Society for Heart Failure and Transplantation

SOCIETY FOR HEART FAILURE AND TRANSPLANTATION'S

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Promoting Academics to Improve Clinical Outcomes.

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EDITOR'S NOTE

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Dear Readers of The Revival,
Greetings from the Editorial board!

We welcome Dr Aditi Singhvi to the Editorial team. This article by Dr Basha Khan and Dr Syed provides an insight into various strategies which have been used for Donor lung preservation.

Lung transplantation remains the sole effective treatment for patients suffering from end-stage lung disease. However, the availability of suitable donor organs continues to pose a significant challenge, primarily stemming from the limitations in donor lung preservation techniques. As we strive to improve outcomes in lung transplantation, a focus on optimizing preservation methods is critical.

Donor lung preservation encompasses the strategies employed to maintain lung viability from procurement to transplantation. Traditional methods have included cold storage and perfusion with preservation solutions, such as the University of Wisconsin (UW) solution and the increasingly favored Perfadex. The latter, known for its low potassium concentration and inclusion of glucose, addresses many of the shortcomings of older preservation solutions, significantly improving allograft function and reducing the incidence of reperfusion injury.

Recent advancements in controlled hypothermic storage techniques present promising alternatives. Research suggests that storing lungs at temperatures around 10°C could enhance mitochondrial protection and overall organ integrity compared to conventional cold storage methods. Additionally, Ex Vivo Lung Perfusion (EVLP) has emerged as a transformative approach, allowing the evaluation and potential rehabilitation of marginal donor lungs. EVLP facilitates extended ischemia times and offers a platform for therapeutic interventions, thus expanding the donor pool.

The careful selection and application of these preservation technologies are paramount as we seek to optimize organ use and enhance transplant outcomes. As the field progresses, it is essential that transplant centers adopt innovative practices, collaborate on research, and refine protocols to ensure the best possible outcomes for recipients. By addressing the complexities of donor lung preservation, we can bolster the efficacy of lung transplantation and improve the quality of life for countless patients facing dire respiratory challenges.

I thank Dr Basha Khan and Dr Syed Tousheed, our guest authors for having written this update on Donor Lung preservation techniques.

To our Readers, Happy Reading!

Dr Manoj Durairaj
Editor "The Revival"

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Special thanks to Dr Dr Basha J Khan and Dr Syed Tousheed for authoring this month's article.

Designed by Maithili Kulkarni

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Dear Colleagues,

Advancements in donor lung preservation techniques have significantly improved the success rates of lung transplants, offering new hope to patients with end-stage lung disease. Traditional methods, such as static cold storage, have limitations in preventing tissue damage during transport. However, emerging techniques like ex vivo lung perfusion (EVLP) allow for better assessment and rehabilitation of marginal donor lungs by maintaining their function outside the body. These innovations not only expand the donor pool but also enhance the quality of transplanted lungs, reducing complications and improving long-term outcomes. Dr Basha Khan and Dr Syeed offer an in-depth review on these techniques and innovations in this current article for REVIVAL.

Sincerely,
Dr Talha Meeran
Sub Editor "The Revival"

Dear Colleagues,

In this edition of "THE REVIVAL", expert transplant pulmonologists, Drs. Basha Khan and Syed Tousheed delve into the crucial advancements in donor lung preservation techniques, which are paramount for improving lung transplantation outcomes. With the severe scarcity of suitable donor organs, these innovations are vital for ensuring that available lungs remain viable for a longer period, thereby increasing the chances for successful transplants. The article covers various preservation solutions used in static cold storage, such as Perfadex and its glucose-enhanced formula, which supports cellular integrity during prolonged storage. Given the adverse effects of freezing induced by static cold storage, controlled hypothermia devices are now being tested. This article also reviews data from a recent trial examining the use of such a device. Furthermore, emerging methods like Ex Vivo Lung Perfusion (EVLP) show promise for assessing and potentially rehabilitating marginal lungs, thereby expanding the donor pool. As the field advances, the article highlights the need for ongoing research to refine these techniques and explore controlled hypothermic storage, potentially allowing flexible surgical scheduling and improved patient outcomes.

