

Impact of HCV Treatment on Liver Transient Elastography (TE): Prospective Data from the CORE Hepatitis Cohort

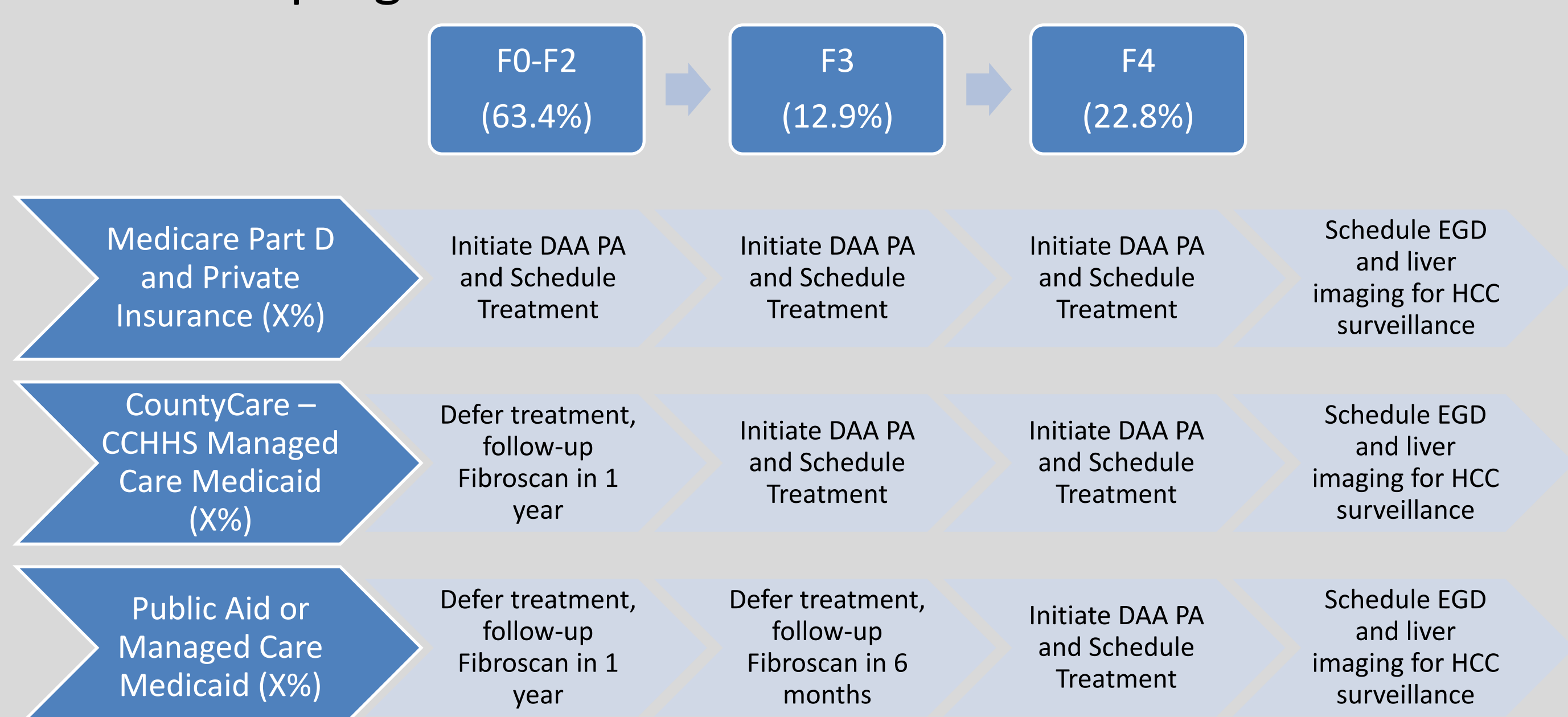
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ID WEEK 2016, OCT 26-30, 2016- NEW ORLEANS, LA
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Background

- In our urban clinic a significant number of HCV patients have not received HCV treatment, primarily due to insurance restrictions on medication coverage.
- In Illinois, Medicaid coverage of HCV therapy is restricted to patients with cirrhosis.
- We initiated an algorithm to ensure that patients who were not treated remained in care with follow up scans to assess fibrosis progression.



