REAL-WORLD EVIDENCE FOR IMPROVEMENT OF CLINICAL SYMPTOMS AND WELLBEING OF OST PATIENTS AFTER THERAPY WITH IFN-FREE SOFOSBUVIR–BASED REGIMENS: RESULTS FROM THE DHC-R

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Objectives

Together with other risk groups, Opioid substitution treatment (OST) patients exhibit the highest prevalence for chronic hepatitis C in Germany. The introduction of new direct acting antivirals (DAA) in 2014 has revolutionized the treatment of chronic hepatitis C. However, to date only limited data exists on the impact of a DAA-mediated cure (SVR12) on well-being and clinical symptoms in OST patients. This analysis aimed to determine the real-world impact of SVR12 on patient-reported outcomes (PRO, based on SF-36 questionnaires) and clinical symptoms (e.g. fatigue) in patients with and without OST (OST, Non-OST).

Methods

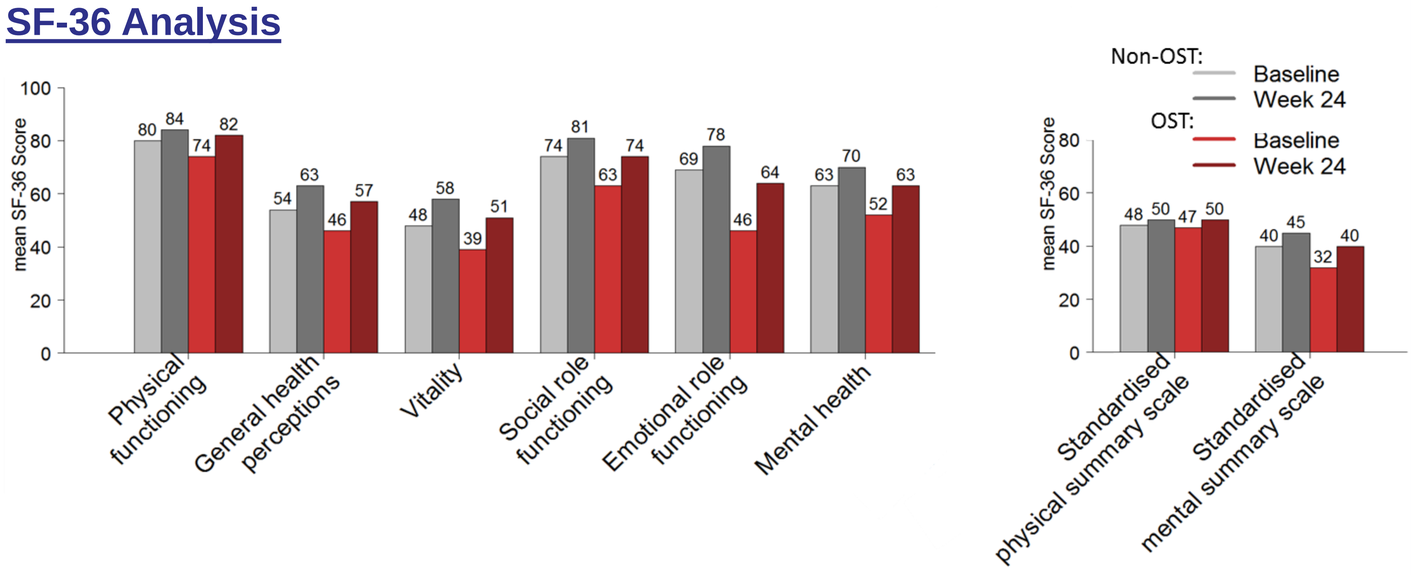
The German Hepatitis C-Registry (DHC-R) is a national, multicenter real-world registry study, where patients are treated at the discretion of the physician. Data is collected using a web based system. This interim analysis includes data of 703 patients, who achieved SVR12 after treatment with interferon (IFN)-free Sofosbuvir (SOF)-based regimens between February 1st, 2014 and June 30, 2016. Only patients with available SF-36 data and data on clinical symptoms at baseline and week 24 after the end of treatment were considered for this analysis (Non-OST: 650 and OST: 53).

