

# Sofosbuvir-based therapy is associated with higher incidence of de-registration for clinical improvement in hepatitis C patients awaiting liver transplantation: An analysis of SRTR-Symphony database

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## Background

- With modern Direct Acting Antiviral agents (DAAs), high rates of sustained virological response (SVR) may be achieved even in patients with hepatitis C virus (HCV) infection and decompensated liver disease.
- SVR in decompensated patients may lead to clinical improvement, including patients awaiting liver transplantation (LT), who represent the subgroup of patients with the most advanced hepatic decompensation.

## Aims

- We investigate whether treatment with sofosbuvir (SOF)-containing regimens is associated with a higher incidence of waitlist removal for improved condition.

## Acknowledgement

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## Methods

### Data Sources:

- Scientific Registry of Transplant Recipients (SRTR): Waitlist registration and follow-up data in all LT candidates with HCV diagnosis with or without HCC
- Symphony database: An integrated database that incorporates prescription and pharmacy coverage data (<http://symphonyhealth.com>)

### Data Analysis

- Individual level data were linked between the SRTR and Symphony databases, allowing for a comprehensive analysis of drug utilization and therapy trends on the waiting list. This linked database provides access to prescription patterns at approximately 70% of all LT recipients.
- All adult patients with HCV diagnosis who were either on the LT waitlist on January 1, 2014 (n=884) or placed on the list during the calendar year of 2014 (n=1125) were identified in the SRTR database (total n=2009).
- After the data linkage, 1093 unique patients were verified to have coverage in the Symphony database.
- Patients who received SOF and those who did not were compared for their demographic and clinical characteristics.
- The incidence of waitlist removal for improved condition was calculated, censoring all other causes of waitlist removal such as transplantation and death.

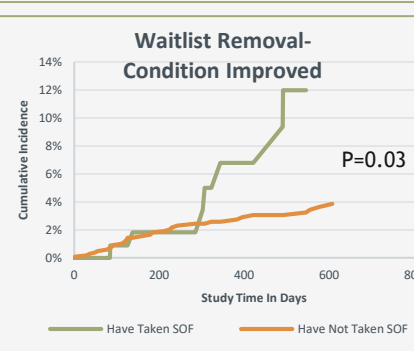
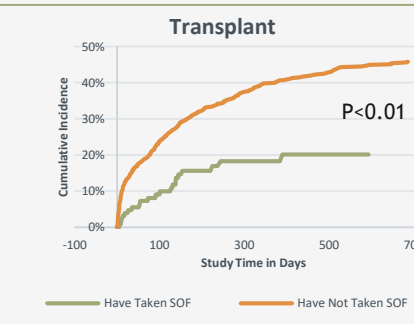
Table 1. Patient Characteristics

	Treated with SOF	Not Treated with SOF	p
Participants	154 (14.09%)	939 (85.91%)	
Time on Waitlist (Days)	921.21 (965.92)	617.26 (928.69)	<.01
Time on Waitlist (Years)	2.52 (2.64)	1.69 (2.54)	<.01
Age at Listing (years)	55.34 (6.82)	55.23 (6.48)	0.84
Male	129 (83.77%)	733 (78.06%)	0.11
White	141 (91.56%)	858 (91.37%)	0.93
Private Insurance	77 (50.00%)	410 (43.66%)	0.14
Lab MELD			
Under 15	108 (70.13%)	446 (47.55%)	<.01
15-29	46 (29.87%)	382 (40.72%)	
30+	0 (0.00%)	110 (11.73%)	
HCC (Exc. Points)	13 (8.44%)	72 (7.67%)	0.74
Bilirubin	2.10 (1.39)	4.88 (7.39)	<.01
Serum Creatinine	1.06 (0.91)	1.34 (1.15)	<.01
Ascites (none)	53 (34.42%)	228 (24.31%)	<.01
Encephalopathy (none)	70 (45.45%)	335 (35.71%)	0.03

Table 2. Medication Profile

	Treated with SOF	Not Treated with SOF	p
<b>HCV medications</b>			
Ribavirin	72 (46.75%)	3 (0.32%)	<.01
Peg-IFN alfa	4 (2.60%)	1 (0.11%)	<.01
Other*	35 (22.73%)	2 (0.21%)	<.01
<b>Other Medications</b>			
Beta Blockers	73 (47.40%)	326 (34.72%)	<.01
Diuretics	110 (71.43%)	480 (51.12%)	<.01
Spironolactone	84 (54.55%)	400 (42.60%)	<.01
Furosemide	100 (64.94%)	427 (45.47%)	<.01
Ciprofloxacin	57 (37.01%)	249 (26.52%)	<.01
Lactulose	86 (55.84%)	412 (43.88%)	<.01
Rifaximin	75 (48.70%)	340 (36.21%)	<.01
Midodrine	4 (2.60%)	51 (5.43%)	0.14
Octreotide	1 (0.65%)	0 (0.00%)	NA

\* Included 'Daklinza', 'Olysio', 'Viekira', 'Zepatier', and 'Technivie'



## Summary

### Table 1

- 14% of LT candidates with HCV received SOF-based DAA therapy.
- SOF-treated patients tended to have less severe decompensation: Majority of SOF-treated patients had MELD<15, while none with MELD>30 were treated.
- There was no significant difference in the proportion of HCC patients.

### Table 2

- SOF-treated patients were more likely to receive other medications commonly used in patients with hepatic decompensation.

### Figures

- SOF-treated patients were less likely to undergo transplant (or die), as expected from their lower MELD.
- SOF-treated patients were more frequently removed from waiting list for improved condition.

## Conclusion

- In this nationally representative pharmacy-linked data, a relatively small fraction of LT candidates with HCV received SOF-based DAA therapy.
- Fewer SOF-treated patients received transplant or died, at least in part because of lower MELD score.
- SOF-treated patients had a higher incidence of being removed for improved condition. This trend became only apparent approximately one year after treatment completion.



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