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"Viability testing and transplantation of marginal livers" - the clinical outcomes of the VITTAL trial

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Introduction: Assessment of livers prior to transplantation is mostly subjective and last year, 599 livers from potential solid organ donors were not used for transplantation. Utilisation also varies widely between centres. The aim of the VITTAL trial was to objectively assess donor liver viability and achieve successful transplantation of discarded livers using normothermic machine perfusion (NMP).

Methods: This prospective, non-randomised, open label, single-arm adaptive phase II trial included livers discarded by all UK centres that met one or more specific high-risk criteria. These included donor risk index ≥2.0, biopsy-proven macrosteatosis ≥30%, transaminases ≥1000IU/mL, or warm ischaemic time ≥30mins in livers donated after circulatory death (DCD). The viability criteria were based on the clearance of perfusate lactate to levels ≤2.5mmol/L within 4 hours of commencing NMP, bile production, glucose metabolism, pH and physiological flow rates. Livers deemed viable were transplanted to adult first-graft recipients without portal vein thrombosis or cardiovascular comorbidities. The co-primary endpoints were liver salvage rate and recipient 90-day survival.

Results: Thirty-one discarded livers met inclusion criteria and were a suitable match for potential consented recipients. Seventeen donors after brainstem death and 14 donors following circulatory death were enrolled and perfused. Of these, 22 (71%) livers were transplanted after a median total preservation time of 18 hours, with 100% patient and graft 90-day survival. Seven (32%) patients developed early allograft dysfunction, and six (27%) patients suffered from Clavien-Dindo complications grade ³3, including four (18%) who required dialysis. During the median follow up of 297 days, 4 (18%) patients developed biliary strictures requiring subsequent re-transplantation. Matched-control comparisons at 180 days showed no differences between patient or graft survival, complication rates or hospital stay.

Conclusion: Viability testing with NMP is feasible, and the criteria enabled the objective assessment and successful transplantation of 71% of perfused discarded livers, with 100% early graft survival.