

Hypothermic Oxygenated Machine Perfusion (HOPE) in Liver and Kidney Transplantation of Extended Criteria Brain Dead Donors (ECD-DBD): First Italian Interventional Clinical Trial

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Study Design

A matched-case analysis was developed: 10 HOPE ECD-DBD livers and 10 HOPE ECD-DBD kidneys, were matched 1:3 to 30 ECD-DBD livers and 30 ECD-DBD kidneys preserved with Static Cold Storage (SCS).

Following organ retrieval and standard static cold transport to the hospital, grafts were cannulated and connected to a newly developed hypothermic oxygenated pump and perfused with Belzer MPS® (Bridge to Life) through the renal artery or hepatic portal vein before implantation. Organs were perfused for between 1 and 3 hours.

	Experimental Group	Control group
	HOPE	SCS
Liver Transplantation	N = 10	N = 30
Donor Age	77.5 (60-84) years	75.5 (53-85) years
Recipient Age	57.5 (50-68) years	60.5 (48-68) years
Cold Ischemia Time	7.1 (6.1-9.6) hours	7 (5.4-10) hours
MELD score	13 (7-16)	13.5 (7-20)
Previous abdominal surgery	5 (50%)	13 (43.3%)
Portal thrombosis	1 (10%)	3 (10%)
Hepatic Steatosis		
> 0% and < 10%	6 (60%)	18 (60%)
≥ 10% and ≤ 30%	4 (40%)	12 (60%)
Kidney Transplantation	N = 10	N = 30
Donor Age	71.5 (60-78) years	69.5 (59-79) years
Recipient Age	61 (50-65) years	60.5 (48-68) years
Cold Ischemia Time	14.5 (10.8-22) hours	14 (8-21) hours

Demographic and clinical features of liver and kidney recipients

	Experimental Group
Liver HOPE	N = 10
Vein Portal Flow	107.5 (65-116) ml/min
Lactate post HOPE	1.8 (1-3) mmol/L
Perfusion Time	2.2 (1-3.5) hours
Kidney HOPE	N = 10
Renal Flow	52.5 (24-85) ml/min
Lactate post HOPE	1.3 (0.7-2.5) mmol/L
Perfusion Time	3.3 (1-6) hours

Perfusion parameters and biochemical characteristics of the HOPE perfusates

All authors have no financial relationships with commercial interest to disclose

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Results

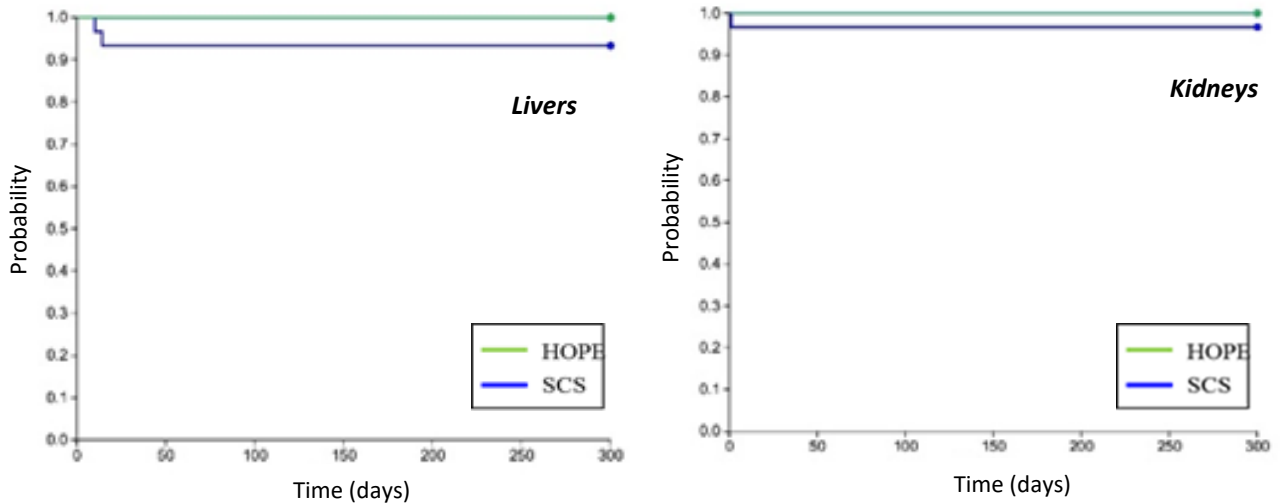
Primary Non-Function (PNF) was 6.6% for livers in SCS vs 0% for HOPE livers, and 3.3% for SCS kidneys vs 0% for HOPE kidneys. In Liver Transplant (LT) Early Allograft Dysfunction (EAD) was 0% for HOPE vs 23.3% in SCS; and in Kidney Transplant (KT) Delayed Graft Function (DGF) was 20% for HOPE vs 40% for SCS.

Median peak aspartate aminotransferase (AST) within 7-days post-LT was significantly higher in SCS, 637 (124-2001) U/L, in comparison to the HOPE livers, 344.5 (166-1132) U/L, (p = 0.0060*).

Graft survival at 30-days post-transplant in livers was 90% for SCS vs 100% for HOPE, and in kidneys 96.7% for SCS vs 100% for HOPE.

Livers	HOPE (N = 10)	Control (N = 30)	p value
PNF, n (%)	0 (0%)	2 (6.6%)	0.8942
EAD, n (%)	0 (0%)	7 (23.3%)	0.6135
Peak AST within 7 days (U/L), median (range)	344.5 (166-1132)	637 (124-2001)	0.0060*
Peak ALT within 7 days (U/L), median (range)	330 (122-1350)	601 (114-1837)	0.1438
Bilirubin at day 7 (mg/dL), median (SD)	3.14 ± 1.54	3.62 ± 3.22	0.5386
INR at day 7, median (range)	1.17 (1.08-1.46)	1.24 (1.02-1.64)	0.0434*
Hospital stay (days), median (range)	11.5 (7-29)	12.5 (7-109)	0.2350
30-day graft survival, n (%)	10 (100%)	27 (90%)	0.8394

Kidneys	HOPE (N = 10)	Control (N = 30)	p value
PNF, n (%)	0 (0%)	1 (3.3%)	0.9478
DGF, n (%)	2 (20%)	12 (40%)	0.6076
Creatinine at 5 day post-transplant, median (SD)	3.5 ± 2	4.1 ± 2.6	0.4572
eGFR on discharge (mL/min/1.73m ²), median (SD)	52.4 ± 25.01	44.43 ± 21.4	0.3762
Hospital stay (days), median (range)	17 (12-30)	24 (11-60)	0.0924
30-day graft survival, n (%)	10 (100%)	29 (96.7%)	0.9478



Kaplan-Meier estimates of survival - SCS and HOPE

Conclusion

This small study suggests that the newly developed hypothermic oxygenated pump used in this study is effective and safe in both liver and kidney perfusion. In livers there were significant improvements in clinical outcomes following HOPE. However, in kidneys there was a trend towards clinical improvement following HOPE, but this did not reach significance.