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Liver Transplantation Trends in the HIV Population

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Abstract

There is a paucity of information on the utilization patterns of liver transplantation (LT) for HIV-positive individuals. The aim of this study is to examine the trends in LT of HIV patients in the US. This study was a retrospective analysis using the UNOS database (1999–2008). There were 135 HIV-positive patients. There was a steady increase in the number of LT recipients over time as well as regional variation. Ethnic minorities accounted for 33.3% and there was no ethnic difference in survival. Though LT for HIV-positive patients is on the rise, significant variations exist in patient demographics, geographic location, and insurance payer.

Keywords

HIV; Liver transplantation; Disparity; Survival

Introduction

Since the introduction of highly active antiretroviral therapy (HAART) in 1996, the life expectancy of individuals infected with the human immunodeficiency virus (HIV) has dramatically improved. Consequently, deaths due to AIDS-related opportunistic infections have decreased, while morbidity and mortality due to end-stage liver disease (ESLD) and hepatocellular carcinoma (HCC) has increased [1]. The most common etiology of ESLD in HIV-positive patients is HBV or HCV co-infection, and compared to the mono-infected individual (HCV or HBV alone), reports from natural history studies suggest a significantly shorter duration of survival following hepatic decompensation [2].

Liver transplantation (LT) has been widely accepted as the therapeutic option of choice for individuals with ESLD and HCC. In the HAART era, there is a growing experience with liver transplantation in the HIV-positive patient. Many no longer consider this life-saving procedure a contraindication. Furthermore, recent reports from several studies in Europe and North America have consistently shown a reasonable patient and graft survival of LT recipients with HIV infection [3–6]. The aim of this study is to examine the recent trends in liver transplantation of HIV-infected patients in the US based upon an analysis of the UNOS registry. We focused our analysis on evaluation of the breadth of transplantation and the

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demographics of HIV transplanted patients compared to all transplanted individuals including characteristics that might influence transplant availability and success.

Methods

Using the UNOS database, we first identified all adults (≥18 years) who received deceased donor liver transplant between 1999 and 2008. Patients who received multi-organ transplantation or re-transplantation were excluded. The data collected included demographics, insurance payer, liver diagnosis, survival information, and UNOS regions. Insurance payer was categorized as private and non-private (i.e., government) insurance. The non-private group was further divided into Medicaid and non-Medicaid Insurance. The race and ethnicity of the study population was categorized based on the classification used in the UNOS database. Race and ethnic group are captured in the UNOS database as ‘‘ethnicity’’ and categorized into the following: white, black, Hispanic, Asian, Pacific Islander and American Indian/Alaska Native. The underlying liver disease was categorized into (1) hepatitis B, (2) hepatitis C, (3) hepatocellular carcinoma (HCC) and (4) others. No data was available on recipients with dual HCV-HCC or HBV-HCC.

The results are reported as medians and ranges for continuous variables and as proportions (%) for categorical variables. Univariate *t* test was used to identify variables that differed significantly between the HIV and non-HIV groups. The Cochran-Armitage tests and χ^2 test was used to evaluate temporal trends in transplantation over the years. The Kaplan–Meier method was used to calculate overall survival and logrank test to compare survival. All statistical analysis was performed using SAS version 9.1 (Statistical Analysis Software; SAS Institute, Cary, NC). *P* values <0.05 were considered statistically significant in all cases.

Results

Study Population

A total of 48,334 patients received liver transplantation during the study period. Of these, 135 were documented as HIV-positive in the UNOS registry. The demographics and clinical characteristics of the study population are shown in Table 1. There were significant differences in age, gender, ethnicity, and underlying liver disease between both groups (HIV and non-HIV). The HIV-positive group was younger and had a higher proportion of male recipients. In addition, there was a significant ethnic variation with a notable higher proportion of African Americans in the HIV group. Though a significant difference in underlying liver disease was observed in both groups, the lack of data on LT recipients with dual diagnosis (HBV-HCC or HCV-HCC) limits our interpretation of this finding.