Results

Demographics:

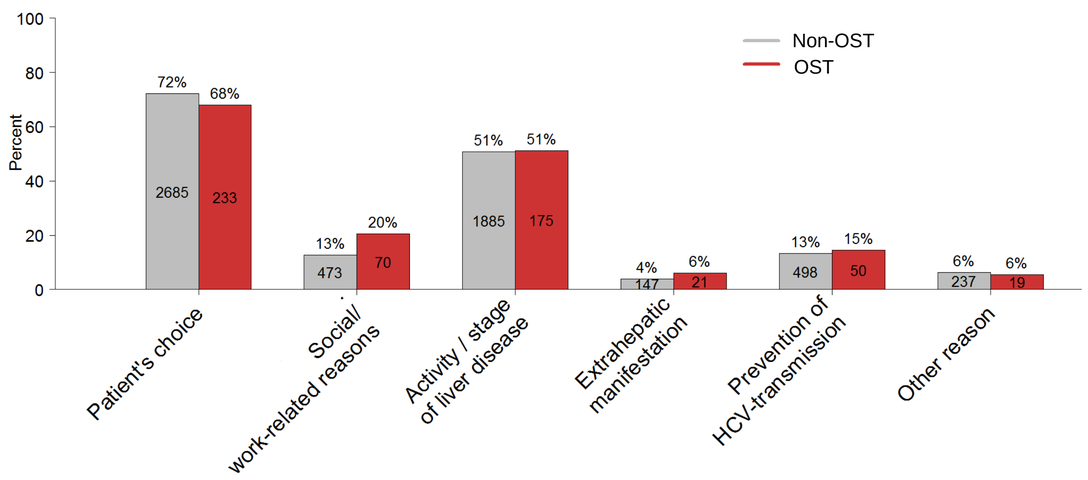
		Non-OST (N=3719)	OST (N=342)	Total (N=4061)
Sex N (%)	male	2044 (55,0)	265 (77,5)	2309 (56,9)
Age (years)	mean (sd)	54,5 (12,4)	46,6 (8,80)	53,8 (12,3)
BMI	mean (sd)	26,0 (4,70)	25,8 (5,10)	26,0 (4,80)
Initial viral load N (%)	not available	45 (1,2)	5 (1,5)	50 (1,2)
	qual. positive nnb.	3 (<1,0)	0 (<1,0)	3 (<1,0)
	< 6000000 IU/ml	3274 (88,0)	293 (85,7)	3567 (87,8)
	≥ 6000000 IU/ml	397 (10,7)	44 (12,9)	441 (10,9)
Previous therapy N (%)	yes	1899 (51,1)	113 (33,0)	2012 (49,5)
	no	1820 (48,9)	229 (67,0)	2049 (50,5)
HCV Genotype N (%)	GT 1	3032 (81,5)	234 (68,4)	3266 (80,4)
	GT 1a	1246 (33,5)	182 (53,2)	1428 (35,2)
	GT 1b	1598 (43,0)	45 (13,2)	1643 (40,5)
	other GT 1 subtype	171 (4,6)	6 (1,8)	177 (4,4)
	GT 2	179 (4,8)	18 (5,3)	197 (4,9)
	GT 3	349 (9,4)	80 (23,4)	429 (10,6)
	GT 4	142 (3,8)	8 (2,3)	150 (3,7)
	other	17 (<1,0)	2 (<1,0)	19 (<1,0)
Estimated duration of infection (years)	mean (sd)	20,2 (12,40)	16,3 (7,50)	19,9 (12,10)
Cirrhosis N (%)	yes	1111 (29,9)	111 (32,5)	1222 (30,1)
	no	2608 (70,1)	231 (67,5)	2839 (69,9)
Status of Employment N (%)	not available	455 (12,2)	33 (9,6)	488 (12,0)
	yes	1675 (45,0)	108 (31,6)	1783 (43,9)
	no	1589 (42,7)	201 (58,8)	1790 (44,1)
HCV/HBV co-infection N (%)	unknown	1985 (53,4)	153 (44,7)	2138 (52,6)
	yes	31 (<1,0)	6 (1,8)	37 (<1,0)
	no	1702 (45,8)	183 (53,5)	1885 (46,4)
Consumption of alcohol N (%)	not available	12 (<1,0)	0 (<1,0)	12 (<1,0)
	no	3264 (87,8)	286 (83,6)	3550 (87,4)
	yes	443 (11,9)	56 (16,4)	499 (12,3)
	> 40 g/day men / > 30 g/day women	56 (1,5)	19 (5,6)	75 (1,8)
	≤ 40 g/day men / ≤ 30 g/day women	387 (10,4)	37 (10,8)	424 (10,4)
Consumption of cannabis N (%)	not available	1 (<1,0)	0 (<1,0)	1 (<1,0)
	yes	100 (2,7)	52 (15,2)	152 (3,7)
	no	3618 (97,3)	290 (84,8)	3908 (96,2)
Tobacco Smoker N (%)	yes	1077 (29,0)	256 (74,9)	1333 (32,8)
	no	2642 (71,0)	86 (25,1)	2728 (67,2)

