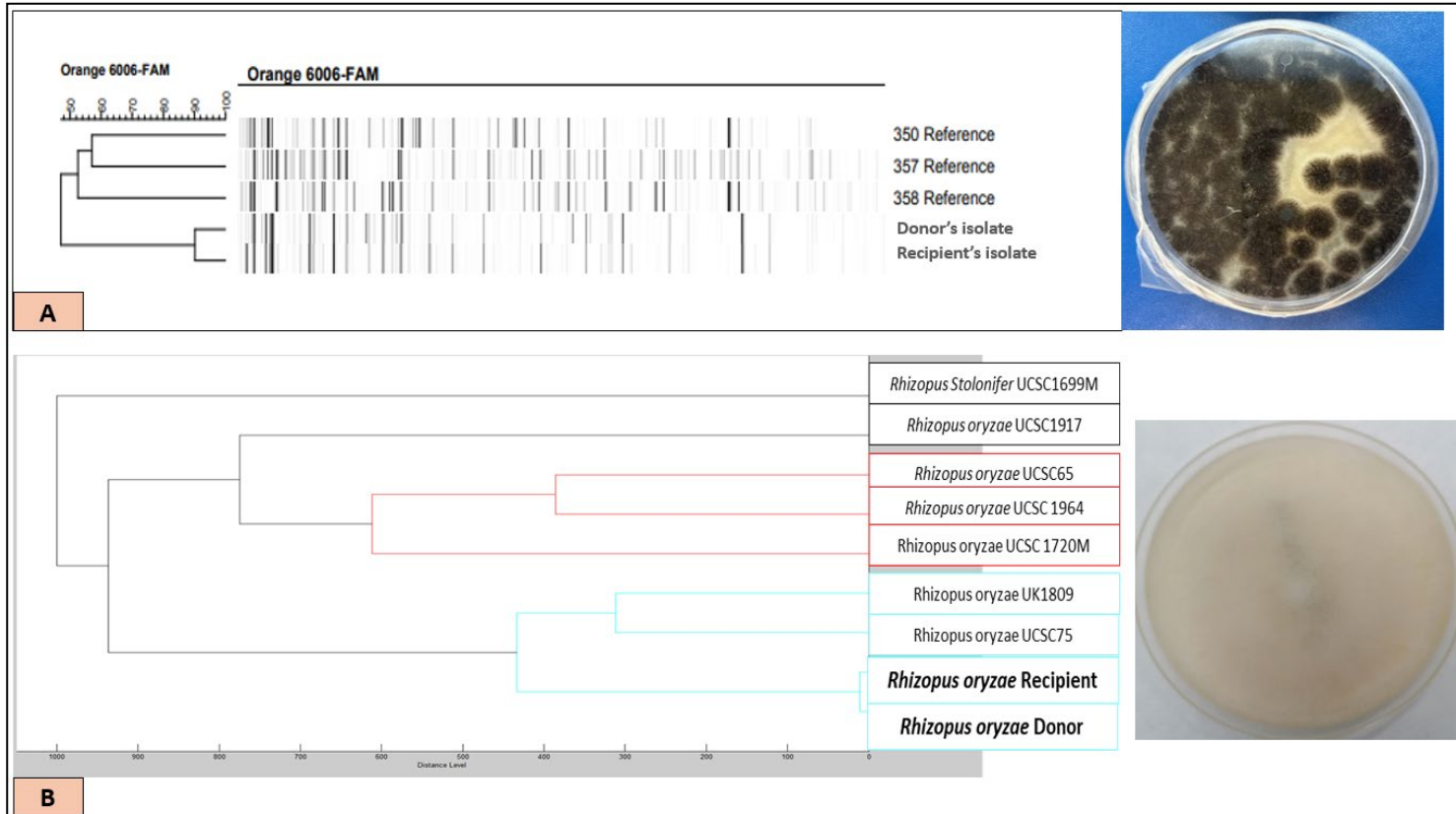
Alessandra Mularoni, Andrea Cona , Giulia Coniglione, Floriana Barbera, Giuseppina Di Martino, Giovanni Mulè, Maria Campanella, Giuseppina Di Mento, Giuseppe Nunnari, Paolo Antonio Grossi, Maurizio Sanguinetti, Malgorzata Mikulska, Elena De Carolis, Alessandro Bertani ... See fewer authors