Sincerely,

Dr Aditi Singhvi
Sub Editor "The Revival"

PRESIDENTIAL MESSAGE

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Dear Members and Colleagues,

At the outset I would like to welcome Dr Aditi Singhvi to our editorial team. She, like Talha Meeran is one of the few trained and certified heart failure and transplant cardiologists in the country who practice heart failure and transplant exclusively and have knowledge and expertise in all aspects of this subspecialty. I hope, in future more cardiologists and pulmonologists choose to specialize in end stage organ failure and replacement therapies, that is the way for the specialty to grow further and more people to obtain training.

As an organization, the Society for Heart Failure and Transplantation gives equal importance to caring for patients with end stage lung disease and lung transplantation as it does for end stage heart disease and transplantation. The time at which the society was formed, lung transplantation was not practiced widely in the country and therefore Lung did not figure in the name of the organization. This is much like ISHLT giving equal importance to pulmonary hypertension including CTEPH and MCS as it does to heart and lung transplantation though PH and MCS are not represented in the name of ISHLT. Similarly, STS is an important association historically for cardio-thoracic surgeons worldwide though thoracic surgery in its contemporary meaning leans more towards non-cardiac thoracic surgery. This had become a sore point for some pulmonologists at the recent joint meeting of SfHFT and INSHLT at the GBM of INSHLT even after several explanations and reassurances.

In this edition of revival, Dr Basha Khan and Dr Syed Tousheed, both highly trained in some of the best centers and having rich worldwide experience in lung transplantation, talk about the advances in lung preservation. Organ preservation traditionally worked on the philosophy that one should not damage the organ that is being retrieved or cause only minimal damage so that it continues to function well after implantation. Prof. Wallwork is quoted to have said the "you cannot make chicken from a fried egg". Meaning that if an organ is damaged during the procurement / preservation process, it is not going to function well after implant. Cold static storage was the gold standard with various solutions developed over time used as the initial preservative. The article has discussed the various solutions and its evolution. The preferred solution today in most centers being Perfedex Plus, which as opposed to Perfedex comes pre-buffered and does not need addition of THAM for buffering.

Storage at 10 degree Celsius has been shown to offer some advantages over storage on ice by better preservation of cellular integrity and extending the safe storage time making lung transplant closer to be what is an elective or semi-elective operation.

Machine perfusion has added a completely new dimension to lung preservation. In addition to better and longer preservation times the ability to assess the lung functionally allows you to decide if a lung, particularly from a marginal donor is functionally adequate. It also allows you the opportunity to treat or repair the lungs to the point that we are going towards an era where one might say that not damaging a donor organ is not enough and one should improve the donor organ prior to implanting.

I once again thank the authors for presenting a complex topic concisely and in an easy to understand manner.

With warm regards,

Dr Julius Punnen

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DONOR LUNG PRESERVATION: AN UPDATE

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Lung transplantation is currently the only viable treatment for patients with end-stage lung failure; Most of the thoracic transplants are done from deceased donors and hence availability of suitable donor organs poses a significant challenge. Effective utilization of the scarce resources depends on the optimal lung preservation system(1).

Donor lung preservation refers to the process of maintaining and protecting a donor lung from the time of lung procurement up until implantation in the recipient. Effective preservation techniques could potentially increase the number of suitable donors and make the donation process more acceptable to both referring hospitals and the families of donors.

Numerous techniques have been developed to to ensure effective preservation of lungs and heart-lung systems. These techniques range from basic methods such as simple graft excision followed by cold storage, to more advanced procedures (working heart-lung preparation) that involves auto-perfusion with donor blood. The most widely used methods at present involves perfusion of heart and lung with preservation solutions, followed by static cold storage(2).