SF-36 Analysis



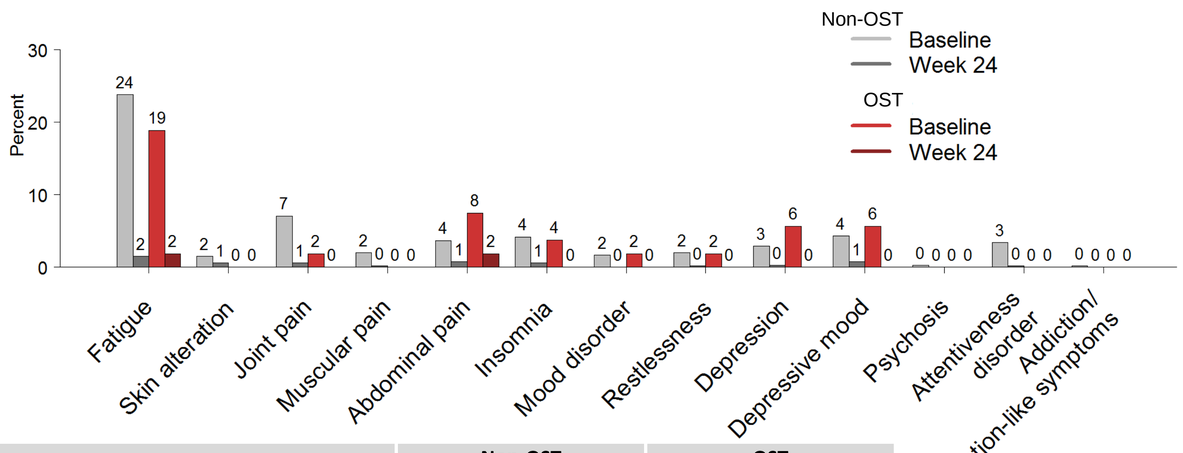
Both patient groups benefit from DAA treatment. In OST patients, distinct improvements were seen in the domains general health perceptions, vitality and emotional role functioning.

Reason for HCV therapy (multiple answers possible)