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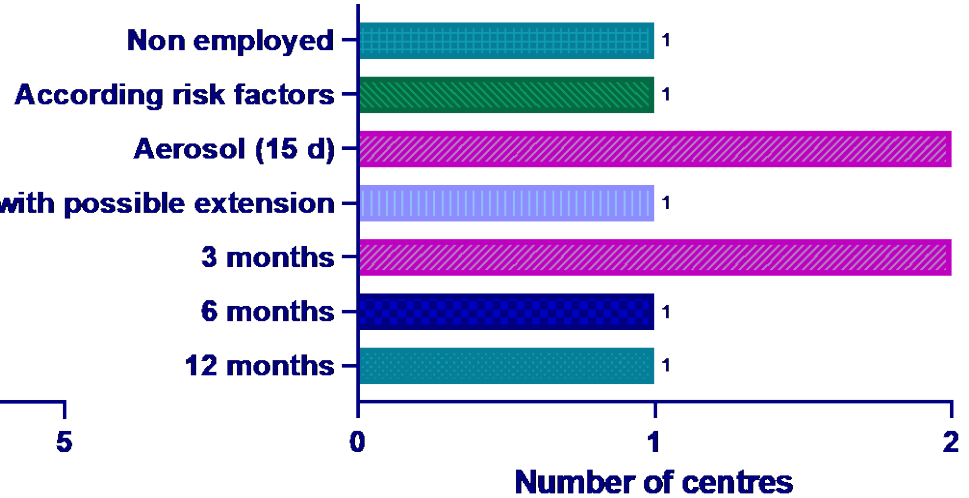
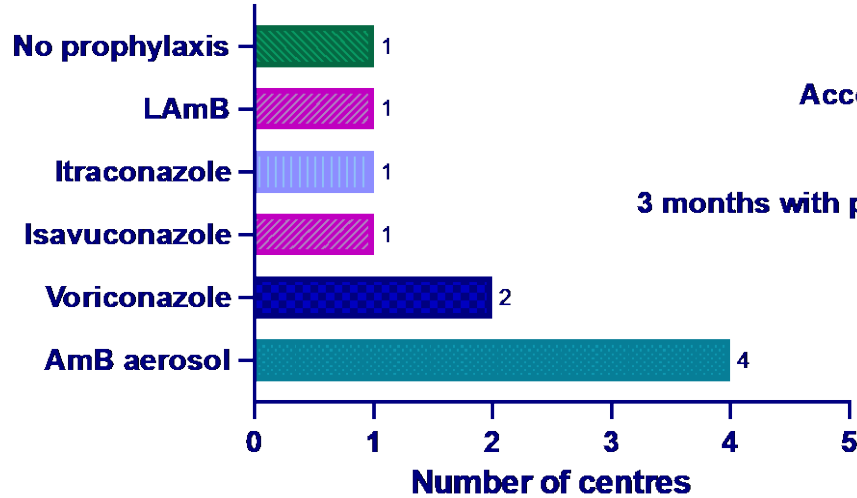


	Donors					Recipients					
Case n°	Cause of donor death	ICU LOS (days)	Results of donor hospital Lab	Results of ISMETT Lab	Donor positive results from Tx	Type of pre-emptive antifungal therapy	Time to introduction of antifungal therapy from Tx	Duration of antifungal therapy (month)	Transmission/ Time to recipient positive results from Tx (days)	Invasive Mold Disease	Graft and patient Survival, follow-up
1	brain hemorrhage	6	BAL positive for <i>Aspergillus niger</i>	BAS and bronchial swab: <i>Aspergillus niger</i>	3 days	LAmB + oral switch to VOR	3 days	5	Yes, 4 days in BAS	No	Yes, 8 years
2	post-anoxic encephalopathy	2	BAL negative	BAL: <i>Rhizopus oryzae</i>	3 days	Day 3-6 VOR Day 6 LAmB + oral switch to ISAV	Day 3 VOR Day 6 LAmB	7	Yes, 6 days in BAL	No	Yes , 2 years
3	head trauma	8	BAL negative	BAL: <i>Aspergillus flavus</i>	3 days	AmB + oral switch to ISAV	3 days	9	Yes, 5 days in sputum and 8 days in BAL	No	Yes, 1.5 years

