

SherpaPak for static cold storage transport of donor hearts

Request for support of Sherpa sharing between transplant units retrieved by a different NORS team

Background

Static cold storage using ice box is a standard practice for transporting donor heart to recipient centres for over 50 years. Although hypothermia decelerates metabolism and the ionic constituents in the cardioplegia solution facilitate rapid cessation of electrical activity, it also activates certain processes that are ultimately can be deleterious to the preserved organ. Experimental studies conducted on animal model demonstrates that almost all parts of the heart reach 0 degrees by 4 hours, between 1 to 2 hours right ventricle, interventricular septum and left ventricle all reach 0 degrees. This is also associated with electron microscopic changes of cellular swelling, mitochondrial calcium overload. Therefore, the current technique of myocardial preservation during transport results in unacceptably low temperature which may be detrimental to the cardiac function. The recently published ISHLT consensus document on donor heart preservation indicates that the ideal temperature for heart is between 4 and 8 degree C. The innovative SherpaPak (Paragonix, USA) is a CE mark and FDA approved device that has been on use in the UK since 2019, maintains the heart between 4 to 8 degrees and reduces freeze injury of the heart.

The need

Primary graft dysfunction (PGD) is a devastating complication following heart transplantation and recently published UK data showed the incidence is as high as 50%. It is associated with high mortality, morbidity in recipients and is also associated with increased cost of care for the transplant centres. There is a need to look at any alternative methods available for improved cold storage to improve recipient outcome and also potentially increased heart utilisation.

SherpaPak

This innovative CE mark and FDA approved device maintains the heart temperature between 4 to 8 degrees consistently. The device consists of 2 sterile cannisters and a shipper (Figure)



The sterile inner cannister has an attachment for the aorta which is secured using a standard tie. The cannister is filled with standard NORS approved cold solution and the lid is shut tight and all air bubbles removed. This is then lowered in to second sterile cannister and is sealed tight which is then moved to the shipper. The shipper securely attaches the cannister and has LCD display of temperature and it also has a storage card for temperature measurement recordings. The cannister is surrounded by a gel pack which is stored in -20-degree freezer prior to departure for retrieval. This gel pack maintains the temperature of the donor heart and no contact of heart or the solution to the gel pack. The shipper comes with an adjustable handle and has wheels for easy transport. There is no need for any power socket, constant temperature measurement or any intervention to the heart during transport. The shipper also has a slot for samples and papers to be handed to recipient centre. It is a simple easy to use device and holds the heart in anatomical position surrounded by cold solution.

On arrival in recipient centre the co-ordinator receives the box and opens the shipper and removes the cannister from the shipper. The lid is removed allowing the surgeon to remove inner cannister in a sterile fashion and move to back table. The inner cannister is opened and the heart is removed after excising the tie holding the aorta. The co-ordinator can download the temperature data for the entire journey from the shipper.

Funding

At present this is a non-commissioned device and units are using charitable funding to purchase the device. Also, this is not part of NORS standard therefore units tend to use the box when they go out to retrieve a heart for themselves. If a centre wants to transport the heart on a Sherpa when they are not on call then they send out a fellow with the box to the donor hospital to transport the heart retrieved by another NORS team. The additional transport cost for the fellow to attend the donor is paid by the individual centre to IMT.

The data

SherpaPak has now been used in over 900 heart transplantation in over 40 transplant units worldwide. The Guardian registry (every SherpaPak heart is entered along with ice box heart at 1:1 ratio in a registry) has over 900 transplants with no loss of organ once the heart is in the cannister. There is 54% reduction in severe PGD, 28% reduction in ICU stay with early return to sinus rhythm for the heart in 41% of cases compared to standard ice box.

Manchester used this device first in the UK in December 2019. Since then, over 30 donor hearts have been transported using this device involving 3 centres (Manchester, Harefield and Papworth). A review of 30 hearts transplanted using Sherpa in the UK was presented in CTAG and an abstract has been submitted to the ISHLT-2022 annual meeting. The results are presented in the following table.