HIV-Positive Liver Transplant Recipients

Transplantation trends during the study period for the HIV-positive patients are illustrated in Fig. 1. There was a steady increase in the number of LT recipients with HIV over time with the exception of a notable decline in 2008. The exact reason for the decrease in the number of LT recipients with HIV during the 2008 period is unknown, but a downward trend was also observed in the non-HIV group. Figure 2 shows the wide variation in geographic location (UNOS region) of the HIV-positive LT recipients during the study period. Though center-specific data was not available for analysis, we found approximately a sevenfold increase in the number of states with centers performing LT in HIV-positive patients during the study period (4–27 US states). The 1-, 3-, and 5-year patient and graft survival for the HIV-positive patients was 79, 65, 53 and 72, 57 and 53%, respectively. With stratification based on underlying liver diagnosis (HBV, HCV, HCC, and others), there was no significant

difference in patient and graft survival ($p = 0.22$ and 0.13, respectively). Furthermore, there were no ethnic differences in patient and graft survival.

In our study cohort, ethnic minorities accounted for 33.3% ($n = 45$) of the LT recipients with HIV infection. Among the ethnic minorities, African Americans represent 64.4% in contrast to 34.4% in the non-HIV group. Table 2 shows the demographics and clinical characteristics of the HIV-positive LT recipients. Though there were no differences in gender and underlying liver disease among ethnic groups, a significant difference in age and insurance payer was observed ($p = 0.008$).

Discussion

In the US, the use of liver transplantation as a therapeutic option for the HIV-infected individual with ESLD has evolved from an absolute contraindication to an indication for those that meet the commonly accepted eligibility criteria of a CD4 count ≥100 cells/mm^3 with undetectable plasma HIV RNA and a stable HAART regimen [7]. Despite recent reports of excellent post-transplant survival in HIV-positive recipients, very few ESLD patients with HIV (ESLD-HIV) have received liver transplantation.

In the present study, only 0.3% ($n = 135$) of the patients who received LT in the past 10 years (1999–2008) were documented as being HIV-positive. The reason for the discordance between recipients with HIV and the ESLD-HIV patients in need of LT is unclear. According to the recent Centers for Disease Control and Prevention estimates, there are about 1.2 million individuals in the US living with HIV. While the exact prevalence of HCV/HIV and HBV/HIV coinfection is unknown, various estimates suggest that more than 250,000 have HCV/HIV coinfection and more than 150,000 have HBV coinfection [8, 9]. Furthermore, the estimated prevalence of advanced fibrosis and cirrhosis in this cohort is 20–30%, with a much higher likelihood of progression to HCC in comparison to the non-HIV population [10–14]. With the reported rapid progression of fibrosis and higher rate of hepatic decompensation in this population, the number of HIV-positive LT recipients in the US probably likely represents a small proportion of those in need [15]. The factors contributing to this underrepresentation have not yet been explored, but may be related to a referral bias from HIV caregivers to transplant centers, a transplant workup bias, or a failure of patients to survive long enough to get to transplant centers.

Disparities in access to transplantation have been described within the entire transplant cohort. Inequitable access to organ transplant centers has been attributed to several factors including delayed referral, socioeconomic status, type of insurance payer (public or private), and geographic location [16–21]. Although this study was not designed to address accessibility to transplantation in the HIV population, we found significant variations in insurance status and geographic location of the LT recipients. In the non-HIV transplant population, non-private insurance has been associated with delayed referral for transplantation and lower likelihood of wait-listing or receipt of organ transplant [17, 22–24]. In our study cohort, a higher proportion of the recipients had non-private insurance (56%) compared to reports from the non-HIV transplant population (~28%) [17, 25]. It is uncertain if non-private insurance poses a similar barrier to LT in ESLD-HIV as has been described in the non-HIV population. In a recent study by Heslin et al. [26], the investigators report that in contrast to non-private insurance, those with private insurance have a higher likelihood of access to physicians with HIV expertise. It is not known if provision of care by an infectious disease specialist directly improves access to transplantation in those with ESLD-HIV. Therefore, studies to further examine the association between type of insurance and access to LT in ESLD-HIV will greatly improve our understanding of this complex interaction.

The exact reason for the observed differences in geographic location of LT recipients with HIV in our study is unknown. Barriers at the organ transplant center can indirectly contribute to geographic variation. At the institutional level, the lack of an LT center with expertise in HIV care and/or participation in the US-based multi-site HIVTR study may impede accessibility at different geographic locations [27]. Similarly, at the provider-level, variations in determination of LT eligibility for ESLD-HIV could influence accessibility at different geographic locations. Published surveys targeting program directors, HIV specialists, and transplant surgeons report a wide variation (33–50%) in the acceptance of ESLD-HIV as appropriate transplant candidates [28–30]. The geographic impact of the reported variations in practice and policies at LT centers is unknown. Identification of the factors contributing to geographic variation in LT accessibility for ESLD-HIV will provide useful insights into the obstacles that are unique to this population.

