

Machine perfusion in Thoracic Transplantation: HEART

PART 1: HEART

PICO 1: In heart transplantation, for which heart should machine perfusion be performed?

Population:

Adult/paediatric heart transplantation

Intervention:

Ex-vivo heart perfusion / ex-situ heart perfusion / machine perfusion

Comparator:

Static cold storage

Outcomes:

Primary graft failure, survival, rate of discarded organs, rate of marginal donor organs transplantation, major complications (renal failure, respiratory failure, bleeding, ICU LOS)

Study design:

Randomised controlled trials, observational studies, case-control studies, registry analyses, systematic reviews, validation studies

Exclusion criteria:

- _Any language other than English
- _Studies published <2000
- _Congress abstracts

Rationale and analysis of literature

The use of MP in heart transplantation (Ex-Situ Heart Perfusion-ESHP) has been reported increasingly during the last decade. The current literature and separate studies/reports have proposed different inclusion/exclusion criteria to perfuse heart grafts during machine perfusion. The rationale of this PICO is to clarify if there is a consensus on how to identify (internally or on a macroregional level) donor hearts that could benefit from machine perfusion and if a shred of evidence emerged on the use in some type of organs. The Australian experience demonstrates the weight of logistical factors that could push the adoption of such a technology to expand the donor pool by reducing the ischemic time of the grafts.

STATEMENTS:

1. The use of machine perfusion is safe and effective for graft preservation in heart transplantation, but other devices for advanced graft preservation are under investigation

Quality of Evidence:

moderate

Recommendation strength:

moderate

Ardehali A, Esmailian F, Deng M, et al; PROCEED II trial investigators. Ex-vivo perfusion of donor hearts for human heart transplantation (PROCEED II): a prospective, open-label, multicentre, randomised non-inferiority trial. *Lancet*. 2015;385(9987):2577-84.

DOI: [https://doi.org/10.1016/S0140-6736\(15\)60261-6](https://doi.org/10.1016/S0140-6736(15)60261-6)

Chan JL, Kobashigawa JA, Reich HJ, R, et al. Intermediate outcomes with ex-vivo allograft perfusion for heart transplantation. *J Heart Lung Transplant*. 2017 Mar;36(3):258-263.

DOI: <https://doi.org/10.1016/j.healun.2016.08.015>

Sato T, Azarbal B, Cheng R, et al. Does ex vivo perfusion lead to more or less intimal thickening in the first-year post-heart transplantation? *Clin Transplant*. 2019 Aug;33(8):e13648

DOI: <https://doi.org/10.1111/ctr.13648>

Pyra YVK, Kaliyev RB, Bekbossynova MS, et al. 3-year outcomes with ex vivo allograft perfusion for heart transplantation: comparison of Custodiol vs warm blood cardioplegia and conditioning. *Clin Exp Surg Petrovsky J*. 2020;8:27–31.

DOI: <https://dx.doi.org/10.33029/2308-1198-2020-8-3-27-31>

Langmuur SJJ, Amesz JH, Veen KM, et al. Normothermic Ex Situ Heart Perfusion With the Organ Care System for Cardiac Transplantation: A Meta-analysis. *Transplantation*. 2022

DOI:

https://journals.lww.com/transplantjournal/Fulltext/9900/Normothermic_Ex_Situ_Heart_Perfusion_With_the.60.aspx

Qin G, Jernryd V, Sjöberg T, Steen S, Nilsson J. Machine Perfusion for Human Heart Preservation: A Systematic Review. *Transpl Int*. 2022;35:10258

DOI: <https://doi.org/10.3389/ti.2022.10258>

Chen Q, Singer-Englar T, Kobashigawa JA, et al. Long-term outcomes after heart transplantation using ex vivo allograft perfusion in standard risk donors: A single-center experience. *Clin Transplant*. 2022;36(5):e14591

DOI: <https://doi.org/10.1111/ctr.14591>

2. The use of machine perfusion is safe and effective to prolong the preservation time in heart transplantation, but other devices for advanced graft preservation are under investigation

