M07: Prolonged duration normothermic perfusion of the kidney prior to transplantation – preliminary data from a phase 1 clinical trial

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Abstract

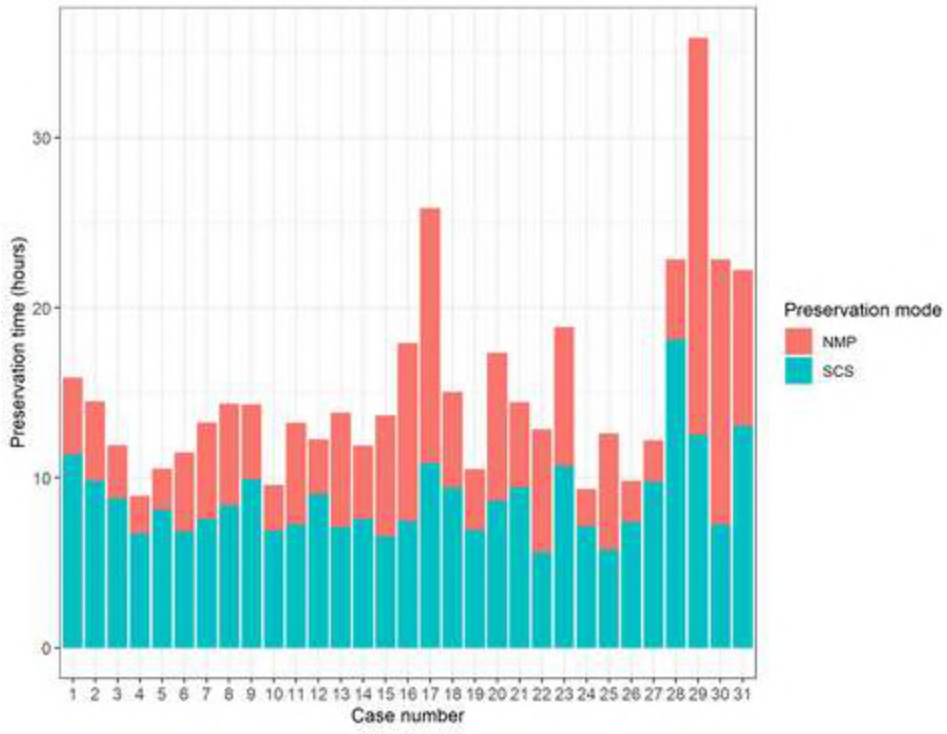
Introduction: Normothermic Machine Perfusion of the Kidney (NMP-K) prior to transplantation offers multiple potential domains of benefit, including reduction of preservation injury, organ assessment, optimisation of logistics, and as a platform for delivery of therapeutics. Previous clinical reports have been limited to a short duration of perfusion, and anatomically suitable organs. Normothermic Kidney Perfusion Phase 1 (NKP1) is a single centre trial investigating the safety and feasibility of prolonged duration NMP-K following static cold storage, using an automated mobile system (OrganOx, UK) designed for 24-hour perfusion.

Methods: Target recruitment is 36 patients. Perfusion duration is determined primarily by logistical considerations, with maximum permissible perfusion times increasing from 6 to 12 to 24 hours in consecutive study phases (each n=12). Kidneys are prepared, cannulated, and then perfused at 37°C with red cell based perfusate, and urine recirculation. Immediately prior to implantation, the kidney is removed from the device and cold-flushed. Comparison has been made to historical controls, ratio 1:2, selected by a pre-defined matching algorithm.

Results: 31/36 deceased-donor kidney transplants have so far been performed after NMP-K. Minimum perfusion time was 2h11, maximum 23h22 (Fig. 1). 25 patients have reached 30-day follow-up with 100% dialysis independence, and no adverse events related to the technique. Cold ischaemia times (CIT) were substantially shorter than typical for our centre (8h47 vs mean 14h18, control pool n=762). Total preservation time was median 15h14 (range 9h45-37h19). Measures of early graft function are comparable to a control cohort matched on cold ischaemia time (Table 1).

Discussion: Based on these preliminary data, prolonged duration NMP-K appears safe and feasible. In a real-world setting it enables a reduction in cold ischaemia time as well as a prolongation of total preservation time, thereby facilitating daytime operating. This platform also provides opportunities for ex-vivo assessment and treatment of deceased donor kidneys prior to transplantation.

Fig. 1: Preservation Duration by Case



	NKP1 (n=31)	Controls (n=62)
Matching criteria		
CIT, hh:mm, mean (sd)	08:47 (02:33)	09:15 (02:25)
DRI, mean (sd)	1.42 (0.62)	1.36 (0.57)
Induction agent	22 Alemtuzumab 9 Basiliximab	44 Alemtuzumab 18 Basiliximab
Donor type, DCD, n (%)	12 (38.7)	24 (38.7)
Outcomes		
DGF (dialysis in first 7 days)	11 (35.5)	25 (40.3)
Day 2 creatinine reduction ratio, mean (sd)	0.35 (22)	0.18 (0.30)
30-day eGFR, mean (sd)	46.1 (15.6)	44.7 (22.0)
3-month eGFR, mean (sd)	49.8 (16.0)	49.9 (20.5)

Categories: Organ preservation and retrieval (novel technologies - NORS - donor surgery)