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Outcomes of lung transplantation from donors with hepatitis C viremia with outpatient initiation of antiviral therapy

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KEYWORDS:
lung transplantation;
hepatitis C;
mortality;
acute cellular rejection;
outpatient antiviral therapy

Transplantation of lungs from donors with active hepatitis C viremia with early initiation of antiviral therapy has been shown to have similar short- and medium-term outcomes compared to transplantation of lungs from nonviremic donors. Consideration of hepatitis C viremic lungs is particularly helpful in patients with anticipated prolonged time on the waiting list. Whether clinical outcomes remain favorable with delay of initiation of antiviral therapy to the outpatient setting or in patients with higher severity of illness is not well understood. Our transplant center considered hepatitis C nucleic acid testing positive (NAT^+) donors for all waitlisted lung transplant candidates without chronic liver disease. For those transplanted with hepatitis C NAT^+ lungs, we initiated antiviral therapy in the outpatient setting and continued treatment for 12 weeks. In a retrospective single-center study of 15 lung transplant recipients receiving hepatitis C NAT^+ lungs and 88 recipients receiving nonviremic lungs, we tested the hypothesis that deferral of antiviral therapy after transplantation of lungs from hepatitis C NAT^+ donors to the outpatient setting would result in similar 1-year survival compared to transplantation of lungs from nonviremic donors. Patients receiving hepatitis C NAT^+ lungs had similar baseline characteristics but had longer index hospital lengths of stay (24 vs 13 days, $p = 0.021$). Patients receiving hepatitis C NAT^+ lungs had fewer episodes of acute cellular rejection in the first year. Patients receiving hepatitis C NAT^+ lungs had similar 1-year survival to patients receiving lungs from nonviremic donors, after controlling for age and lung allocation score ($p = 0.638$). In this small single-center study, outpatient initiation of antiviral therapy for donor-derived hepatitis C is associated with acceptable clinical outcomes and can be considered in patients with high severity of illness.

JHLT Open 2024;3:100029

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https://doi.org/10.1016/j.jhlto.2023.100029

Background

Demand for lung transplantation exceeds supply of donor lungs and currently 15% to 20% of patients die on the lung transplant waiting list each year. To increase access to suitable donor lungs, transplantation of lungs from donors with active hepatitis C viremia (NAT^+, nucleic acid testing positive) has been implemented. Although this results in donor-derived transmission of hepatitis C, treatment with direct-acting antiviral therapy has a high rate of sustained virologic response.

Current data suggest that transplantation of lungs from hepatitis C viremic donors has acceptable clinical outcomes. A recent analysis from the Scientific Registry of Transplant Recipients reported that patients who received lungs from hepatitis C viremic donors (NAT^+) had similar graft and patient survival at 3 years post-transplant compared to patients who received lungs from hepatitis C seronegative donors, also without significant differences in acute rejection or ancillary respiratory support after transplant.[1] Another analysis of United Network of Organ Sharing data reported that overall rates of acute rejection were similar in lung transplant recipients who received NAT^+ donor lungs compared to those with nonviremic lungs.[2] These data are encouraging that transplantation of lungs from hepatitis C NAT^+ donors results in acceptable recipient outcomes. However, the optimal patient selection and treatment details are not well understood.

Initially, transplantation of hepatitis C NAT^+ lungs was considered for patients with anticipated prolonged waitlist duration. Several United Network of Organ Sharing studies have reported that recipients of NAT^+ lungs had lower lung allocation scores (LAS) and more chronic obstructive pulmonary disease than recipients of nonviremic lungs.[2-4] These patient groups typically have longer waiting times to achieve transplantation and consideration of NAT^+ lungs may have been used to increase access to transplant. Whether clinical outcomes using lungs from NAT^+ donors are favorable in patients with higher pretransplant severity of illness has not been well studied.

