Disclosures. All Authors: No reported Disclosures.

87. Heart and Lung Transplants From HCV-Viremic Donors to Uninfected Patients: Longer-Term Follow-Up
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Background. 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 (DAAs). The 6-month results from that study of 35 patients are encouraging, but longer-term data from a larger cohort are needed to better define the risk-benefit profile.

Methods. We conducted 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 pre-emptively administered for 4 weeks, beginning within hours of transplant. The primary outcome was a composite of HCV clearance and graft survival at 6 months post-transplant. Secondary outcomes included graft survival and mortality at 12 months and the occurrence of grade 3 or higher adverse events (AEs). This protocol is IRB approved and all participants provided written informed consent (NCT03086044).

Results. Between March 2017 and March 2019, 57 participants were enrolled: 46 received lung and 11 received heart transplants. The median donor HCV viral load (VL) was 889,817 IU/mL (IQR 212,062–4,641,078). Of the 57 recipients, 33 (53%) had detectable HCV VL immediately after transplant, with median VL of 1,460 IU/mL (IQR 463–6,618). HCV VL became negative by about 2 weeks and subsequently remained undetectable in all participants.

Forty-nine of 49 (100%) and 34 of 35 (97%) recipients were alive with excellent graft function and an undetectable HCV VL at 1 year post-transplant, respectively. No treatment-related serious 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. In patients who received thoracic organs from HCV viremic donors, a 4-week antiviral treatment course initiated within hours of transplant prevented the establishment of HCV infection. These data demonstrate that thoracic organs from HCV viremic donors can be transplanted safely with excellent graft and recipient survival at 12 months with a similar AE profile compared with transplant recipients who received thoracic organs from non-HCV donors. Two-year outcomes will be available in October 2019.

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In the United States, all deceased donors (DD) are evaluated for behavioral risk factors for human immunodeficiency virus (HIV), hepatitis B (HBV), and hepatitis C (HCV) infection during the past 12 months. DD with behavioral risk factors or hemodialysis are designated as PHS increased risk donors (IRD). Since 2013, the number of IRD has increased from 13.4% of DD to 27% in 2018. Despite a low residual risk of disease transmission after a negative nucleic acid test for HIV/HBV/HCV, the considerable underutilization of IRD has driven an interest in revisiting the PHS IRD 2013 guidelines. The objective of this study was to describe the epidemiology of IRD with the goal of guiding policy change and maximize organ use.

Methods. This is a retrospective cohort study of DD during 2018. Characteristics of IRD were compared with non-IRD. A random 10% sample of IRD was selected for manual review of text narratives and donor questionnaires submitted by organ procurement organizations to determine specific PHS IRD factors. Categorical variables were compared using the χ² test and continuous variables were compared using a 2-sample t-test for independent samples.

Results. Among 10,721 DD in 2018, 2,904 were designated IRD (27.1%) with regional variability noted (Figure). Compared with non-IRD, IRD were younger (median age 35 vs. 45 years, P < 0.001) and more often died from drug intoxication (33.2 vs. 5.6%, P < 0.001). Hemodialysis was found in 6.8% of all IRD and was the only factor for IRD designation in 60% of pediatric donors <12 years old. The random sample of IRD (N = 288) was similar to IRD population for age, gender, ethnicity, cause of death, and region of recovery (Table). Descriptive analysis of the random sample showed that intravenous drug use was the most common behavioral risk factor (N = 124, 43.1%), followed by incarceration (N = 108, 37.5%). Most DD met only 1 criterion (N = 179, 62%); 21% met 2 criteria; and 17% had >3 criteria.

Conclusion. This study represents the most detailed description of PHS IRD factors since the adoption of the new guidelines in 2013. Understanding the prevalence of factors that lead to IRD designation will help inform future policy development, optimize safe DD use, and increase the number of transplants.

Table: Deceased-Donor Demographics and PHS Risk Factors in 2018

| Characteristic | All 2018 | Random Sample of 2018 | All 2018 | Random Sample of 2018 |
|---------------|---------|----------------------|---------|----------------------|
| Number of DDs (N) | 10,721 | 2,904 | 2,904 | 293 |
| Donor Age (median, IQR) | 41 (28–56) | 33 (27–46) | 30 (27–40) | 29 (27–43) |
| Pediatric (≤ 18) | 475 (6.7%) | 177 (11.8%) | 3 (1.8%) | 2 (6.9%) |
| Mechanism of Death | Drug Intoxication (N, %) | 1445 (50.1%) | 194 (32.3%) | 92 (31.7%) |
| Males (♂/♀) | 2125 (59.4%) | 286 (47.5%) | 52 (17.7%) |
| White | 7608 (69.7%) | 1160 (19.7%) | 211 (72.2%) |
| Black or African-American | 1728 (16.1%) | 458 (23.6%) | 10 (11.4%) |
| Hispanic | 1206 (11.4%) | 200 (21.2%) | 12 (11.4%) |
| Other/Multiracial | 477 (4.6%) | 161 (15.7%) | 5 (1.7%) |
| Diabetes (N, %) | 36 (0.3%) | 10 (0.2%) | 2 (0.2%) |
| NO (N, %) | 224 (0.2%) | 9 (0.2%) | 1 (0.2%) |
| Infections | 197 (1.9%) | 53 (0.9%) | 15 (0.5%) |
| Serologic/Infectious History | 37 (0.4%) | 10 (0.2%) | 2 (0.1%) |
| Hemodialysis | 197 (1.9%) | 53 (0.9%) | 15 (0.5%) |
| Humoral/eve | 27 (0.3%) | 7 (0.1%) | 1 (0.1%) |
| Serologic/Infectious History (N, %) | 37 (0.4%) | 10 (0.2%) | 2 (0.1%) |
| Seroconversion | 35 (16.9%) | 6 (12.7%) | 1 (0.5%) |
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Fig 1 - Breakthrough IFI during antifungal prophylaxis

Fig 2 - Mortality of lung transplant patients

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