Use of the Sherpa-Pak cardiac transport system improves freedom from requirement for mechanical circulatory support, reduced early acute cellular rejection and preserves early LV function when compared to conventional cold storage.

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Purpose

Historically, iceboxes have been the predominant transport and storage method for donor hearts[1]. Ice storage can cause tissue injury whereas higher storage temperatures may cause ischemic injury[2]. The use of Paragonix Sherpa-Pak system addresses these issues by providing consistent cooling through its proprietary cool safe technology which maintains donor heart temperatures between 4-8°C.

Endomyocardial biopsy (EMB) and Echocardiogram (ECHO) still represents the gold standard for routine surveillance of heart transplant rejection. The objective of this study was to look at the early outcomes of heart transplantation utilising the Sherpa-Pak storage and transport system and to compare this with icebox cold storage and transport.

Methods

Prospectively collected single transplant centre data collected between April 2018 and March 2022 included 74 patients of whom 20 patients were transplanted using the Sherpa-Pak system and 54 were transplanted using the conventional icebox for transportation. Endomyocardial biopsies were obtained 2 weekly for the first 3 months, monthly until 6 months and then at 3-monthly until 12 months with the International Society of Health and Lung Transplantation (ISHLT) grading system used to evaluate Acute Cellular Rejection (ACR). Transthoracic ECHO data was analysed at 3 months and 1-year timepoints were chosen for this analysis. Postoperative complications, length of Cardiothoracic Critical Care Unit (CTCCU) stay, total hospital stay, incidence of severe Primary Graft Dysfunction (PGD) requiring Extra-corporal Membrane Oxygenation (ECMO) and rate of mortality were compared between the two groups. Respiratory complications were defined as patients who had prolonged ventilation ≥ 10 days, tracheostomy or a chest infection requiring intravenous antibiotics.

Postoperative outcome data was analysed using GraphPad Prism v8 software using the Chi squared test for categorical and the Mann- Whitney U test for continuous variables. Kaplan Meier survival plots were used to compare the survival between the two groups over time.

Results

There were no statistically significant differences in demographic data or risk profile between the two groups (Table 1). A significant reduction in the requirement for the use of ECMO for severe PGD (35.2% vs.10.0%, p=0.04), in respiratory complications (61.1% vs 10.0%, p=0.0001) and infectious complications (57.4% vs. 10.0%, p=0.0002) was seen in the transplant recipients utilising the Sherpa-Pak system. There were no positive blood cultures in the Sherpa-Pak group patients until 30 days post-surgery. There was no statistically significant difference in ICU length of stay between the Sherpa-Pak and Icebox groups (14.1±12.6 vs 19.3±16.0, p=0.19); or total length of hospital stay (30.6±16.6 vs 35.6±20.4, p=0.32). The incidence of Intra-aortic balloon pump post-surgery was slightly high in the icebox group (15% vs 27.8%, p=0.36). Thirty-day mortality (0% vs 5.6%, p=0.56) and survival analysed to July 2022 did not differ between the groups (p=0.26) (Figure 1). Total mean cost of transplantation per patient was lower in the Sherpa-Pak group (£39,532.60) compared to the Icebox group (£53,489.91), however, this difference was not statistically significant in this study (p=0.19).

A significantly lower occurrence of ACR was observed at 2 months and 12 months in the Sherpa group (both p=0.02). A significantly greater proportion of patients in the icebox group had LV dysfunction at 3 months (p=0.0004) and RV dysfunction (p=0.053 and p=0.002 at 3 and 12 months) compared to the Sherpa group with all Sherpa patients displaying normal function at these time point. More patients in the Sherpa group had normal LV wall thickness, with significantly greater incidence of concentric LVH reduced longitudinal function, or regional wall motion abnormality in the non-Sherpa group (p=0.01 and p=0.03 for 3 and 12 months).

Table 1: Demographic data and Outcomes of Sherpa-Pak and Icebox groups

	Sherpa-Pak (n=20)	Icebox (n=54)	p-value
Donor Age	30.5±11.2	34.2±12.1	0.23
Donor Sex (% Male/Female)	50/50	55.6/44.4	0.79
Donor BMI	24.9±5.7	24.7±3.8	0.90
Recipient age	41.3±14.1	44.3±13.1	0.40
Recipient Sex (% Male/Female)	50/50	63/37	0.42
Recipient BMI	25.6±4.0	24.8±4.0	0.46
Time on waiting list (days)	355.7±484.9	393.8±693.8	0.82
Mean PA	21.1±8.6	24.3±8.8	0.26
Mean PVR	1.97±1.1	2.05±0.8	0.77
Pre-op IABP (%)	0.0	7.4	0.57
Total Ischaemic Time	173.8±46.6	188.4±53.7	0.29
Post-transplant outcomes			
Post-surgery ECMO (%)	10.0	35.2	**0.04**
Respiratory complications (%)	10.0	61.1	**0.0001**
Infection (%)	10.0	57.4	**0.0002**
Mean CTCCU stay (days)	14.1±12.6	19.3±16.0	0.19
Hospital stay (days)	30.6±16.6	35.6±20.4	0.32
30 days mortality (%)	0.0	5.6	0.56
Mean Total Cost (£)	39532.60	53489.91	0.19

