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Table 1. Characteristics by Donor-Recipient Sex Group

| | Male to Male (n=6846) | Male to Female (n=2581) | Female to Female (n=3822) | Female to Male (n=2347) | P-value |
|---|--------------------------|----------------------------|------------------------------|----------------------------|---------|
| Panel reactive antibody - % | 3.7 [2.8-4.7] | 15.0 [11.2-18.8] | 13.7 [10.9-16.5] | 5.5 [3.6-7.4] | < 0.001 |
| HLA mismatch level at 2 alleles - no. (%) | | | | | |
| A-locus | 3118 (51) | 1186 (51) | 1808 (52) | 1054 (49) | 0.200 |
| B-locus | 4367 (71) | 1647 (71) | 2458 (71) | 1502 (70) | 0.731 |
| DR-locus | 3406 (55) | 1185 (51) | 1828 (53) | 1140 (53) | 0.007 |
| Time to transplant - days | 129 [108-149] | 213 [166-260] | 264 [204-324] | 119 [72-165] | < 0.001 |
| Five year outcome - no. (%) | | | | | — |
| Bronchiolitis obliterans syndrome | 2821 (41) | 1129 (44) | 1574 (41) | 943 (40) | |
| Graft dysfunction | 1016 (15) | 432 (17) | 526 (14) | 359 (16) | |
| Survival | 4107 (62) | 1570 (64) | 2411 (66) | 1374 (61) | |

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Long-Term Outcomes in Heart and Lung Transplants from HCV-Viremic Donors to Uninfected Recipients: The Donate HCV Trial

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Purpose: An early 6-month analysis of the DONATE HCV Trial demonstrated that hearts and lungs can be safely transplanted from HCV-infected donors using a shortened, 4-week, pre-emptive course of direct acting antivirals (DAA). Whether early findings are sustained in the longer-term remain an important area of investigation.

Methods: DONATE HCV is a single-center trial to transplant thoracic organs from HCV viremic donors, irrespective of HCV genotype, to HCV-uninfected adults. Sofosbuvir/velpatasvir, a pan-genotypic DAA, was administered for 4 weeks, beginning within hours of transplant. The primary composite outcome of HCV clearance and graft survival at 6 months post-transplant are now extended to the longer-term at 1- and 3-years. We also report on grade 3 or higher adverse events (AEs). (NCT03086044)

Results: Between March 2017 and December 2019, 65 participants were enrolled: 53 received lung and 12 received heart transplants. The median donor HCV viral load (VL) was 742,000 IU/mL (IQR 127,000 - 4.69 million). 56 of 65 (86%) recipients had detectable HCV VL immediately after transplant, with median VL of 2,000 IU/mL (IQR 800 - 9,000). HCV VL became negative by 2 weeks and subsequently remained undetectable in all participants. 63 of 65 (97%), 60 of 63 (95%), 46 of 51 (90%), and 19 of 24 (79%) participants were alive with excellent graft function and an undetectable HCV VL at 6 months, 1-year, 2-years, and 3-years post-transplant, respectively. 22 of 65 (34%) and 28 of 63 (44%) had acute cellular rejection requiring treatment at 6 months and 1-year post-transplant, respectively. 3 of 65 (5%) and 3 of 63 (5%) had antibody mediated rejection at 6 months and 1-year post transplant, respectively. No treatment-related AEs were identified. Outcomes between transplant recipients from HCV donors vs. non-HCV donors were similar, including the occurrence of renal failure, respiratory failure, and non-HCV infections.

Conclusion: These data demonstrate that recipients of thoracic organs transplanted from HCV viremic donors who receive a shortened antiviral treatment course initiated within hours of transplant, have excellent longer-term graft and recipient survival with similar AE profiles compared to transplant recipients who received thoracic organs from non-HCV donors.

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Should Lungs from Hepatitis C NAT+ Donors Continue to Be Transplanted? A UNOS Registry Analysis

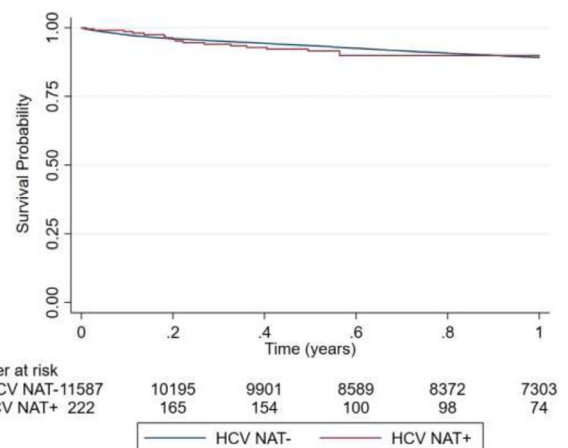
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Purpose: With the advent of a cure for HCV, HCV NAT+ donor lungs are being increasingly utilized for transplantation, but their outcomes are understudied. Our goal was to examine one-year survival of lung transplant recipients from HCV NAT+ donors.

Methods: We conducted retrospective review of all primary adult lung transplant recipients in the UNOS registry between January 1, 2015 and June 12, 2020. Donors were identified as being HCV NAT+ or HCV NAT-. One-year survival was examined with the Kaplan Meier method and a multivariable Cox-proportional hazards model.

Results: Of 11809 lung transplants performed during the study period, 222 (2%) came from HCV NAT+ donors. HCV NAT+ donors tended to be younger (33±8 vs 35±14 yrs, p=0.01) and were more likely to be white (82% vs 61%, p<0.01), blood group O (61% vs 50%, p<0.01), CDC high risk (84% vs 24%, p<0.01), and have drug intoxication as cause of death (61% vs 12%, p<0.01). Recipients of HCV NAT+ donor lungs were less likely to have diabetes (10% vs 20%, p<0.01), cystic fibrosis (5% vs 9%, p<0.01), IPF (28% vs 36%, p<0.01), have chronic steroid use (32% vs 44%) or be treated with IV antibiotics 2 weeks prior transplant (5% vs 12%, p=0.02). They had lower LAS scores (42±15 vs 48 ± 18, p<0.01), oxygen requirements at rest (4.5 vs 5.5 L, p<0.01), and were more likely to receive double lungs (83% vs 74%, p<0.01). One-year survival was not significantly different among recipients of HCV NAT+ and NAT- donor lungs on univariate (HR 1.00, 95% CI 0.62-1.62, p=0.98) or multivariate analysis (aHR 0.94, 95% CI 0.53-1.67, p=0.84). Incidence of treatment for acute rejection at one year was also not significantly different (23% vs 23%, p=0.86).

Conclusion: Despite coming from high-risk donors, HCV NAT+ lungs have similar one-year survival and acute rejection as those coming from HCV NAT- donors. While longer-term studies are necessary, this report supports the use of NAT+ donor lungs among lung transplant candidates.



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Factors Influencing Acceptance and Transplantation of Hearts from Hepatitis C+ Donors

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