Management of Hepatocellular Carcinoma (HCC) in a Real Life Multinational, Longitudinal, Observational Study (TARGET-HCC)

TARGET-HCC

Roniel Cabrera[1], Amit Singal[2] , Massimo Colombo[3], Anthony El-Khoueiry[4] , R. Kate Kelley[5], Hannah Lee[6], Laura Malahias[7], Tim Meyer[8], Pippa Newell[9], Neehar Parikh[10], Bruno Sangro[11], K Rajender Reddy[12], Richard Zink[7], Adrian Di Bisceglie[13]

[1] University of Florida, Gainesville, Fl , [2] University of Texas Southwestern Medical Center, Dallas, TX ,[3]Center for Translational Research in Liver Disease, Humanitas Research Hospital, Rozanno Italy, [4] University of Southern California, Los Angeles, CA, [5]University of California, San Francisco, [6]Division of Gastroenterology, Hepatology and Nutrition, Virginia Commonwealth University, Richmond, VA, [7] TARGET PharmaSolutions, Chapel Hill, NC, [8] Royal Free Hospital and UCL Cancer Institute, University College London, UK, [9] The Oregon Clinic, Portland, OR, [10] Division of Internal Medicine, University of Michigan, Ann Arbor, MI, [11] Department of Internal Medicine, Clinica Universidad de Navarra, Madrid Spain,[12] Department of Medicine, University of Pennsylvania, Philadelphia, PA, [13] Health Saint Louis University Hospital, Saint Louis University Liver Center, Saint Louis, MO

INTRODUCTION

Multiple therapeutic approaches are available for the treatment of patients with HCC. Treatment sequencing is usually based on stage at time of presentation. Recently, there has been an expansion of systemic therapeutic options including tyrosine kinase inhibitors and immune checkpoint inhibitors for HCC. **This study evaluated the prevalence of treatment within the first six months of diagnosis according to BCLC stage among patients enrolled in TARGET-HCC.**

METHODS

TARGET HCC

- TARGET-HCC is an ongoing longitudinal, observational cohort of patients with HCC managed according to local practice standards at 55 academic and community sites (including hepatology and oncology clinics) in the US and Europe.
- Participating clinics provided redacted medical records (structured and unstructured data) from consented patients. Patient narratives, laboratory, endoscopic, pathology, infusion, and imaging data were extracted and stored in a secured database. Patient reported outcome (PRO) measures were also collected on a quarterly basis at select sites. Patients also contributed blood samples to a biospecimen repository for biomarker validation and translational research.
- HCC was staged at diagnosis using the Barcelona Clinic Liver Cancer (BCLC)

Study Population

This study included 1,027 patients with a diagnosis of HCC enrolled in TARGET-HCC between January 9, 2017 to January 28, 2019

Patients with HCC diagnosed within three years of enrollment
N=1,027

Stage 0	Stage A	Stage B	Stage C	Stage D
N=106	N=556	N=250	N=94	N=21

Outcome Measure

- Treatment for HCC was defined as “any treatment” within six months of diagnosis

Follow up period

Three years — Enrollment — Right Censored 1/28/2019

Statistical Analysis

The percentage of patients with a given treatment was calculated by BCLC staging at diagnosis. Chi squared and t tests were used to assess the difference in proportions and means respectively.

RESULTS

Figure 1. Distribution of treatment interventions among patients with HCC within six months of diagnosis by BCLC stage at diagnosis

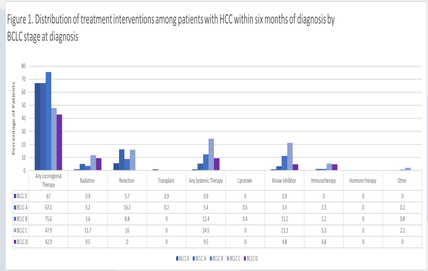
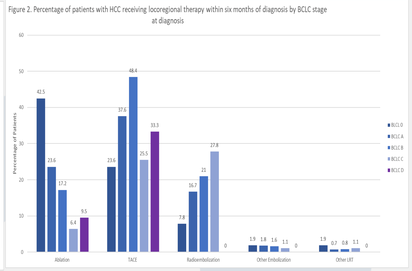


Figure 2. Percentage of patients with HCC receiving locoregional therapy within six months of diagnosis by BCLC stage at diagnosis