Figure 1: Kaplan Meier Survival plot between Sherpa and non-Sherpa (Icebox)

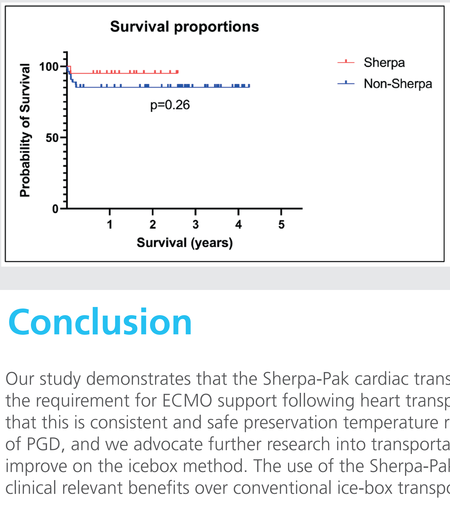

Table 2: Ventricular function assessment over time

	Sherpa	Non-Sherpa	p-value
LV function at 3 months			
Normal	16 (80.0%)	14 (32.6%)	0.01
Mild concentric LVH reduced longitudinal function	2 (10.0%)	14 (32.6%)	
Mild symmetrical LVH reduced longitudinal function	1 (5.0%)	6 (14.0%)	
LV inferior wall hypokinetic	1 (5.0%)	6 (14.0%)	
RWMA	0 (0.0%)	3 (7.0%)	
LV function at 12 months			
Normal	15 (93.8%)	22 (51.2%)	0.03
Mild concentric LVH reduced longitudinal function	0 (0.0%)	11 (25.6%)	
Mild symmetrical LVH reduced longitudinal function	0 (0.0%)	5 (11.6%)	
LV inferior wall hypokinetic	1 (6.3%)	2 (4.7%)	
RWMA	0 (0.0%)	3 (7.0%)	
RV function at 3 months			
Normal	12 (60.0%)	13 (30.2%)	0.05
Mild dysfunction	5 (25.0%)	11 (25.6%)	
Dilated RV at base level	3 (15.0%)	10 (23.3%)	
Severely impaired dilated RV	0 (0.0%)	9 (20.9%)	
RV function at 12 months			
Normal	13 (92.9%)	15 (34.9%)	0.002
Mild dysfunction	0 (0.0%)	12 (27.9%)	
Dilated RV at base level	1 (7.1%)	12 (27.9%)	
Severely impaired dilated RV	0 (0.0%)	4 (9.3%)	

Table 3: Histopathology assessment of tissue biopsies

Biopsy result	Sherpa				Non-Sherpa				p-value
	No rejection	Mild	Moderate	Severe	No rejection	Mild	Moderate	Severe	
1 month	16 (80%)	3 (15%)	1 (5%)	0 (0%)	27 (55%)	11 (22%)	6 (12%)	5 (10%)	0.20
2 months	19 (100%)	0 (0%)	0 (0%)	0 (0%)	26 (57%)	17 (37%)	2 (4%)	1 (2%)	0.02
3 months	16 (80%)	4 (20%)	0 (0%)	0 (0%)	28 (61%)	15 (33%)	2 (4%)	1 (2%)	0.42
4 months	16 (80%)	4 (20%)	0 (0%)	0 (0%)	27 (60%)	16 (36%)	2 (4%)	0 (0%)	0.25
6 months	14 (70%)	5 (25%)	1 (5%)	0 (0%)	31 (69%)	12 (27%)	1 (2%)	1 (2%)	0.85
9 months	18 (90%)	2 (10%)	0 (0%)	0 (0%)	31 (70%)	13 (30%)	0 (0%)	0 (0%)	0.09
12 months	13 (100%)	0 (0%)	0 (0%)	0 (0%)	26 (59%)	17 (39%)	1 (2%)	0 (0%)	0.02

Conclusion

Our study demonstrates that the Sherpa-Pak cardiac transport system reduces the requirement for ECMO support following heart transplantation. We suggest that this is consistent and safe preservation temperature reduces the incidence of PGD, and we advocate further research into transportation systems that can improve on the icebox method. The use of the Sherpa-Pak system has clear clinical relevant benefits over conventional ice-box transportation.

References

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