Quality of Evidence:

moderate

Recommendation strength:

Strong

Sunjaya AF, Sunjaya AP. Combating Donor Organ Shortage: Organ Care System Prolonging Organ Storage Time and Improving the Outcome of Heart Transplantations. *Cardiovasc Ther*. 2019 Apr 1;2019:9482797

DOI: <https://doi.org/10.1155/2019/9482797>

Jawitz OK, Devore AD, Patel CB, Bryner BS, Schroder JN. EXPANDING the Donor Pool: Quantifying the Potential Impact of a Portable Organ-Care System for Expanded Criteria Heart Donation. *J Card Fail*. 2021 Dec;27(12):1462-1465.
doi: 10.1016/j.cardfail.2021.07.018. Epub 2021 Aug 15. PMID: 34407451.

Dang Van S, Gaillard M, Laverdure F, et al. Ex vivo perfusion of the donor heart: Preliminary experience in high-risk transplantations. *Arch Cardiovasc Dis*. 2021 Nov;114(11):715-726
DOI: <https://doi.org/10.1016/j.acvd.2021.07.003>

Feizpour CA, Gauntt K, Patel MS, Carrico B, Vagefi PA, Klassen D, MacConmara M. The impact of machine perfusion of the heart on warm ischemia time and organ yield in donation after circulatory death. *Am J Transplant*. 2022;22(5):1451-1458
DOI: <https://doi.org/10.1111/ajt.16952>

Laurence C, Nachum E, Henwood S, et al. Pediatric heart transplantation following donation after circulatory death, distant procurement, and ex-situ perfusion. *J Heart Lung Transplant*. 2022 May 4:S1053-2498(22)01934-9
DOI: <https://dx.doi.org/10.1016/j.healun.2022.04.013>

3. Machine Perfusion should be used in DBD and DCD donors whenever organ viability and quality need to be assessed before implantation.

Quality of Evidence:

moderate

Recommendation strength:

moderate

Sponga S, Bonetti A, Ferrara V, Beltrami AP, Isola M, Vendramin I, Finato N, Ortolani F, Livi U. Preservation by cold storage vs ex vivo normothermic perfusion of marginal donor hearts: clinical, histopathologic, and ultrastructural features. *J Heart Lung Transplant*. 2020 Dec;39(12):1408-1416.
doi: 10.1016/j.healun.2020.08.021. Epub 2020 Sep 4. PMID: 33041182.

Saemann L, Guo Y, Ding Q, et al. Machine perfusion of circulatory determined death hearts: A scoping review. *Transplant Rev (Orlando)*. 2020;34(3):100551
DOI: <https://dx.doi.org/10.1016/j.trre.2020.100551>

Ontario Health (Quality). Portable Normothermic Cardiac Perfusion System in Donation After Cardiocirculatory Death: A Health Technology Assessment. *Ont Health Technol Assess Ser*. 2020 Mar 6;20(3):1-90.
DOI: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7077939/>

Dhital, K., Ludhani, P., Scheuer, S. et al. DCD donations and outcomes of heart transplantation: the Australian experience. *Indian J Thorac Cardiovasc Surg* 2020;36: 224–232.
DOI: <https://doi.org/10.1007/s12055-020-00998-x>

Shemie SD, Torrance S, Wilson L, et al. Heart donation and transplantation after circulatory determination of death: expert guidance from a Canadian consensus building process. Can J Anaesth. 2021;68(5):661-671.

DOI: <https://doi.org/10.1007/s12630-021-01926-2>

Alomari M, Garg P, Yazji JH, Wadiwala IJ, Alamouti-Fard E, Hussain MWA, Elawady MS, Jacob S. Is the Organ Care System (OCS) Still the First Choice With Emerging New Strategies for Donation After Circulatory Death (DCD) in Heart Transplant? Cureus. 2022 Jun 24;14(6):e26281.

doi: 10.7759/cureus.26281. PMID: 35754437; PMCID: PMC9229932.

