



Patient Reported Outcomes Among Pediatric Patients with Nonalcoholic Fatty Liver Disease: TARGET-NASH

Bryan Rudolph¹, Jacob Bilhartz², Cheryl Schoen³, Praveen Selvakumar⁴, Sirish Palle⁵, Stavra Xanthakos⁶, Patrick McKiernan⁷, Alisha Mavis⁸, A Sidney Barritt⁹, Miriam Vos¹⁰

¹Children's Hospital at Montefiore, Bronx, NY; ²University of Michigan, Ann Arbor, MI; ³TARGET PharmaSolutions, Durham, NC; ⁴Cleveland Clinic, Cleveland, OH; ⁵University of Oklahoma, Norman, OK; ⁶Cincinnati Children's Hospital, Cincinnati, OH; ⁷Children's Hospital of Pittsburgh, Pittsburgh, PA; ⁸Duke University, Durham, NC; ⁹University of North Carolina at Chapel Hill, Chapel Hill, NC; ¹⁰Emory University, Atlanta, GA

INTRODUCTION

- Children with nonalcoholic fatty liver disease (NAFLD) are believed to have poorer overall quality of life (QOL) than children without NAFLD. Whether QOL varies by severity of NAFLD is unknown

OBJECTIVE

- To describe self-reported feelings of fatigue, anxiety, and depression among children with non alcoholic fatty liver disease

METHODS

Cohort

- TARGET-NASH is an ongoing longitudinal, observational cohort of >3,700 patients with NAFLD managed according to local practice standards at 55 academic and community sites in the United States. Patient narratives, laboratory, pathology, and imaging data were extracted and stored in a secured database. Patient reported outcomes (PRO) measures were collected annually. Patients contributed blood samples to a biospecimen repository for biomarker validation and translational research

Study Population

- Of 413 pediatric patients with NAFLD enrolled in TARGET-NASH between August 2016 and March 2019, data on 215 pediatric patients (52%) with complete PROs were analyzed

Outcome Measure

- At the time of enrollment, patients completed the Validated Patient-Reported Outcomes Measurement Information System (PROMIS) short form measures for the following domains: fatigue, anxiety, and depression

In the past 7 days...	Never	Almost Never	Sometimes	Often	Almost Always
Being tired made it hard for me to keep up with my schoolwork	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Being tired made it hard for me to play or go out with my friends as much as I'd like	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

- Scores for each domain were reported as Standardized T scores with a Mean of 50 and a SD of 10