In summary, it is a safe device for transporting the heart, the 30 days outcome is comparable to the national data (93% compared to 91.5%). Interestingly the need for ECMO support is only 13% in this cohort. Further studies will be required to prove the efficacy of this device.

Time period: December 2019 – September 2021

Number of transplants		30
Retrieval team	Birmingham	5
	Harefield	5
	Manchester	12
	Newcastle	3
	Papworth	5
Transplant team	Harefield	11
	Manchester	16
	Papworth	3
Transplant type	Heart only	29
	Heart-kidney	1
Urgency of recipient	Non-urgent	4
	Urgent	20
	Super-urgent	6
Median recipient age (range)	50 years	(19-61)
Median donor age (range)	31 years	(17-53)
Median ischaemia time (range)	3.1 hours	(1.8-7.0)
ECMO support post-op	Yes	4
	No	26
Median ITU stay (range)	9 days	(3-59)
Missing	5	
Median hospital stay (range)	30 days	(15-104)
Missing	7	
30 day survival outcome	Alive	25
	Dead	2
	Missing	3

30 day survival rate: 93% (95% CI: 75-98)

Request for Sherpa Sharing

Following discussions between transplant unit directors in our meeting and also during CTAG we have agreement from all centres to start sharing the Sherpa during retrievals. This was presented in last RINTAG meeting and was supported and a paper was requested for discussion in this meeting.



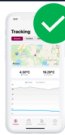
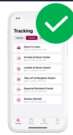


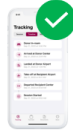


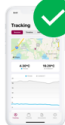
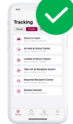
It is based on the principle that the box is unfunded and the accepting centre should replace the retrieving unit with a new kit if they want heart to be transported in Sherpa. If the retrieving centre does not have access to a new Sherpa then it will be responsibility of the implanting centre to send one immediately without causing delay to NORS process. If the retrieving centre does not have access to the Sherpa then standard ice box transport will happen.

We are grateful for RINTAG and NHSBT to support this innovation. Once we can establish safe sharing of Sherpa between centres we will be able to look at the data about ischaemic time, PGD rate and outcomes. This will then enable us to propose a national study comparing with standard ice box and find a way to get funding for this device.

Unsupervised Sherpa transport

The company has already developed a smart phone app to be used in conjunction with the Sherpa. The retrieving centre will invite accepting centres co-ordinator and surgeon to the new session and arrive in donor hospital. Every time they update the app then all members will be able to get the data real time. Once the heart is accepted then the Sherpa kit is opened. Once the heart is retrieved and goes in to the shipper then the retrieving team handover the shipper to the SNOD for transport to the accepting centre. At this time the retrieving team will hand-over the administrator role to the accepting team co-ordinator.

The heart is transported by the IMT driver in the usual way and arrive in transplant centre. There is no intervention, monitoring required by the driver. On arrival the administrator is able to get all data on to the app. Also, the SD card will have all temperature data. Transplant happens in usual fashion.

Recovery Step	User Connected to SherpaPak System	App Thermal Data	App Communications
1) Recovery 	Recovery Team 	Thermal data logged in real-time GPS location of connected user transmitted 	Communication and status tracking always available to team 
2) Transport 	No one (Assumes NHSBT driver does not have the App)	Physical display always available to driver  No monitoring or interaction required for proper function	Communication and status tracking always available to team 
3) Transplant 	Transplant Team 	On re-connection, all data stored on device is uploaded to logs 	Communication and status tracking always available to team 

Data collection

Data of all Sherpa transported hearts will be collected and will be presented during CTAG meetings. The data on unsupervised Sherpa retrieval will be looked at specifically. Data on Sherpa versus icebox will be looked by the NHSBT statistics team and we will be able to present this data.

Future perspectives

A study comparing Sherpa versus ice box transport looking at the outcomes, cost effectiveness will be conducted.