- Transient elastography (TE), an approved point of care method for fibrosis assessment is used in our clinic.
- Among treated patients, data on post cure fibrosis regression in HIV/HCV coinfection are sparse.
- We evaluated changes in fibrosis as measured by TE to assess the impact of HCV treatment.

Methods

- All HCV RNA+ patients with two or more TEs performed as part of routine care at the Ruth M. Rothstein CORE center, Chicago from April 2014 to April 2016 were analyzed.
- HCV treatment status was identified for all patients.
- Mann Whitney and Fisher's exact tests were used to determine differences in TE scores in follow up scans between the treated and untreated pts.

FIBROSCANS

- Scans with at least 10 valid measurements and IQR >30% are considered valid.
- Fibrosis staging is based on transient elastography (TE) scores:
 - F4 (Cirrhosis) ≥ 12.5 kPa
 - F3: 9.5-12.4 kPa
 - F2: 7.1-9.4 kPa
 - F0-F1: <7.1 kPa

Results

Table 1: PATIENT CHARACTERISTICS	Total, n=232 Median or N (%)	Treated, n=50 Median or N (%)	Not treated, n=182 Median or N (%)	p-value
Age at first visit	57	56.6	57	.601
Male	161(69.4)	35(70)	126(69.2)	1.000
Female	71(30.6)	15(30)	56(30.8)	
African American	155(66.8)	32(64)	123(67.6)	
White	38(16.3)	7(14)	30(16.5)	
Latino	36(15.5)	11(22)	25(13.7)	
HIV Status				<0.001
HIV Positive	149(64.2)	43(86)	106(58.2)	
HIV Negative	82(35.3)	7(14)	75(41.2)	
Medicare	53(22.8)	13(26)	40(22)	
Medicaid	98(42.2)	20(40)	78(42.9)	
County Care	62(26.7)	13(26)	49(26.9)	
Private Insurance	5(2.2)	2(4)	3(1.6)	
Self-Pay/Uninsured	14(6)	2(4)	12(6.6)	
Fibrosis stage, Baseline				<0.001
F0-F1 (<7.1)	89 (38.4)	4 (8)	85 (46.7)	<0.001
F2 (7.1-9.4)	58 (25)	8 (16)	50 (27.5)	.1391
F3 (9.5-12.5)	30 (12.9)	10 (20)	20 (11)	.1001
F4 (>12.5) Cirrhosis	52 (22.8)	28 (56)	25 (13.7)	<0.001

- Patients who were treated were more likely to be HIV+ (86% vs 58%; p<0.001) and had more significant fibrosis (F3 or F4); 76% vs 25% (p <0.001).