Another area of uncertainty is the optimal timing of antiviral therapy initiation after transplantation of NAT^+ lungs. Thus far, most lung transplant recipients receiving hepatitis C NAT^+ lungs received direct-acting antiviral therapy soon after transplant. In the first clinical trial of NAT^+ lung transplantation, 36 patients receiving NAT^+ lungs began sofosbuvir-velpatasvir within a few hours of transplantation and continued therapy for 4 weeks.[4] Other studies administered glecaprevir-pibrentasvir beginning immediately after transplant,[5] within 3 days of transplant,[6] or along with ezetimibe for 1 dose before transplant and 7 daily doses after transplant[7]; each of these treatment strategies achieved sustained viral responses within 8 weeks. These data strongly support that very early antiviral initiation successfully eliminates donor-derived hepatitis C. Whether deferral of initiation of antiviral therapy to the outpatient setting is equally efficacious is less clear. For many transplant centers, immediate perioperative antiviral therapy is not available, partially due to inpatient formulary restrictions, drug cost, or concerns about interruption of oral therapy in critically ill patients. Thus, if outpatient initiation of antiviral therapy after the index hospital stay is efficacious, it may increase access to transplantation.

In this study, we report our single-center experience with transplantation of hepatitis C NAT^+ lungs into patients irrespective of lung allocation score and with deferral of initiation of antiviral therapy to the outpatient setting. We hypothesized that delayed antiviral therapy would be successful after hepatitis C NAT^+ lung transplantation and that clinical outcomes would be similar to those receiving lungs from nonviremic donors.

Materials and methods

Study population

This is a single-center retrospective analysis of 103 lung transplant recipients at Vanderbilt University Medical Center between January 2019 and June 2021. All waitlisted adult lung transplant candidates without pre-existing liver dysfunction were offered consideration of hepatitis C NAT^+ lungs, with 69% (n = 71) patients consenting for NAT^+ organs. There were 15 lung transplant recipients who received NAT^+ lungs and there were 88 recipients who received nonviremic lungs. Two heart-lung transplant recipients receiving NAT^+ organs were excluded from the analysis. Patients receiving hepatitis C NAT^+ lungs had viral polymerase chain reaction (PCR) testing weekly while inpatient, with plans to request inpatient initiation of antiviral therapy if aspartate aminotransferase and alanine aminotransferase exceeded 3 times the upper limit of normal. The choice of antiviral therapy was based on hepatitis C genotype, drug interactions, and insurance coverage. While on antiviral therapy, hepatitis C polymerase chain reaction was performed monthly and liver enzymes were monitored at least every 2 weeks. The study was approved by the Vanderbilt University Medical Center Institutional Review Board.

Clinical outcomes

The primary outcome was time to death within 1 year of transplantation. Secondary outcomes included grade 3 primary graft dysfunction at 72 hours, hospital length of stay, 30-day survival, acute cellular rejection within 1 year, donor-specific antibody detection within 1 year, forced expiratory volume in 1 second (FEV_1) at 1 year, and forced vital capacity (FVC) at 1 year. For NAT^+ lungs, we also analyzed viral genotype, time to antiviral initiation, achievement of sustained viral response at 12 weeks, and time from treatment initiation to viral clearance.

Statistical analysis

Descriptive analyses were summarized as median and interquartile range (IQR) for continuous and number with percentage for categorical variables. Baseline variables were compared between recipients of NAT^+ lungs and recipients whose donors were hepatitis C nonviremic using Wilcoxon rank-sum test for continuous variables and chi-square test for categorical variables. The primary clinical outcome was time to death within 1 year of transplant. Kaplan-Meier curves or Cox regression was applied to compare

the 2 groups. Individuals were censored at the date of their last known follow-up. For secondary outcomes, multivariable logistic and linear regression were performed for binary and continuous outcomes, respectively, adjusting for baseline covariates. All statistical analyses were performed using R software, version 3.5.1 (R Core Team, 2022). A p-value less than 0.05 was predetermined to be statistically significant.

Results

Study population

The clinical characteristics of the study population are shown in Table 1. There were 15 lung transplant recipients who received NAT$^+$ lungs. Patients receiving lungs from hepatitis C NAT$^+$ donors were older than those receiving lungs from nonviremic donors. There were no statistically significant differences between groups in recipient age, sex, recipient race/ethnicity, indication for transplantation, or receipt of bilateral lung transplantation. Lung allocation scores were statistically similar between groups ($p = 0.146$) although numerically higher in those receiving NAT$^+$ lungs (44.9 in NAT$^+$ vs 38.7 in nonviremic). Hospitalization at the time of organ offer and use of extracorporeal membrane oxygenation as a bridge to transplant were also similar between groups.