The role of patient-specific characteristics such as age, gender, and ethnicity on accessibility to LT has been extensively studied in the non-HIV population [31–33]. In a recent study by Moylan et al. [32], the investigators report female candidates as being less likely to receive LT in the MELD era. We show a similar disparity in LT recipients among HIV-positive females in our study cohort. With the recent reports from epidemiologic data showing a rise in the incidence of new HIV infections among females, particularly of African American ethnicity and a trend towards increasing liver-related deaths among women, studies to elucidate the specific barriers encountered in this group are necessary [34–36]. Consistent with reports from non-transplant settings, several studies have documented ethnic disparities in access, utilization and survival in LT population [33, 37, 38]. However, there is limited information on ethnicity and LT in the HIV population. Though there were no ethnic differences in age, gender, or liver disease among the HIV-positive LT recipients, there was a significant difference in insurance payer. African Americans were less likely to be covered by private insurance compared to the other ethnic groups. In particular they had a higher proportion of Medicaid coverage when compared to others. Despite this difference in insurance coverage, African Americans were not under-represented among the HIV LT recipients as opposed to the non-HIV LT population. Since African Americans are disproportionately affected with HIV, our findings may be a reflection of the current epidemiologic trend. Regarding post-transplant outcome, though there was a trend towards a decreased survival among African Americans, this was not statistically different. Future studies to determine if the reported lower post-LT survival among African Americans in the non-HIV population exists in recipients with HIV infection will provide invaluable information to the transplant community [38, 39].

Other patient-related factors not addressed in this study include the restrictive eligibility criteria and waiting list mortality for the ESLD-HIV population. In the HIV Organ Sharing and Transplantation (HOST) study, only 18.2% of the UNOS status 2A/B candidates with ESLD-HIV were eligible for LT based on an inclusion criteria of a CD4 count ≥200 cells/mm^3 with undetectable plasma HIV RNA [40]. Though the CD4 level in the latter study was higher than the traditional cut-off (≥100 cells/mm^3) used in US transplant centers, the findings provide insight into the viral-related barriers to wait list addition. Another barrier contributing to the inequitable LT access, which was not addressed in this study, is the reported higher waiting-list mortality observed in ESLD-HIV compared to the non-HIV population (36.2% vs. 15.5%) [41].

The primary limitations of this study are related to the retrospective nature and circumscribed reporting characteristics of the UNOS database. Despite these limitations, this study provides insight into the trends and patterns of LT utilization for the ESLD-HIV population in the US. The observed variation in patient demographics and geographic location identifies specific areas for future implementation of strategies to improve

accessibility and availability of LT, in anticipation of the expected burden of liver disease in this population. Furthermore, with the higher liver-related mortality in the ESLD-HIV population and recent reports of improved post-LT survival in those with and without concomitant HCC, it is imperative for the transplant community to provide a uniform guideline on criteria for transplant eligibility [42, 43]. The guidelines for transplant candidacy in the HIV population differs by transplant centers and also by respective countries. Though transplant programs mandate an undetectable HIV viral load, they differ in the requirement for CD4 levels and opportunistic infections. The US transplant centers primarily reflect the criteria based on the HIVTR study (CD4 count ≥100 or ≥200 cells/mm^3 in those with a history of opportunistic infections) [7]. This differs from the Spanish group, which excludes candidates with a history of opportunistic infections and uses a cut-off CD4 count of ≥100 cells/mm^3, while the British HIV Association recommends a CD4 count ≥200 or ≥100 cells/mm^3 in the presence of portal hypertension in contrast to the Italian criteria of a CD4 count ≥200 cells/mm^3 in candidates who have never been on ART therapy or ≥100 cells/mm^3 in patients without hepatic decompensation or those that are intolerant to ART therapy [44–47]. This variation in inclusion criteria impairs access to transplantation and makes it difficult to compare LT outcomes across geographic locations. Despite the issues highlighted above, the past decade has witnessed an increase in the use of liver transplantation as a modality for management of end-stage liver disease and HCC in HIV-infected individuals. Many key questions will potentially be answered when data from prospective trials of HIV transplantation in the US and Europe are reported in full.