Dendrogram and isolate of donor and recipient *Aspergillus niger* (A) performed by AFLP analysis; dendrogram and isolate of donor and recipient *Rhizopus oryzae* (B) obtained by MALDI-TOF MS analysis



Antifungal prophylaxis



Centres performing Lung Tx in Italy



FIRST STEP: Survey of current practices Dec 2023-Jan 2024 (52 Questions!!)

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2. Overview of the Italian scenario
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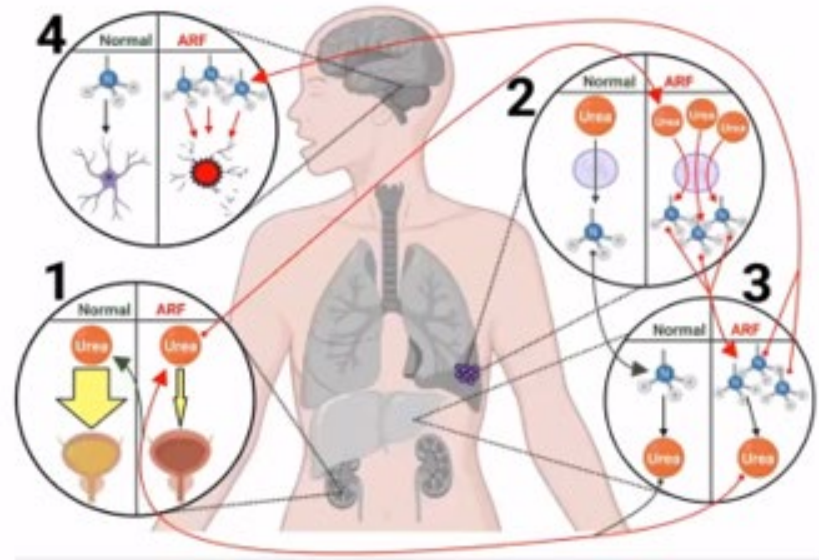


SECOND STEP: Meeting in Palermo to discuss the Survey result and explore needs

- Shared Protocols (CMV, Prophylaxis of IFI, MDR treatment..)
- Future Studies: *Ureaplasma* and *Mycoplasma*, HHV8, MDR in lung
- Studies with **SITA** on MDR bacteria and Fungi in Lung Tx
- Antimicrobial and EVLP

Fatal Hyperammonemia Syndrome Post Lung Transplantation

- SOT (> LTR) are vulnerable to hyperammonemia syndrome (HS)
- Incidence rates in LTR: 1-6%
- Mortality 70%
- *Ureaplasma* spp. harbor ureases
- Postoperative LTR commonly experience uremia
- HS in LTR is strongly correlated with *Ureaplasma* spp. infection of respiratory tract



Prevention is a key issue and clinicians must maintain a high index of suspicion and remain vigilant in staying up to date on emerging infections.

KEY POINTS

- Unusual clinical syndromes or clusters of infections in SOT receiving organs from the same donor should suggest a DDI as a possible source.
- Early recognition, timely reporting, close monitoring, and appropriate management are essential to mitigate the risk of DDI.
- Transplantation of nonlung non bowel organs from donors with active SARS-CoV-2 infection is possible and well tolerated without evidence of SARS-CoV-2 transmission and with good short-term outcome.
- Uncertainties of clinical outcomes in immunosuppressed people have led to concern for the risk of Mpox DDI for SOT recipients.



- Routine donor testing for HTLV-1/2 is a matter of debate and policies differ significantly among countries with no screening, universal, or risk factors-based screening.
- Routine donor lung screening of mollicutes followed by preemptive therapy should be considered at transplantation.
- Screening for *Strongyloides stercoralis* in all at risk donors and recipients should be performed. Prophylactic ivermectin in recipients of organs from infected donors and post-transplant monitoring are crucial.
- Clinicians caring for SOT recipients should maintain awareness of DDI caused by molds and *Cryptococcus* spp. especially when manifest early in the immediate posttransplant period.