Lung preservation:

Pulmonary artery flush, the most commonly employed lung preservation technique, rapidly cools both lungs, significantly enhancing allograft function. The effectiveness of this technique is positively correlated with the duration of infusion and the total volume used. To address the reflex pulmonary vasoconstriction caused by preservation solutions, prostaglandins, such as epoprostenol or alprostadil, are often added to these solutions. The selective pulmonary vasodilators improves the distribution of the pulmonary arterial flush, thereby enhancing lung preservation.(1,3)

Lung preservative solutions are used for anterograde and retrograde flush through the pulmonary vessels. Anterograde flush involves delivering a flush solution through the pulmonary artery, with the fluid draining out via the pulmonary veins. Typically, the volume used is around 50 to 60 mL/kg, approximately 4 liters of flush is used. On the other hand, a retrograde flush administers the flush solution into each pulmonary vein, usually about 250 mL per vein, with the fluid draining through the pulmonary artery. Combination of these maneuver's appears to result in improved lung function and is commonly adopted by most transplant centers across the globe.(4)

Preservation Solutions:

Initially ,Intracellular solutions like Euro collins and University of Wisconsin(UW) were developed for lung preservation. The composition of the solutions closely resembled (high potassium/low sodium) the cellular milieu to minimize potential concentration gradients across the plasma membrane that could favor potassium efflux. Euro Collins (EC) solution designed in the 1960s was considered as the solution of choice for over 15 years until the introduction of University of Wisconsin (UW) solution in 1988 . The main drawback of intracellular solutions was the risk of hyperkalemia induced pulmonary vasoconstriction in view of high potassium concentration. High molecular weight compounds such as Hydroxyethyl starch (HES), resulted in high viscosity which was attributed to organ dysfunction in few of the intracellular solutions like the UW solutions. (3)

This stimulated the development of less vicious crystalloid extra cellular solutions with low potassium concentration. Various extracellular (low potassium) solutions such as HTK, CELSIOR, Papworth, and Plegisol were established over a period of time.Extracellular solutions, such as the Wallwork solution and Papworth , utilizes donor blood as well. Celsior, histidine-tryptophan-ketoglutarate (HTK), and low-potassium dextran (Perfadex; XVIVO Perfusion AB, Gothenburg, Sweden), are the other extracellular solutions designed with different electrolyte compositions. (3)

Experimental studies and clinical evidence have consistently shown a preference for extracellular preservation solutions over intracellular. Extracellular solutions, such as LPD solutions are composed of dextran and low-potassium . Dextran-40 serves as an oncotic agent in the LPD solution, helping to retain water within the intravascular space, which in turn reduces the formation of interstitial edema. Additionally, Dextran-40 has rheologic properties that decrease the aggregation of erythrocytes and circulating thrombocytes, potentially enhancing microcirculation and minimizing cellular activation. While the low-potassium concentration helps maintaining normal pulmonary artery pressures during the infusion process.(3)

Perfadex, an LPD solution, is an advancement with addition of glucose into it .Perfadex is the most widely used preservation solution in lung transplant programs globally and is now widely available. The addition of glucose to a lung preservation solution leverages the lung's unique ability to supply oxygen directly to its parenchyma even during storage, thereby supporting low-level aerobic metabolism, hence maintaining cellular integrity during the prolonged storage. It is also buffered with phosphate and supplemented with calcium ions to maintain endothelial integrity. Research has shown that using Perfadex for lung procurement results in a significantly lower incidence and severity of reperfusion injury, better allograft function, and improved survival compared to other EC fluids.

Composition of various solutions used for lung preservation(3)

	EC	UW	HTK	Perfadex	Papworth
Type	IC	IC	EX	EX	EX
Na	10	25	15	138	115
K	115	120	10	06	03
Colloid	Glucose	HES, LactoB	mannitol	Dextran	Mannitol,Alb
Buffer	PO4-, HCO3-	PO4--	Histidine	PO4--	-
Antioxidant	-	GSH, AlloP	Trp, Mannitol	-	Mannitol
Osmolarity	375	330	310	292	440
$Ca2^+$	-	-	0.02	-	Und
$Mg2^+$	-	5	4	0.8	-
Cl-	15	20	32	142	Und
Glucose	180	-	-	5	-
others			Alfa-KG	SO4--, Dextran	Donor Blood, Heparin