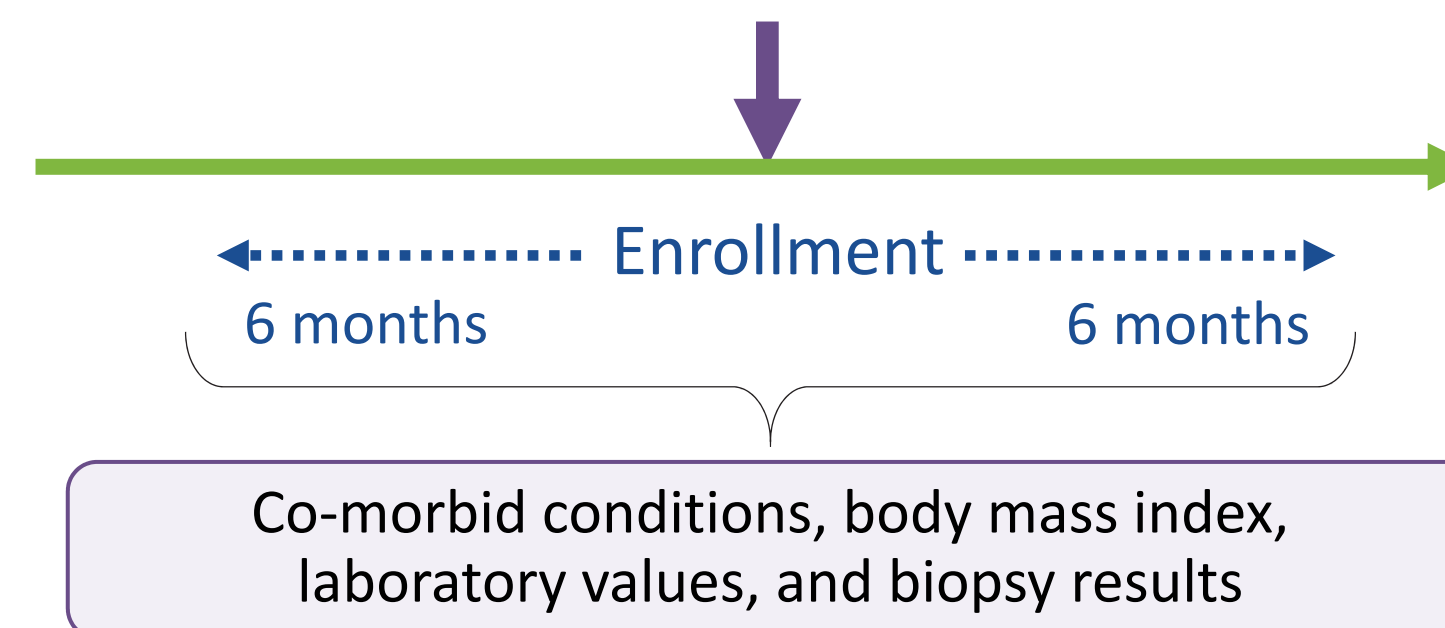
Statistical Analysis

- Mean PROMIS standard T scores were compared by Fisher T test

METHODS

Patient Characteristics

- Patient characteristics were captured within 6 months of enrollment



RESULTS

Table 1. Distribution of Clinical Characteristics by Liver Disease Severity

Severity	NAFLD Cirrhosis/NASH N (%)	NAFL N (%)	P Value
Age at Study Entry (mean, SD)	N = 162 13.7 (2.8)	N = 53 13.7 (3.0)	0.93
Gender			0.67
Male	108 (66.7)	37 (69.8)	
Race			0.31
White	109 (67.3)	41 (77.4)	
Black or African American	8 (4.9)	3 (5.7)	
American Indian/Alaska Native	4 (2.5)	1 (1.9)	
Asian	1 (0.6)	0 (0.0)	
Native Hawaiian/Other Islander	1 (0.6)	0 (0.0)	
Other	19 (11.7)	4 (7.5)	
Not Reported	20 (12.3)	4 (7.5)	
Ethnicity			0.40
Hispanic	74 (45.7)	20 (37.7)	
Percentile for Body Mass Index			0.38
<85 th	4 (2.5)	3 (5.7)	
85 th -95 th	7 (4.3)	2 (3.8)	
>95 th	138 (85.2)	45 (85.0)	
Not Available	13 (8.0)	3 (5.7)	
History of Type II Diabetes			0.71
Yes	24 (14.8)	9 (17.0)	
ALT (IU/L)			0.02
<75	81 (50.0)	37 (70.0)	
75-250	64 (39.5)	13 (24.5)	
>250	7 (4.3)	1 (1.9)	
Not Available	10 (6.2)	2 (3.8)	

RESULTS

Table 2. Distribution of PROMIS Scores by Liver Disease Severity

PROMIS Questionnaire T-Score	NAFLD Cirrhosis/NASH (N=162) Mean (SD)	NAFL (N=53) Mean (SD)	P Value
Pediatric Fatigue	44.3 (10.1)	50.5 (11.7)	<0.01
Pediatric Anxiety	46.7 (10.4)	49.0 (12.4)	0.19
Pediatric Depression	45.1 (10.5)	49.9 (12.0)	0.01

Table 3. Distribution of PROMIS Scores by ALT Category

PROMIS Questionnaire T-Score	<75 U/L (N= 118) Mean (SD)	75-250 U/L (N=77) Mean (SD)	>250 U/L (N=8) Mean (SD)	P Value
Pediatric Fatigue	45.5 (11.17)	46.6 (10.67)	42.9 (10.46)	0.59
Pediatric Anxiety	46.5 (11.00)	48.1 (10.87)	50.1 (11.97)	0.44
Pediatric Depression	45.6 (10.64)	47.1 (11.81)	47.4 (12.38)	0.64

CONCLUSIONS

- There was no difference in mean anxiety QOL scores among pediatric patients when stratified by NAFLD disease severity (i.e. NAFL, NASH/NAFLD Cirrhosis) or ALT
- Patients with NAFLD Cirrhosis/NASH reported lower fatigue and depression QOL scores than those with NAFL
- Findings may be limited by heterogeneity between the groups (i.e. NAFL,NASH/NAFLD Cirrhosis) or by non-response bias among sicker patients

SOURCES & ACKNOWLEDGEMENTS

<http://www.healthmeasures.net/score-and-interpret/interpret-scores/promis>

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