Seth AK, Mohanka R, Navin S, Gokhale AGK, Sharma A, Kumar A, et al. Organ Donation after Circulatory Determination of Death in India: A Joint Position Paper. Indian J Crit Care Med 2022;26(4):421-438.

DOI: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9067489/>

PICO 2: In heart transplantation which protocol/perfusate/perfusion strategy for ex-vivo/ex-situ heart perfusion leads to the best clinical outcomes posttransplant?

Population:

Adult/paediatric heart transplantation

Intervention:

Ex-vivo heart perfusion / ex-situ heart perfusion / machine perfusion

Comparator:

Static cold storage / different perfusion strategies

Outcomes:

Primary graft failure, survival, rate of discarded organs, rate of marginal donor organs transplantation, major complications (renal failure, respiratory failure, bleeding, ICU LOS)

Study design:

Randomised controlled trials, observational studies, case-control studies, registry analyses, systematic reviews, validation studies

Exclusion criteria:

- _Any language other than English
- _Studies published <2000
- _Congress abstracts

Rationale and analysis of literature

The use of MP in heart transplantation (Ex-Situ Heart Perfusion-ESHP) has been reported increasingly during the last decade. The current literature and separate studies/reports have proposed different inclusion/exclusion criteria to perfuse heart grafts during machine perfusion. The rationale of this PICO is to clarify if there is a consensus on how to manage donors during the travel time to warrant an optimal preservation.

STATEMENTS:

1. The current machine perfusion protocol(s) have been sufficiently validated for clinical use.

Quality of Evidence:

moderate

Recommendation strength:

weak

2. The choice of the current solutions for cold static storage has been sufficiently validated.

Quality of Evidence:

low

Recommendation strength:

weak

PICO 3: In heart transplantation, which biomarker / parameter is capable to predict the graft survival, graft function, primary non function during ex vivo heart perfusion?

Population:

Adult heart transplantation

Intervention:

Ex-vivo heart perfusion / ex-situ heart perfusion / machine perfusion

Comparator:

Static cold storage

Outcomes:

Transplantability, primary graft failure

Study design:

Randomised controlled trials, observational studies, case-control studies, registry analyses, systematic reviews, validation studies, retrospective case series

Exclusion criteria:

- _Any language other than English
- _Congress abstracts

Rationale and analysis of literature

The use of MP in heart transplantation (Ex-Situ Heart Perfusion-ESHP) has been reported increasingly during the last decade. The current literature and separate studies/reports have proposed different inclusion/exclusion criteria to perfuse heart grafts during machine perfusion. The rationale of this PICO is to clarify if there is a sufficient consensus on using single or multidimensional parameters to evaluate the quality of the organs.

STATEMENTS:

1. Angiography is a possible tool to assess the heart during machine perfusion
Quality of Evidence:
low
Recommendation strength:
weak
2. Lactate is a sufficient parameter to assess the heart function during normothermic machine perfusion with different meaning in DBD and DCD donors
Quality of Evidence:
low
Recommendation strength:
weak
3. Other biological/functional tools should be developed to assess heart quality during machine perfusion
Quality of Evidence:
low
Recommendation strength:

Weak

Bona M, Wyss RK, Arnold M, et al. Cardiac Graft Assessment in the Era of Machine Perfusion: Current and Future Biomarkers. *Journal of the American Heart Association*. 2021;10:e018966
DOI: <https://doi.org/10.1161/JAHA.120.018966>

Deng M, Soltesz E, Hsich E, Naka Y, Mancini D, Esmailian F, Kobashigawa J, Camacho M, Baran D, Madsen J, et al. Is lactate level during warm perfusion a predictor for post transplant outcomes? *J Heart Lung Transplant*. 2013;32:S156–S157.
DOI: <https://doi.org/10.1016/j.healun.2013.01.363>