ORIGINAL ARTICLE · Articles in Press, November 15, 2024

Open Access

Serologic screening and molecular surveillance of Kaposi sarcoma herpesvirus (KSHV)/human herpesvirus-8 (HHV-8) infections for early recognition and effective treatment of KSHV-associated inflammatory cytokine syndrome (KICS) in solid organ transplant recipients

Alessandra Mularoni¹ · Andrea Cona² · Matteo Bulati² · Pier Giulio Conaldi² · Paolo Antonio Grossi²⁰ · Mario Luppi⁹ · Show more

Severe Donor Derived HHV8 infection in Lung Transplant



Disseminated Kaposi Sarcoma plus KICS Syndrome

Bacteriophages: an option to fight antimicrobial resistance



With the rapid spread of antimicrobial resistance there is renewed interest in phage therapy

1. They target bacteria specifically without targeting human cells or the surrounding microbiota
2. Phages can self-amplify resulting in lysis of the host bacteria. This process is self-limiting in the absence of the targeted bacteria.
3. The specificity of phages restricts the emergence of bacterial resistance
4. Some phages contain polysaccharide depolymerases that can degrade biofilms

Table 1. Summary of recent phage therapy cases in transplant recipients, left ventricular assist device patients and pretransplant patients

Patient	Organism	Clinical syndrome	Case details	Ref.
Lung transplant	<i>Pseudomonas aeruginosa</i>	Pneumonia	Episode 1: Phage (route): cocktail (i.v. and nebulized) + Abx: Piperacillin-tazobactam and colistin i.v. Episode 2: Phage (route): Phage cocktails + additional single phage (i.v. and nebulized) Abx: Piperacillin-tazobactam and tobramycin i.v. with inhaled colistin Suppression: Phage cocktail only Outcome: Success AE: None	[15**,28, 29]
Lung transplant	<i>Pseudomonas aeruginosa</i>	Pneumonia	Phage (route): Cocktail (i.v.) Abx: Inhaled colistin Outcome: Success AE: None	[28]
Lung transplant	<i>Burkholderia dolosa</i>	Pneumonia	Phage (route): Cocktail (i.v.) Abx: Ceftazidime and piperacillin-tazobactam (i.v.) Outcome: Failed AE: None	
Lung transplant	<i>Achromobacter xylooxidans</i>	Pneumonia	Phage (route): Cocktail (nebulized) Abx: Imipenem Outcome: Success	
Lung transplant	<i>Mycobacterium abscessus</i> subsp. <i>massiliense</i>	Pneumonia/disseminated	Phage (route): Cocktail (i.v.) Abx: Amikacin, rifampin, clofazimine, isoniazid Outcome: Success AE: None	
Lung transplant	<i>Pseudomonas aeruginosa</i>	Wound infection	Phage (route): Cocktail (i.v.) Abx: Ceftazidime Outcome: Success AE: None	
Kidney transplant	<i>Klebsiella pneumoniae</i>	UTI	Phage (route): Unknown preparation (i.v.) Abx: Meropenem (i.v.) Outcome: Success AE: None	
Kidney transplant	<i>Klebsiella pneumoniae</i>	UTI/epididymitis	Phage (route): Unknown (single cocktail) p.o. and intravesicular Abx: Meropenem i.v. Outcome: Success AE: None	
Liver transplant	<i>Escherichia coli</i>	Recurrent UTI/prostatitis	Phage (route): Cocktail (i.v.) Abx: Ertapenem (i.v.) Outcome: Success AE: None	[15,28]
Liver transplant	<i>Enterococcus faecium</i> (VRE)	Intraabdominal infection	Phage (route): Cocktail (i.v.) Abx: TMP-SMX, linezolid (i.v.) Outcome: Success AE: None (premedicated with steroid/H1-blocker)	[39]
Cystic fibrosis	<i>Achromobacter</i> spp.	Pneumonia	Phage (route): Single (i.v.) Abx: Cefidericoll and meropenem-vaborbactam Outcome: Success AE: None	[40]

Five cases were successfully treated with a combination of phages and antibiotics.



not associated with rejection episodes

Regulatory Issues!!!