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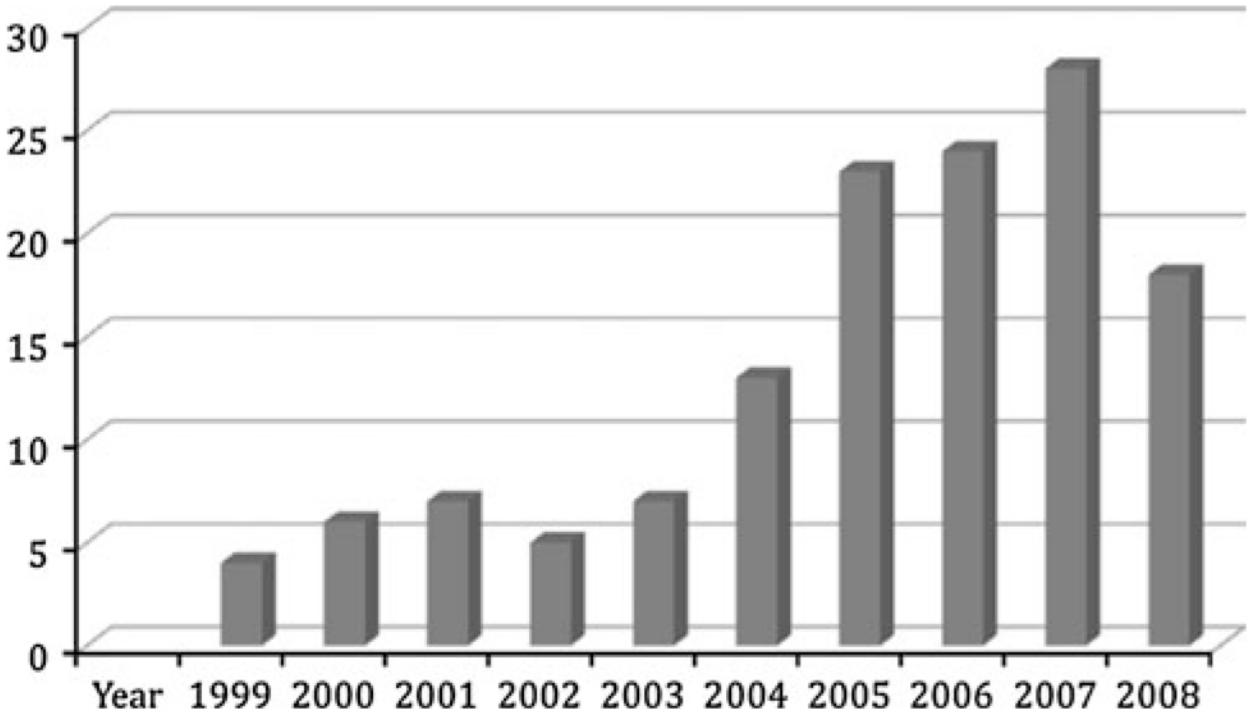

Fig 1.
Liver transplantation trends for HIV-positive recipients (1999–2008) ($p \leq 0.001$)