Hamed A, Tsui S, Huber J, Lin R, Poggio EC, Ardehali A. Serum lactate is a highly sensitive and specific predictor of post cardiac transplant outcomes using the organ care system. *J Heart Lung Transplant*. 2009;28:S71.
DOI: <https://doi.org/10.1016/j.healun.2008.11.025>

Page A, Messer S, Axell R, Naruka V, Colah S, Fakelman S, Ellis C, Abu-Omar Y, Ali A, Berman M, et al. Does the assessment of DCD donor hearts on the organ care system using lactate need redefining? *J Heart Lung Transplant*. 2017;36:S16–

Cernic S, Page A, Messer S, Bhagra S, et al. Lactate during ex-situ heart perfusion does not predict the requirement for mechanical circulatory support following donation after circulatory death (DCD) heart transplants. *J Heart Lung Transplant*. 2022:S1053-2498(22)01805-8.
DOI: <https://doi.org/10.1016/j.healun.2022.02.003>

Załęska-Kocięcka M, Dutton J, Morosin M, Garda RF, Piotrowska K, Lees N, Aw TC, Sáez DG, Simon AR, Stock U, Doce AH. Prognostic significance of serum lactate following cardiac transplantation. *Biomark Med*. 2022 Jun;16(8):599-611.
DOI: <https://doi.org/10.2217/bmm-2021-1041>

Cobert ML, Merritt ME, West LM, et al. Metabolic characteristics of human hearts preserved for 12 hours by static storage, antegrade perfusion, or retrograde coronary sinus perfusion. *J Thorac Cardiovasc Surg*. 2014 Nov;148(5):2310-2315.e1
DOI: <https://doi.org/10.1016/j.jtcvs.2014.02.023>

PICO 4:

In heart transplantation, which recipients will benefit from a heart assessed by machine perfusion?

Population:

Adult/paediatric heart transplantation

Intervention:

Ex-vivo heart perfusion / ex-situ heart perfusion / machine perfusion

Comparator:

Static cold storage

Outcomes:

Primary graft failure, survival, rate of discarded organs, rate of marginal donor organs transplantation, major complications (renal failure, respiratory failure, bleeding, ICU LOS)

Study design:

Randomised controlled trials, observational studies, case-control studies, registry analyses, systematic reviews, validation studies

Exclusion criteria:

- _Any language other than English
- _Studies published <2000
- _Congress abstracts

Rationale and analysis of literature

The use of MP in heart transplantation (Ex-Situ Heart Perfusion-ESHP) has been reported increasingly during the last decade. The current literature and separate studies/reports have proposed different inclusion/exclusion criteria to perfuse heart grafts during machine perfusion. Thus, the indication for ESHP is based predominantly on logistical aspects or on aspects of the donor graft. However, specific aspects related to the transplantation procedure and the status of the recipient (urgency, indication of transplantation) might be important to justify and indicate ESHP for the donor graft. The rationale of this PICO is to assess the consensus on recipient-driven factors.

STATEMENTS:

1. The use of Machine perfusion is safe and effective to perform heart transplantation in VAD patients.

Quality of Evidence:

moderate

Recommendation strength:

strong (Two abstract never published?)

García Sáez D, Zych B, Mohite PN, Sabashnikov A, Patil NP, Popov A, et al. Lvad Bridging to Heart Transplantation with Ex Vivo Allograft Preservation Shows Significantly Improved: Outcomes: A New Standard of Care? J Heart Lung Transplant (2015) 34(4):S95.

[doi:10.1016/j.healun.2015.01.252](https://doi.org/10.1016/j.healun.2015.01.252)

Kaliyev, R., Lesbekov, T., Bekbossynov, S. et al. Heart transplantation of patients with ventricular assist devices: impact of normothermic ex-vivo preservation using organ care system compared with cold storage. *J Cardiothorac Surg* 2020;15:323.