Units- All in Mmol/L

Abbrevations- IC- intracellular, EX extra cellular, EC- Euro collins, UW- University of Wisconsin, HTK- Histidine-tryptophan-ketoglutarate, Und-Undetermined. LactoB- Lactobionate, HES- Hydoxyethyl starch, GSH- Glutathione, AlloP- Allopurinol Trp- Tryptophan, Alfa KG- Alfa keto glutarate

Current practices for the temperature of preservation solutions:

The ideal temperature for preservation solutions has been a topic of debate. Most transplant centers prefer easily manageable flush temperature by using solutions that have been stored on ice. Traditionally, this temperature is believed to be between 4 to 8°C, while some unpublished data suggest that ice storage temperatures may be closer to 0°C. Though the standard ice storage may significantly decrease the metabolic demand, it results in freezing injury with progressive mitochondrial dysfunction.(4)

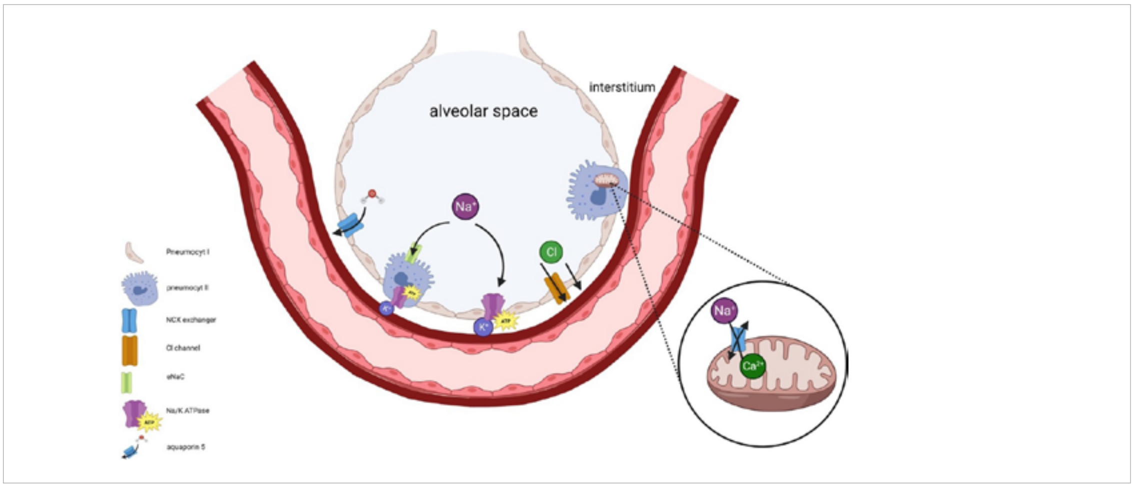
Effect of freezing on Mitochondria(5)

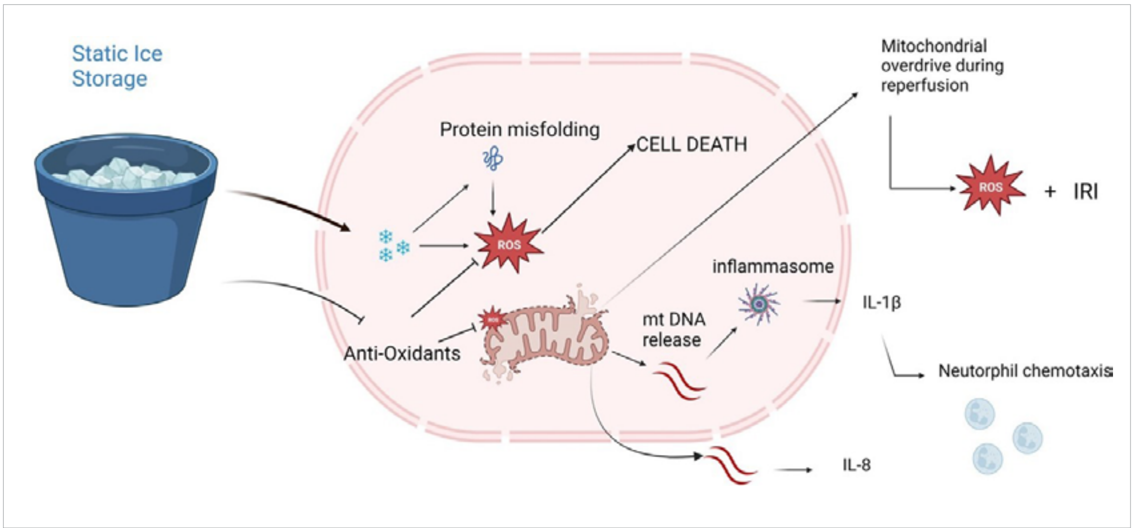
The Na-K ATPase pump maintains the cell membrane potential. Dysfunction of Na^+/K^+ ATPases results in extramitochondrial accumulation of Na^+ and Ca^+2 which in-turn cause's damage to Ca-Na exchanger in the mitochondria. This leads to increased mitochondrial Ca levels and resulting in mitochondrial swelling. Excess Ca^+2 activates proteases which leads to conversion of xanthine dehydrogenase to xanthine oxidase. Xanthine oxidase and increased hypoxanthine are the predominant ROS during anoxic ischemia reperfusion injury (IRI) .