Hepatitis C characteristics and treatment

Thirteen of the 15 lung transplant recipients who received NAT$^+$ donor lungs had viral genotype 1. Fourteen patients received antiviral treatment: sofosbuvir-ledipasvir ($n = 6$), glecaprevir-pibrentasvir ($n = 6$), or sofosbuvir-velpatasvir ($n = 2$). One patient died during the index hospitalization and did not receive antiviral therapy. The median time to antiviral initiation was 43 days (IQR 31-61). The median viral load prior to treatment initiation was 8.8 million units/ml (IQR 2.8-13.2 million). The median aspartate aminotransferase was 35 units/liter (IQR 22-52), alanine aminotransferase was 35 units/liter (IQR 23-58), and total bilirubin was 0.5 mg/dl (IQR 0.3-0.6). All treated patients achieved sustained viral response at 12 weeks. The median time from treatment to first negative viral load was 44 days (IQR 35-54 days). One patient had recurrence of viremia after sofosbuvir-ledipasvir, thought to be related to concurrent proton pump inhibitor therapy, and required repeat therapy with sofosbuvir-ledipasvir-voxilaprevir before achieving sustained viral response.

One-year mortality

There were 2 deaths within 1 year among patients receiving NAT$^+$ lungs (13% mortality) and 6 deaths among patients receiving nonviremic lungs (7% mortality). The Kaplan-Meier curve of survival over time is shown in Figure 1. Univariate analysis showed that recipient age and lung allocation score had significant impact on mortality, but that NAT$^+$ lung status or hospital length of stay was not associated with mortality (Table 2). Although patients receiving hepatitis C NAT$^+$ donor lungs had numerically higher mortality and patients receiving single lung transplants had numerically lower mortality, this did not reach statistical significance because of wide confidence intervals. We then performed a multivariable Cox regression to determine whether the effect of hepatitis C NAT$^+$ donor lungs on mortality was altered by confounding variables; we selected age and LAS as the best recipient covariates to include. Multivariable Cox regression controlling for age and lung

Table 1 Characteristics of Lung Transplant Recipients Who Received Hepatitis C NAT$^+$ or Nonviremic Lungs at Vanderbilt University Medical Center, 2019 to 2021

Characteristic	Hepatitis C NAT$^+$ $n = 15$	Control nonviremic $n = 88$	p-value
Age (years)	61 (57-65)	61 (55-65)	0.896
Single lung transplant	5 (33%)	28 (32%)	0.907
Indication			0.498
COPD/emphysema	2 (13%)	18 (20%)	
Pulmonary hypertension	1 (7%)	1 (1%)	
CF/bronchiectasis	1 (7%)	5 (6%)	
Fibrotic lung disease	11 (73%)	64 (73%)	
Male recipient	6 (40%)	50 (57%)	0.227
Race/ethnicity			0.872
White	14 (93%)	74 (84%)	
Black	1 (7%)	8 (9%)	
Hispanic	0 (0%)	4 (5%)	
Other	0 (0%)	2 (2%)	
Lung allocation score	44.9 (38.0-52.7)	38.7 (34.8-48.5)	0.146
Hospitalized at organ offer	3 (20%)	20 (23%)	0.815
ECMO pretransplant	0 (0%)	7 (8%)	0.258

Abbreviations: CF, cystic fibrosis; COPD, chronic obstructive pulmonary disease; ECMO, extracorporeal membrane oxygenation; NAT$^+$, nucleic acid test positive.

Categorical variables are displayed as n (%) and continuous variables as median (interquartile range).