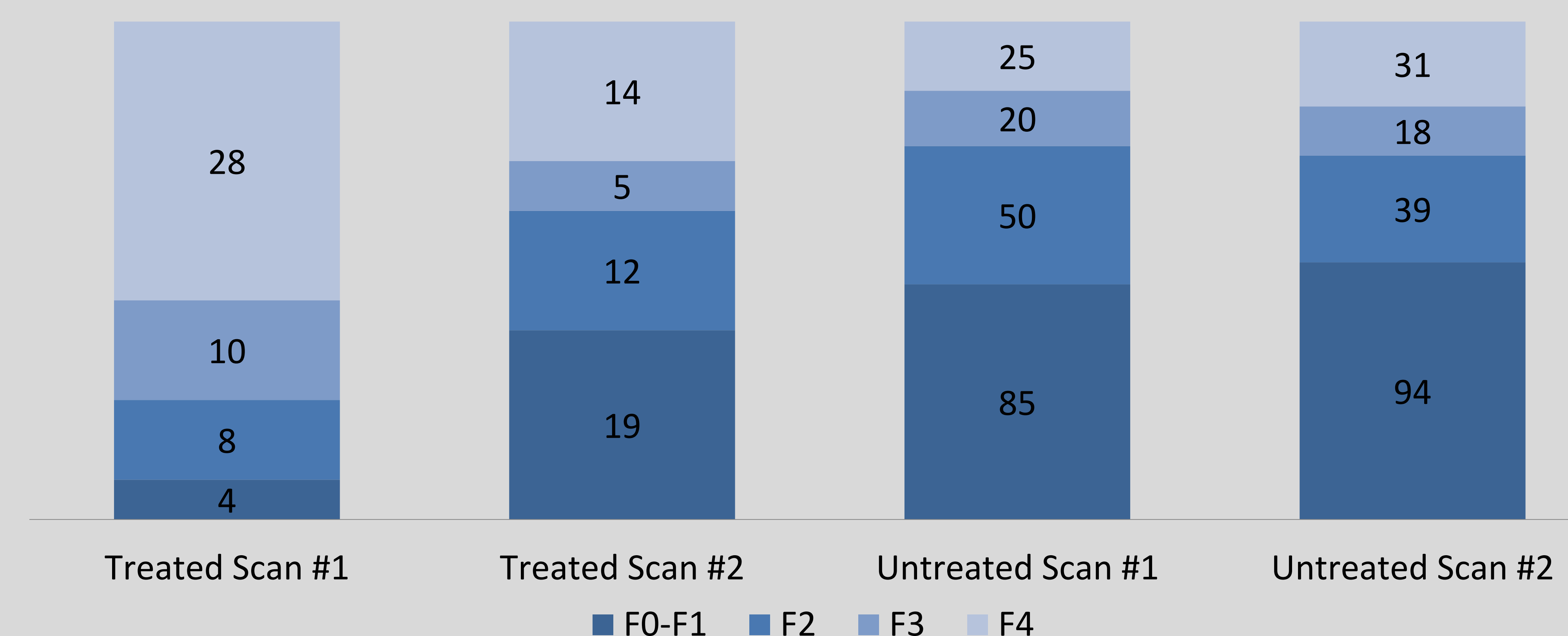
- Forty-six (92%) of the treated patients achieved SVR12. The four patients who relapsed were cirrhotic, and two were treatment experienced.
- Among untreated pts, female sex and baseline fibrosis F3 were associated with fibrosis progression (p=0.002).
- HIV co-infection was not associated with fibrosis progression.

Results

Table 2: FIBROSCAN SCORES AT BASELINE AND FOLLOW UP	Total, n=232	Treated, n=50	Not treated, n=182	p-value
Fibroscan score, Baseline	8.1 (6.1, 11.8)	13.6 (9.9, 7.9)	7.5 (5.5, 9.9)	<0.001
Fibroscan score, Follow-up	7.2 (5.5, 10.2)	8.5 (6, 12)	7.1 (5.4, 9.9)	.069
Months between scans	10 (7,13)	10 (8, 13)	10 (6, 13)	.385
% Improved 1 Stage	49 (21.1)	13 (26)	36 (19.8)	.335
% Cirrhotic at follow up	44 (19)	14 (28)	30 (16.4)	.1013

Table 3: PATIENT RESULTS	Total, n=232 N (%)	Treated, n=50 N (%)	Not treated, n=182 N (%)	p-value
Change in Fibroscan score (absolute change)	-.7 (-2.5, 1.3)	-4.6 (-6.3,-2.4)	-.1 (-1.7,1.7)	<0.001
% Improved 2 Stages	19 (8.2)	13 (26)	6 (3.3)	<0.001
% Worsened 1+ Stages	39 (16.8)	3 (6)	36 (19.8)	.0192

Figure 1: FIBROSIS STAGE AT FIBROSCAN #1 and #2 BY TREATMENT STATUS



Conclusions

- HCV treatment was a significant predictor of fibrosis regression in our cohort, with the majority of the treated pts patients improving >1 fibrosis stage on follow up.
- Fibrosis progression >1 stage was significantly increased in untreated pts over a median of 10 months with baseline significant fibrosis associated with progression.
- These results underscore the pathophysiological benefit of treatment for patients with chronic HCV and further highlights the need for policies to enable treatment for a greater number of patients, especially those belonging to vulnerable populations.