Alveolar fluid clearance (AFC) via type I and II pneumocytes also depends on an osmotic gradient towards the interstitium created by Na^+/K + ATPase basolaterally and Na^+ transport across the apical membrane through epithelial sodium channels. Due to the dysfunction of this transporter there is accumulation of fluid in the interstitium.

In tissues exposed to temperatures around 0°C, There is formation of ice crystals which causes electrolyte and osmotic imbalances. This also contributes to mitochondrial swelling and dysfunction. The freezing temperatures also leads to misfolding of proteins and denaturation of proteins.

Effect of hypothermia on the graft function





DONOR LUNG PRESERVATION AT 10^{0}C:

Over 30 years ago, research indicated that 10°C might be the optimal temperature for storing and preserving lungs. Higher lung tissue levels of glutathione and ascorbate which are the predominant anti oxidants were detected at 10°C compared to standard ice storage.

In large animal models, storing lungs at 10°C for 36 hours resulted in lower airway pressures, better compliance, and improved oxygenation compared to lungs stored at the conventional temperature of 4°C. These functional improvements were partly attributed to higher levels of mitochondrial protective metabolites and overall better mitochondrial health in the 10°C group.

Building on these initial preclinical findings, a prospective, multicenter, nonrandomized trial was recently published in *The New England Journal of Medicine*. In this study, 70 patients received lungs that were stored at 10°C for a prolonged period, allowing for a delay in transplantation and avoiding surgeries overnight. An "overnight transplant" was defined as any transplant procedure where anesthesia was initiated between 6 p.m. and 5 a.m. The lungs were procured following standard procedures, transported on ice, and then placed in a 10°C incubator upon arrival. The study also included 140 matched control patients. In the extended cold static preservation group, the first and second lungs were preserved for 12.4 and 14.2 hours, respectively. The study found no significant differences between the standard ice storage group and the extended 10°C preservation group in terms of ICU length of stay, need for ECMO, overall hospital stay, or one-year survival. (6)

Controlled hypothermic devices (CHS)

Following are the characteristics of currently available CHS.

	My Temp 65HC	LUNGguard	Vitalpack Evo	X port lung transport
Coolin source	Electrical	Sherpa cooling	Eutectic plates	Gel packs
Preparation	Custom temp	-20C 48 hrs	-18C 24 hrs	4C 48hrs
Temp range	10C	4-8C	2-8C	10C
Time b/w temp	continous	40hrs	40hrs	36hrs
FDA		Yes		
CE mark		Yes	Yes	
Monitor	Temperature	Temp & Location	Temp and location	Temp & location
Data	Pre & Clinical Multicentric non RCT	Ongoing clinical		Ongoing clinical Multicentric RCT

Mitochondrial metabolic activity in the donor organ is known to persist despite all these hypothermic perfusion storage measures, necessitating substrates to maintain tissue energy stores .Consequently, many lungs that become available for donation are ultimately deemed unsuitable due to physiological impairment. To address these challenges, alternative preservation techniques that can extend both the lung storage further and improve lung function.