Treatment pending: BCLC stage 0: 10.4%, stage A:10.4%, stage B:6.8%, stage C:13.8%, stage D: 14.3%)

Categories are not mutually exclusive and include patients that had a treatment within 6 months of diagnosis

CONCLUSIONS

- 47% of patients with BCLC stage C/D received some type of locoregional therapy within 6 months of diagnosis
- Ablation was most common (42.5%) among patients with BCLC stage 0 whereas TACE was more frequent therapy (37.6%) for patients with BCLC-A stage HCC
- TACE was most common (48.4%) among patients with BCLC stage B
- Patients with BCLC stage C were more than twice as likely to receive any systemic therapy compared to all other stages
- The rate of locoregional therapy within 6 months of diagnosis of was higher than expected in patients with advanced stages of HCC and inconsistent with current practice guidelines

ACKNOWLEDGEMENTS

TARGET-HCC is a study sponsored by Target PharmaSolutions (TPS). TPS is a real-world clinical data company based in Durham, NC. The authors would like to thank all the investigators, participants and research staff associated with TARGET-HCC. ClinicalTrials.gov Identifier: NCT02954094

Table 1. Descriptive characteristics of the patients with HCC by BCLC stage at diagnosis

Patient Characteristics	BCLC 0 (N=106)		BCLC A (N=556)		BCLC B (N=250)		BCLC C (N=94)		BCLC D (N=21)	
Age at Diagnosis (years); Median(min-max)	64 (26-88)		64 (31-88)		64 (43-88)		63 (39-89)		61 (44-76)	
Months from Diagnosis to enrollment; Median (min-max)	10 (0-34)		6.0 (0-35)		6.0 (0-35)		3.0 (0-35)		4.0 (0-26)	
	N	%	N	%	N	%	N	%	N	%
Gender										
Female	35	33	129	23.2	44	17.6	27	28.7	6	28.6
Male	71	67	427	76.8	206	82.4	67	71.3	15	71.4
Race										
White	76	71.7	393	70.7	164	65.6	66	70.2	17	81
Black	19	17.9	95	17.1	59	23.6	22	23.4	2	9.5
Other	4	3.8	46	8.3	16	6.4	4	4.3	1	4.8
Not Available	7	6.6	22	4	11	4.4	2	2.1	1	4.8
Ethnicity										
Hispanic or Latino	13	12.3	71	12.8	27	10.8	10	10.6	4	19
Not Hispanic or Latino	86	81.1	457	82.2	212	84.8	81	86.2	16	76.2
Other			4	0.7	1	0.4				
Not Available	7	6.6	24	4.3	10	4	3	3.2	1	4.8
Etiologies of Liver Disease*										
Hepatitis C	65	61.3	320	57.6	157	62.8	60	63.8	9	42.9
Hepatitis B	23	21.7	84	15.1	36	14.4	13	13.8	1	4.8
Nonalcoholic fatty liver disease **	14	13.2	66	11.9	24	9.6	8	8.5	4	19
Alcohol use***	26	24.5	121	21.8	61	24.4	15	16	6	28.6
Macrovessel Invasion										
Yes	0	0	0	0	0	0	40	42.6	1	4.8
Extrahepatic Spread										
Yes	0	0	0	0	0	0	53	56.4	0	0
Child Pugh at Diagnosis										
A	44	41.5	144	25.9	69	27.6	28	29.8	0	0
B	1	0.9	78	14	31	12.4	15	16	1	4.8
C	0	0	0	0	0	0	0	0	19	90.5
Not Available	61	57.5	334	60.1	150	60	51	54.3	1	4.8
Cirrhosis at Diagnosis	71	67	313	56.3	143	57.2	46	48.9	21	100
Survival Status										
Alive	100	94.3	485	87.2	203	81.2	60	63.8	15	71.4
Dead	6	5.7	71	12.8	47	18.8	34	36.2	6	28.6

*Conditions of interest at timing of initial BCLC staging among patients diagnosed within three years of enrollment
** Documentation of nonalcoholic fatty liver disease in either the medical history or as an adverse event, documentation of NAFLD in the medical record may be an under representation of the actual prevalence in this population
*** Patients with a history of alcohol abuse or an audit score ≥7 at the time of diagnosis