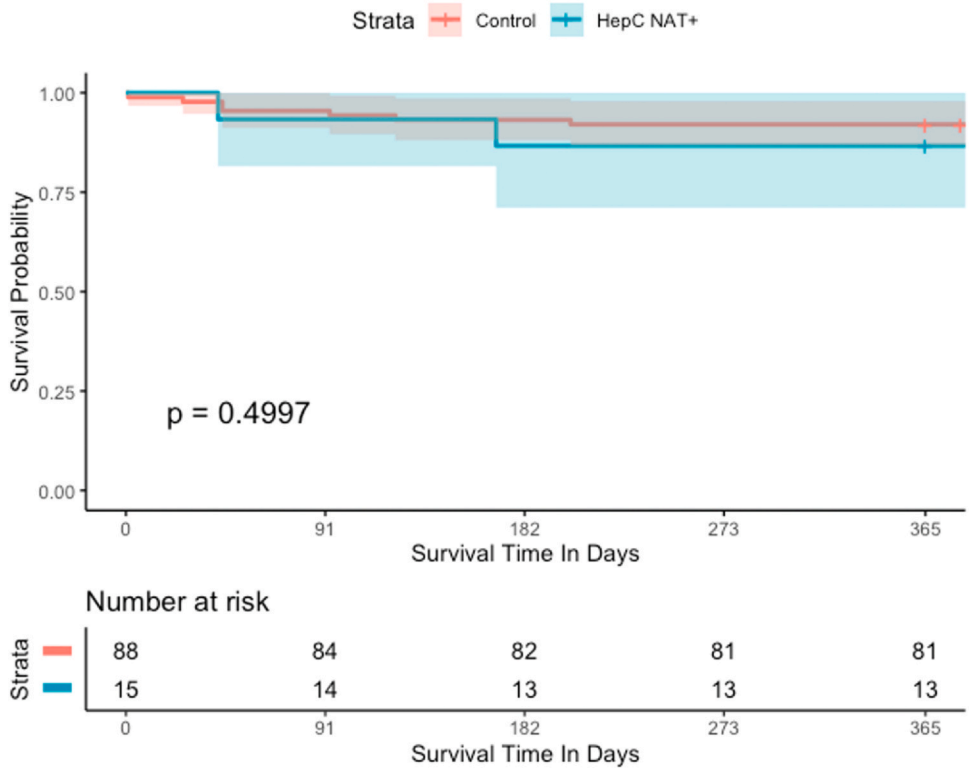

FIGURE 1 Survival in patients transplanted with hepatitis C NAT$^+$ lungs with delayed initiation of antiviral therapy compared to those transplanted with lungs without hepatitis C.

Table 2 Cox Proportional Hazards Regression-Derived Hazard Ratios For the Association Between Receipt of NAT$^+$ Lungs and 1-Year Mortality

Variable	Univariate HR (95% CI)	*p*-value	Multivariable HR (95% CI)	*p*-value
Hepatitis C NAT$^+$	1.70 (0.35-8.20)	0.506	1.46 (0.30-7.06)	0.638
Age (per year)	0.95 (0.90-0.99)	0.014	0.96 (0.91-1.02)	0.173
Lung allocation score (per point)	1.05 (1.02-1.08)	0.003	1.04 (1.00-1.07)	0.029
Fibrotic lung disease	0.72 (0.18-2.88)	0.643		
Single lung transplant	0.61 (0.13-2.92)	0.532		
Hospital LOS (per day)	1.00 (0.98-1.03)	0.684		

Abbreviations: CI, confidence interval; HR, hazard ratio; LOS, length of stay; NAT$^+$, nucleic acid test positive.

Cox proportional hazard analysis was performed as univariable or multivariable analysis with the variables indicated. n = 15 for hepatitis C NAT$^+$ group and n = 88 for control.

allocation score did not detect an association between NAT$^+$ lung status and 1-year mortality (Table 2). Higher lung allocation score was associated with a small but statistically significant increase in 1-year mortality.