DOI: <https://doi.org/10.1186/s13019-020-01367-w>

Sponga S, Ius F, Ferrara V, Royas S, Guzzi G, Lechiancole A, et al. "Normothermic Ex-Vivo Perfusion for Donor Heart Preservation in Transplantation of Patients Bridged with Ventricular Assist Devices." *J Heart Lung Transplant* (2020) 39(4):S245.

doi:10.1016/j.healun.2020.01.926

2. There is a lack of consensus on recipient criteria that might indicate the need to perform machine perfusion on the donor's heart despite some groups of recipients are under investigation

Quality of Evidence:

very low

Recommendation strength:

weak

García Sáez D, Zych B, Sabashnikov A, Bowles CT, De Robertis F, Mohite PN, Popov AF, Maunz O, Patil NP, Weymann A, Pitt T, McBrearty L, Pates B, Hards R, Amrani M, Bahrami T, Banner NR, Simon AR. Evaluation of the organ care system in heart transplantation with an adverse donor/recipient profile. *Ann Thorac Surg*. 2014 Dec;98(6):2099-105; discussion 2105-6.

doi: 10.1016/j.athoracsur.2014.06.098. Epub 2014 Oct 23. PMID: 25443013.

Dang Van S, Gaillard M, Laverdure F, et al. Ex vivo perfusion of the donor heart: Preliminary experience in high-risk transplantations. *Arch Cardiovasc Dis*. 2021 Nov;114(11):715-726

DOI: <https://doi.org/10.1016/j.acvd.2021.07.003>

Verzelloni Sef A, Sef D, García Saez D, Trkulja V, Walker C, Mitchell J, McGovern I, Stock U. Heart Transplantation in Adult Congenital Heart Disease with the Organ Care System Use: A 4-Year Single-Center Experience. *ASAIO J*. 2021 Aug 1;67(8):862-868.

doi: 10.1097/MAT.0000000000001482. PMID: 34039886.

Fleck TPK, Ayala R, Kroll J, Siepe M, Schibilsky D, Benk C, Maier S, Reineker K, Hoehn R, Humburger F, Beyersdorf F, Stiller B. Ex Vivo Allograft Perfusion for Complex Pediatric Heart Transplant Recipients. *Ann Thorac Surg*. 2021 Oct;112(4):1275-1280.

doi: 10.1016/j.athoracsur.2020.12.025. Epub 2021 Jan 7. PMID: 33421388

Rojas SV, Avsar M, Ius F, Schibilsky D, Kaufeld T, Benk C, Maeding I, Berchtold-Herz M, Bara C, Beyersdorf F, Haverich A, Warnecke G, Siepe M. Ex-Vivo Preservation with the Organ Care System in High Risk Heart Transplantation. *Life (Basel)*. 2022 Feb 7;12(2):247.

doi: 10.3390/life12020247. PMID: 35207534; PMCID: PMC8877453.

PART 2: LUNG

PICO 1: In lung transplantation, for which lung should ex vivo lung perfusion be performed?

Population:

Adult and pediatric lung transplantation
Single or bilateral lung transplantation
End stage lung failure

Intervention:

Ex-vivo lung perfusion / ex-situ lung perfusion
EVLP
Machine perfusion

Comparator:

Grafts assessed and improved with and without EVLP

Outcomes:

Primary graft failure distribution
Survival
Rate of discarded organs
Rate of marginal donor transplanted

Study design:

Randomised controlled trials, observational studies, case-control studies, registry analyses, systematic reviews, validation studies

Exclusion criteria:

Rationale and analysis of literature

The use of MP in lung transplantation (EVLP) has been reported increasingly during the last decade. The current literature and separate studies/reports have used different inclusion/exclusion criteria to perfuse pulmonary grafts during EVLP. The rationale of this PICO is to clarify if there is a consensus in what organs would benefit from ex vivo lung perfusion and if EVLP is both safe and effective for different types of organs. In addition, the question is raised if there is sufficient consensus to define the concept of “extended donor lungs”. Both geographical and institutional practices and differences should be taken into account to define and personalize the organ that might benefit from EVLP.