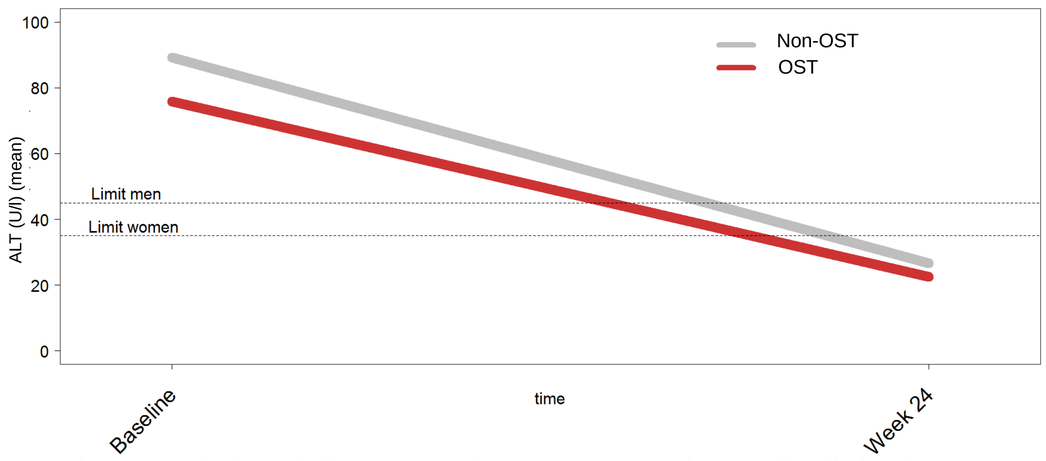


Patient‘s choice was the most common reason for initiating treatment for hepatitis C in both patient groups.

Clinical symptoms & ALT values



	Non-OST (N=650)		OST (N=53)	
Clinical symptom	**Baseline**	**Week 24**	**Baseline**	**Week 24**
Fatigue N (%)	155 (23,8)	10 (1,5)	10 (18,9)	1 (1,9)
Skin alteration N (%)	10 (1,5)	4 (<1,0)	0 (<1,0)	0 (<1,0)
Joint pain N (%)	46 (7,1)	4 (<1,0)	1 (1,9)	0 (<1,0)
Muscular pain N (%)	13 (2,0)	1 (<1,0)	0 (<1,0)	0 (<1,0)
Abdominal pain N (%)	24 (3,7)	5 (<1,0)	4 (7,5)	1 (1,9)
Insomnia N (%)	27 (4,2)	4 (<1,0)	2 (3,8)	0 (<1,0)
Tetchiness N (%)	11 (1,7)	0 (<1,0)	1 (1,9)	0 (<1,0)
Restlessness N (%)	13 (2,0)	1 (<1,0)	1 (1,9)	0 (<1,0)
Depression N (%)	19 (2,9)	2 (<1,0)	3 (5,7)	0 (<1,0)
Depressive mood N (%)	28 (4,3)	5 (<1,0)	3 (5,7)	0 (<1,0)
Psychosis N (%)	2 (<1,0)	0 (<1,0)	0 (<1,0)	0 (<1,0)
Attentiveness disorder N (%)	22 (3,4)	1 (<1,0)	0 (<1,0)	0 (<1,0)
Addiction/ detoxication-like symptoms N (%)	1 (<1,0)	0 (<1,0)	0 (<1,0)	0 (<1,0)



At week 24 of the follow-up phase, a number of clinical symptoms had decreased compared to Baseline, with the highest decrease seen in fatigue. Mean ALT values were within the normal range for men and women in both patient groups at this time point.

DHC-R Deutsches Hepatitis C-Register — Leberstiftungs-GmbH

Die hier gezeigten Daten stammen aus dem **Deutschen Hepatitis C-Register** (DHC-R), das die Deutsche Leberstiftung (über die Leberstiftungs-GmbH Deutschland) in Kooperation mit dem Berufsverband Niedergelassener Gastroenterologen Deutschlands (bng) führt.

Wissenschaftlicher Leiter: Dietrich Hüppe, Herne

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Das Deutsche Hepatitis C-Register wird von folgenden pharmazeutischen Unternehmen unterstützt: AbbVie Deutschland GmbH & Co. KG, Bristol-Myers Squibb GmbH & Co. KGaA, Gilead Sciences GmbH, Janssen-Cilag GmbH, MSD Sharp & Dohme GmbH und Roche Pharma AG.

Conclusion

For the first time our analysis describes the impact of a DAA-mediated cure on well-being and clinical symptoms (especially fatigue) in patients with and without OST in the real-life setting. In summary, both patient groups benefit from HCV therapy besides achieving SVR12.

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