Hospital length of stay, PGD, acute rejection, augmentation of immunosuppression, and spirometry

Next, we used univariate analysis to assess several secondary clinical outcomes between patients receiving NAT$^+$ lungs and those receiving nonviremic lungs (Table 3). Patients receiving NAT$^+$ lungs had a longer hospital length of stay (median 24 days) compared to those receiving nonviremic lungs (median 13 days) ($p = 0.021$). Grade 3 PGD rate was 27% in the NAT$^+$ group and 20% in the control group ($p = 0.504$). The rate of any biopsy-proven acute cellular rejection was 33% in NAT$^+$ and 61% in control ($p = 0.043$). When this analysis was restricted to A2 or greater acute cellular rejection, there was no statistical difference in rejection rates between groups ($p = 0.548$). Detection of DSA was similar between groups, as was treatment for antibody-mediated rejection. Finally, the FEV_1 is similar between groups, although the FVC was lower in the hepatitis C NAT$^+$ group.

Discussion

While previous research has shown effective treatment of hepatitis C viremia in lung transplant patients with early treatment, it was uncertain whether similar clinical outcomes could be achieved with delayed initiation of antiviral

Table 3 Univariable Analysis of Secondary Clinical Outcomes Comparing Patients Transplanted With Lungs From Hepatitis C NAT$^+$ Lungs Compared to Control

Variable	Hepatitis C NAT$^+$ $n = 15$	Control nonviremic $n = 88$	p-value
Primary graft dysfunction grade 3 at 72 hours	4 (27%)	17 (20%)	0.504
Hospital LOS (days)	24 (14-36)	13 (11-22)	0.021
Any ACR in 1st year	5 (33%)	54 (61%)	0.043
Grade 2 or 3 ACR in 1st year	3 (20%)	26 (30%)	0.548
Donor specific antibody	3 (23%)	20 (25%)	> 0.999
Lymphocyte-depleting therapy for acute rejection	2 (13%)	20 (23%)	0.516
PLEX or IVIg or rituximab	3 (20%)	21 (24%)	> 0.999
FEV_1 at 1 year (liters)	2.10 (1.78-2.45)	2.43 (1.91-2.97)	0.176
FEV_1 % predicted at 1 year	75 (68-89)	84 (67-98)	0.369
FVC at 1 year (liters)	2.38 (2.12-2.82)	3.00 (2.55-3.58)	0.025
FVC % predicted at 1 year	67 (61-79)	79 (67-93)	0.077

Abbreviations: ACR, acute cellular rejection; FEV_1, forced expiratory volume in 1 second; FVC, forced vital capacity; IVIg, intravenous immunoglobulin; LOS, length of stay; NAT$^+$, nucleic acid test positive; PLEX, plasma exchange.

Categorical variables are displayed as n (%) and continuous variables as median (interquartile range).

therapy or whether treatment would be effective in a sicker population of lung transplant candidates.[8,9] To address these questions, we performed a retrospective single-center study of transplantation of hepatitis C NAT$^+$ lungs with treatment initiation after initial hospital discharge. We show that delayed treatment of donor-acquired hepatitis C viremia after lung transplantation is effective. In this small cohort, recipients of hepatitis C NAT$^+$ lungs had longer hospital length of stay, but similar 1-year mortality compared to recipients of nonviremic lungs. These findings were independent of severity of illness as measured by lung allocation score.

Our data support a growing body of work showing that clinical outcomes after transplantation of lungs from hepatitis C viremic donors are acceptable and similar to transplantation from nonviremic donors; moreover, our findings extend these data to show that sustained viral clearance with favorable clinical outcomes can be achieved with delayed initiation of antiviral therapy to the outpatient setting after hepatitis C NAT$^+$ lung transplantation. Most published data on hepatitis C treatment after lung transplantation have used either prophylactic or immediate treatment strategies. Our data add to reports of individual cases and a case series showing successful viral eradication using sofosbuvir-daclatasvir beginning 5 months post-transplant,[10] sofosbuvir-ledipasvir beginning 6 weeks after transplant,[11] or sofosbuvir-ledipasvir or sofosbuvir-velpatasvir beginning 1 month after lung transplant.[12] More recently, a clinical trial used ex vivo lung perfusion (EVLP) with or without ultraviolet therapy on NAT$^+$ lungs prior to transplant and then began sofosbuvir-velpatasvir therapy a median of 21 days post-lung transplant.[13] In our study, 1 patient with severe gastroesophageal reflux disease requiring proton-pump inhibitor therapy had recurrence of viremia approximately 6 weeks after cessation; this individual was retreated and achieved permanent viral clearance. These data together show high rates of successful viral clearance with delayed initiation of antiviral therapy.