Ex Vivo Lung Perfusion (EVLP) (7-8)

Ex vivo lung perfusion (EVLP) refers to the utilization of a mechanical perfusion and ventilation system to evaluate and potentially treat donor lungs before they are transplanted into a recipient. This method allows for the reassessment and possible improvement of donor organs that may not initially meet the criteria for transplantation. EVLP plays a crucial role in evaluating and managing the broader pool of uncontrolled donation after circulatory death (DCD), where traditional assessment methods are not feasible. However, EVLP is a resource-intensive approach for donor lung assessment. There is a strong case for implementing stricter selection criteria, conducting further cost-effectiveness studies, and undertaking randomized trials to enhance its utility

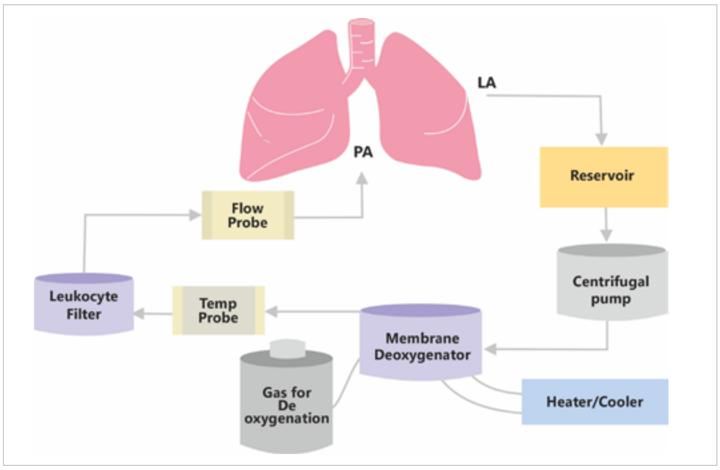
Technique: After being transported in a cold solution, the lungs are placed in a specially designed organ chamber. They are then connected to a modified heart-lung bypass machine, along with a ventilator and a filtration or ex vivo lung perfusion (EVLP) system. A specialized nutrient-rich solution, known as perfusate, is pumped from the EVLP system through a perfusion circuit. The circuit consists of a gas exchange membrane, heat exchanger, and leukocyte filter. The perfusate solution is delivered under optimal colloid pressure through the pulmonary artery to the lungs. The pulmonary effluent, drained from the pulmonary veins, returns to the EVLP system for recirculation. The perfusion flow is gradually increased while carefully monitoring pulmonary artery pressure.

Protective, controlled mechanical ventilation is initiated with low tidal volumes and positive end-expiratory pressure. The lungs are slowly rewarmed to body temperature as the flow reaches its target level. EVLP can be sustained for several hours after the lungs are removed from the donor. During this time, the lungs can be thoroughly assessed and, if needed, treated to remove excess fluid and re-expand collapsed areas (atelectatic areas). If the lungs respond well to EVLP treatment, they may be deemed suitable for transplantation using standard procedures.

Beyond its role as an assessment tool, EVLP has several potential applications in lung transplantation (LTx):

- It can be used to safely extend donor organ ischemia time for logistical purposes, such as scheduling LTx surgeries during daytime hours, facilitating long-distance organ transport, or supporting complex multiorgan transplantation.
- EVLP also serves as a platform for therapies aimed at repairing damaged donor lungs. In experimental settings and emerging clinical applications, EVLP has been used to administer high-dose antibiotics, apply UV light for hepatitis C treatment, deliver fibrinolytics, introduce viral vector-induced interleukin-10, and provide surfactant therapy. Additionally, it can function as a mechanical trap for cytokines and inflammatory cells.

Schematic representation of EVLP



Conclusion:

Lung transplantation and preservation techniques have evolved significantly over time. Due to the scarcity of donor lungs it is imperative to utilize the available organ more effectively. Emerging results from controlled hypothermic devices in preserving donor lung function are promising. Additionally,Ex vivo lung perfusion (EVLP) is a novel tool in the field of lung transplantation that has the potential to revolutionize outcomes by improving the quality and viability of donor lungs.

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