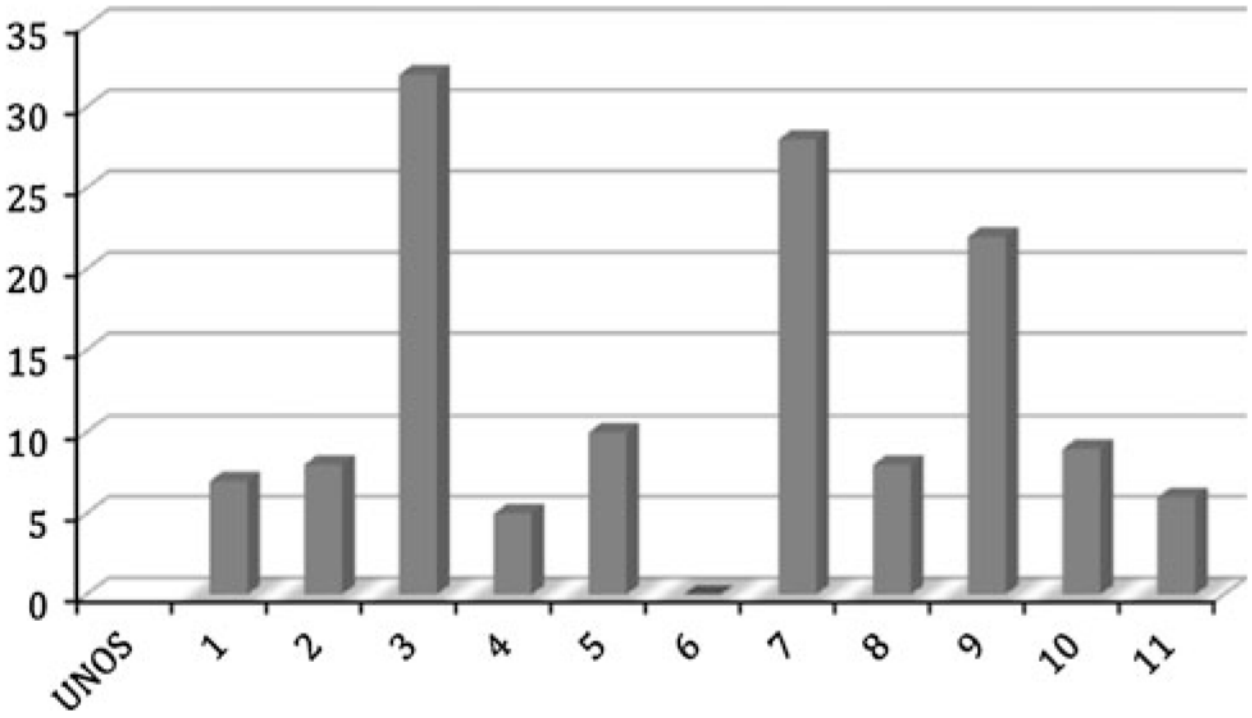

Fig 2.
Liver transplantation trends for HIV based on UNOS regions ($p \leq 0.001$)

Table 1

Demographics and clinical characteristics of the study population

Characteristic	Variable	HIV	Non-HIV	Total	*p* value
Age	*n*	135	48,199	48,334	<0.0001
	Mean ± SD	47.6 ± 8.54	52.0 ± 10.28	51.9 ± 10.28	
	Range	23.0–70.0	18.0–84.0	18.0–84.0	
	Median	48.0	53.0	53.0	
Gender	Female	26 (19.3%)	16,337 (33.9%)	16,363 (33.9%)	0.0003
	Male	109 (80.7%)	31,862 (66.1%)	31,971 (66.1%)	
Ethnicity	Asian	1 (0.7%)	2,038 (4.2%)	2,039 (4.2%)	<0.0001
	Black	29 (21.5%)	4,012 (8.3%)	4,041 (8.4%)	
	Hispanic	15 (11.1%)	5,862 (12.2%)	5,877 (12.2%)	
	Other	0 (0.0%)	498 (1.0%)	498 (1.0%)	
	White	90 (66.7%)	35,789 (74.3%)	35,879 (74.2%)	
Diagnosis group	HBV	14 (10.4%)	1,414 (2.9%)	1,428 (3.0%)	<0.0001
	HCC	17 (12.6%)	4,871 (10.1%)	4,888 (10.1%)	
	HCV	59 (43.7%)	16,230 (33.7%)	16,289 (33.7%)	
	Other	45 (33.3%)	25,684 (53.3%)	25,729 (53.2%)	

Table 2

Demographics and clinical characteristics of HIV-positive recipients

	Variable	Black	Hispanic	White	Total	*P* value
Age	*N*	29	15	90	134	0.008
	Mean ± SD	51.2 ± 8.88	49.9 ± 7.17	46.1 ± 8.32	47.6 ± 8.57	
	Range	23.0–67.0	41.0–63.0	24.0–70.0	23.0–70.0	
	Median	51.0	51.0	47.0	48.5	
Gender	Female	10 (52.6%)	4 (26.7%)	12 (13.3%)	26 (19.4%)	0.0333
	Male	19 (47.4%)	11 (73.3%)	78 (86.7%)	108 (80.6%)	
Diagnosis group	HBV	0 (0.0%)	2 (13.3%)	12 (13.3%)	14 (10.4%)	0.1785
	HCC	3 (10.4%)	3 (20%)	11 (12.2%)	17 (12.7%)	
	HCV	13 (44.8%)	4 (26.7%)	41 (45.5%)	58 (43.3%)	
	Other	13 (44.8%)	6 (40%)	26 (29%)	45 (33.6%)	
Insurance	Private	9 (31%)	7 (47%)	43(48%)	59 (44%)	0.016
	Medicaid	12(41%)	5 (33%)	15(17%)	32 (24%)	
	Non-Medicaid	7 (24%)	3 (20%)	29(32%)	39 (29%)	
	Other	1(4%)	–	3(3%)	4 (3%)	