Because of concerns about interruption of antiviral therapy, need for oral administration, and cost of medication, our program delayed initiation of antiviral therapy to the outpatient setting. The median time to treatment initiation in our cohort was 43 days. Because the viral load was greater, our patients required 6 weeks of therapy to achieve viral clearance, rather than < 4 weeks as shown in other studies using immediate antiviral treatment strategies. Therefore, our study has important implications for increased use of hepatitis C viremic donors. First, it is reassuring that there do not appear to be major adverse effects of delaying antiviral treatment in our patient cohort. We did not detect any increase in acute rejection after outpatient initiation of antiviral therapy. Some initial studies of the use of hepatitis C NAT$^+$ lungs[4] and hearts[14] were concerning for increased acute cellular rejection early after transplant, although later follow-up studies with extended follow-up periods and larger patient cohorts have not shown this consistently.[1,15-17] The data in our study support a possible reduction in mild acute cellular rejection, but not severe (> A2 rejection) in patients receiving hepatitis C NAT$^+$ lungs. Second, should treatment be deferred or begin with greater viral loads, truncated treatment duration may not be ideal. Additional studies will be needed to optimize treatment duration after transplantation of hepatitis C viremic organs. Finally, because our data support that deferral of antiviral therapy to the outpatient setting after transplantation of hepatitis C NAT$^+$ lungs is safe, this may allow additional centers without inpatient access to anti-hepatitis C therapies to consider the use of hepatitis C NAT$^+$ lungs given increased outpatient availability of drug.

While many programs have used hepatitis C NAT$^+$ organs to achieve transplantation for those with lower allocation scores, our approach was to consider hepatitis C NAT$^+$ lungs for all waitlisted candidates without known liver disease. Our cohort had higher lung allocation scores than previously published work, with a difference in median LAS scores of > 6 points between recipients receiving NAT$^+$ vs nonviremic lungs. Despite this increased severity of illness at the time of transplantation, the rates of primary graft dysfunction and post-transplant mortality were similar. We also found reduced acute cellular rejection

in patients who received NAT^+ lungs, although this was not statistically significant for more severe rejection episodes. The mechanisms underlying this observation are unknown and we did not have biospecimens available to investigate this in the current study. One possibility may be that improved PaO_2/FiO_2 ratios and lower age of hepatitis C NAT^+ donors may limit adverse consequences associated with transplantation.[2,3,17] Overall, our data are encouraging and suggest that use of hepatitis C NAT^+ lungs for high acuity patients may increase timely access to transplant, just as it has for patients with lower allocation scores or COPD.

Our study has several strengths. We approached all patients being activated on the lung transplant waiting list, except those with known chronic liver disease, for consideration of hepatitis C NAT^+ lungs. In addition, we had a very high consent rate for consideration of NAT^+ lungs. Together, these study features may reduce bias in the patients undergoing NAT^+ transplants. The primary weakness of our study is that this is a single-center retrospective report with a small sample size. It is possible that our limited statistical power may have obscured important differences in clinical outcomes, in part by limiting our ability to control for confounding variables that may be important, such as laterality of transplant, underlying pulmonary diagnosis, pulmonary artery pressures, or hospital readmissions. While reassuring of the safety and efficacy of deferred antiviral initiation, our findings will require validation in larger study cohorts prior to widespread adoption. When interpreted along with other studies of hepatitis C NAT^+ lung transplantation, our data add to the literature supporting success with these organs, albeit with new insight into treatment regimens.

In conclusion, these data support broad consideration and utilization of hepatitis C NAT^+ lungs for transplantation. This is an important tool to increase access to transplantation and potentially reduce waitlist mortality.

Disclosure statement

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Ciara M. Shaver reports financial support provided by National Institutes of Health. Jinyuan Liu reports financial support was provided by Vanderbilt University Medical Center.

Funding: NIH K08 HL136888, R01 HL160551, Department of Medicine and Department of Surgery at Vanderbilt University Medical Center.

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