STATEMENTS:

1. There is currently sufficient consensus how to define and “extended donor lung” with regard to EVLP

Quality of Evidence:

moderate

Recommendation strength:

moderate

2. Ex vivo lung perfusion is safe and effective in the following donor lungs

- Standard DBD
- Extended DBD
- Standard controlled DCD
- Extended controlled DCD
- Uncontrolled DCD

Quality of Evidence:

low

Recommendation strength:

low

3. Ex vivo lung perfusion is safe and effective in the following circumstances

- Re-evaluation in situations with impaired/questionable graft function in DCD/DBD
- Logistical reasons
- Standard Preservation
- Long expected ischemic times

Quality of Evidence:

low

Recommendation strength:

low

PICO 2: In lung transplantation, which protocol/perfusate/ventilation strategy for ex-vivo/ex-situ lung perfusion leads to optimal outcomes?

Population:

Adult and pediatric lung transplantation
Single or bilateral lung transplantation
End stage lung failure

Intervention:

Ex-vivo [lung perfusion](#) / ex-situ lung perfusion / [EVLP](#)
[Machine perfusion](#)

Additional diagnostic or therapeutic ex-vivo interventions to improve donor lung quality and conversion rate in marginal donor lungs ([active reconditioning – resuscitation](#))

Comparator:

Cold static preservation vs. different perfusion protocols (e.g. duration, open vs. closed circuit, target flow rate, etc.) / perfusion solutions (e.g. type of perfusate, additional drugs) / ventilation strategies (TV, FiO₂, PEEP, RR, NPV) stratified by
- standard criteria vs. extended criteria donor lungs
- DBD vs. DCD

Outcomes:

Conversion rate, pO₂/FiO₂ and PDG rates at 0, 24, 48 and 72 hours posttransplant, duration of ventilation, proportion and duration of postoperative ECMO support, graft survival, patient survival, CLAD free survival

Study design:
Randomised controlled trials, observational studies, case-control studies, registry analyses, systematic reviews, validation studies

Exclusion criteria:

Rationale and analysis of literature

The clinical use of EVLP has been mainly driven by 3 major protocols derived: LUND/TORONTO/OCS. Different centers have reported their own system, however these are considered adaptations from the main 3 major protocols. The rationale of this PICO is to assess the consensus of using the specific protocols for clinical use, to understand if there is sufficient consensus on comparing the different protocols. The purpose of this PICO is to also focus on specific aspects of perfusion, ventilation and perfusate that might be interchangeable between protocols and are more protocol-independent.

STATEMENTS:

1. The current 3 major protocols (LUND/TORONTO/OCS) including the deviated protocols with institutional adaptations have been sufficiently validated for clinical use.

Quality of Evidence:

moderate

Recommendation strength:

low

2. The current 3 major protocols (LUND/TORONTO/OCS) including the deviated protocols with institutional adaptations have been sufficiently validated for the different settings of perfusion , ventilation and perfusate composition.

Quality of Evidence:

low

Recommendation strength:

low

PRELIMINARY DRAFT

PICO 3: In lung transplantation, which parameters (physiological, biomarkers) should be used to determine graft quality during ex vivo lung perfusion?

Population:

Adult and pediatric lung transplantation
Single or bilateral lung transplantation
End stage lung failure

Intervention:

-Ex-vivo lung perfusion/ ex situ lung perfusion / EVLP
Machine perfusion
Lung management (diagnostic / therapeutic) ex-vivo to improve lung quality, aiming for conversion to transplantable lungs (in marginal donor lungs)

Comparator:

-Perfusate volume; perfusate loss; glucose; lactate; pyruvate; glutamate; lactate/pyruvate (L/P) ratio in perfusate and microdialysate; inflammatory biomarkers (e. g. CXCL-1, CCL-2, IL-1 β , IL-18, IL-6, TNF- α , IFN- γ , DAMPs, ROS, metalloproteases, cDNA)
-Pulmonary compliance, wet-to-dry weight ratio, lung weight before / after EVLP (without biopsy for W/D ratio), pulmonary artery pressure, respiratory parameter (e. g. peak airway pressure), vascular resistance, PaO₂/FiO₂ ratio, “gas exchange time” of the lungs (gas transfer rate), oxygen saturation in perfusate
-Ultrasound evaluation (CLUE), MRI, CT parameters
-Bronchoalveolar lavage fluid (BALF) biomarkers
-circulatory / resident immunological cells (e. g. T-cells)

Outcomes:

PGD2/3 (72h), median-time to extubation, period of ECMO support after Tx, ICU stay, 30-day mortality, 90-day mortality, in-hospital mortality, 1/3/5 year mortality, CLAD, QoL, PGD-rate distribution within first 72 hours after Tx

Study design:

Randomised controlled trials, observational studies, case-control studies, registry analyses, systematic reviews, validation studies

Exclusion criteria:

Rationale and analysis of literature

An important question is to assess the donor graft for transplantability during/after ex vivo lung perfusion. Historically, this assessment was driven by the individual physiological parameters based on perfusion, ventilation and gas exchange. Also a lot of studies and retrospective reports have assessed different biomarkers as well in lung tissue, BAL and perfusate. Prediction scores based on different combinations of parameters have been reported. The primary outcome of the graft assessment was basically focused on conversion and early outcome after transplantation. Additional parameters have been investigated based on assessment of lung water accumulation and novel imaging techniques. The aim of this PICO is to assess the consensus in using the different evaluation strategies of the lung graft during/after EVLP prior to transplantation.

STATEMENTS:

1. The physiological parameters (perfusion/ventilation/gas exchange) have been sufficiently validated to accept/decline a donor lung after EVLP in clinical practice.

Quality of Evidence:

weak

Recommendation strength:

moderate

2. The assessment of the graft quality to accept/decline the donor lung using physiological parameters can be done by one single parameter.

Quality of Evidence:

weak

Recommendation strength:

moderate

3. The use of parameters other than the standard physiological parameters should be further developed into clinical practice to define the acceptance/decline of a pulmonary graft.

Quality of Evidence:

moderate

Recommendation strength:

strong

PICO 4: In lung transplantation, which recipients should benefit from a lung assessed by ex vivo lung perfusion?

Population:

Adult and pediatric lung transplantation
Single or bilateral lung transplantation
End stage lung failure

Intervention:

Ex-vivo lung perfusion / ex-situ lung perfusion / EVLP
Machine perfusion

Comparator:

Recipients with allograft from EVLP / without it
DCD – DBD – extended donors

Outcomes:

PGD rates, graft survival, patient survival, CLAD free survival, mortality in waitlist
Study design:
Randomised controlled trials, observational studies, case-control studies, registry analyses, systematic reviews, validation studies

Exclusion criteria:

Rationale and analysis of literature

Currently, the majority of literature has focused the indication for EVLP based on aspects of the donor and the donor graft. However, specific aspects related to the transplantation procedure and the status of the recipient (urgency, indication of transplantation) might be important to justify and indicate EVLP for the donor graft. The rationale of this PICO is to assess the consensus on recipient driven factors. A specific situation where questionable grafts after EVLP might be used for transplantation of a recipient with urgency status is addressed.

STATEMENTS:

1. There are currently no recipient criteria that might indicate the indication to perform EVLP on the donor lung

Quality of Evidence:

weak

Recommendation strength:

moderate

2. Logistical circumstances related to the indication of transplantation (hyperimmunized, combined organ transplantation, re-transplantation) are a good indication to use ex vivo lung perfusion.

Quality of Evidence:

weak

Recommendation strength:

moderate

3. The risk/benefit ratio to transplant the recipient can justify the acceptance of questionable lungs after EVLP assessment.

Quality of Evidence:

weak

Recommendation strength:

strong

PRELIMINARY DRAFT