Phage Selection

PHAGE CANDIDATES:

Patients with persistent recalcitrant infections such as respiratory colonization or vascular device infection can be considered 'stably' sick and can be assessed.

REVIEW ARTICLE

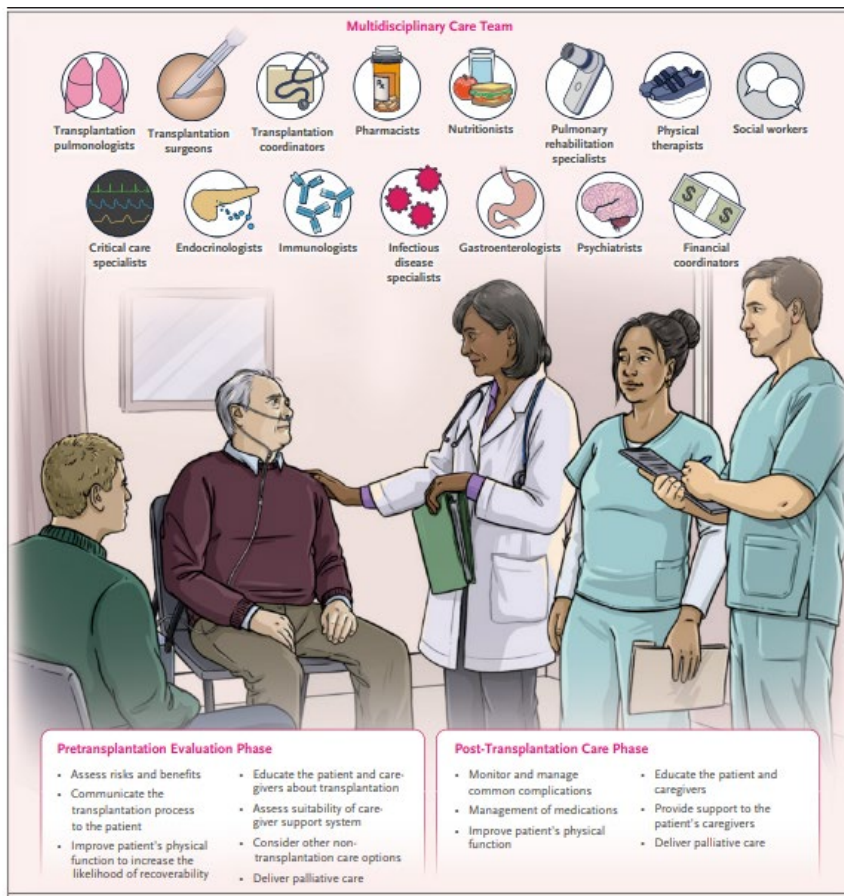
C. Corey Hardin, M.D., Ph.D., Editor

Lung Transplantation

Jason D. Christie, M.D., Dirk Van Raemdonck, M.D., Ph.D.,
and Andrew J. Fisher, Ph.D., B.M., B.S.

LUNG TRANSPLANTATION

- Lung transplantation is growing worldwide
- Candidate selection for lung transplantation involves more flexible assessment, with greater attention to the procedure may outweigh the risk, as well as strategies to minimize their effects to facilitate the procedure
- Methods for donor-organ preservation and transplantation are undergoing rapid innovations, such as those enabling ex vivo perfusion and preimplantation therapeutics to extend preservation time and prevent graft dysfunction, which is the major cause of early mortality
- Maintaining graft function and the overall health of the recipient requires striking a balance between the protective effects of immunosuppression and the risk of infection
- Chronic lung allograft dysfunction remains the leading cause of long-term mortality, and its mechanisms and multicenter clinical trials are being studied
- The assessment and care of lung-transplant recipients involves a team approach with a holistic focus on improving function and quality of life.





Thank you!

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