THE ASSOCIATION BETWEEN TOLERABILITY ISSUES AND HEALTH OUTCOMES AMONG PATIENTS WITH HCV IN BRAZIL

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ABSTRACT

OBJECTIVES: The hepatitis C virus (HCV) is one of the most common blood-borne viral illnesses in Brazil and associated with various sequelae including cirrhosis and hepatocellular carcinoma. Treatment can be effective but also carries the risk of tolerability issues. The current study assessed the prevalence of tolerability issues among HCV patients and their association with health outcomes.

METHODS: Data were derived from the 2011/2012 Brazil National Health and Wellness Survey (N=24,000), an Internet-based health survey administered to a representative sample of the Brazilian adult population. HCV patients with treatment experience were categorized based on the presence or absence of tolerability issues. Patients with a diagnosis of anemia, a diagnosis of depression, or a positive screen for depression based on the Patient Health Questionnaire-9 (i.e., score of 5+) were considered to have tolerability issues. Patients with and without tolerability issues were compared with respect to health outcomes (SF-36v2, Work Productivity and Activity Impairment questionnaire, and healthcare resource use) using regression modeling.

RESULTS: N=197 patients reported a diagnosis of HCV. Of these, N=117 (53.9%) were currently using treatment (77.8% using either ribavirin and/or interferon-alfa) or had been treated in the past. 57.3% of patients (N=67) experienced a tolerability issue. These patients had been diagnosed more recently compared with patients without a tolerability issue (13.4% vs. 6.0%, respectively, were diagnosed <5 years ago; p<.05). No other demographic and healthy history differences were observed. The presence of tolerability issues was associated with worse health utilities (0.63 vs. 0.75), a greater level of overall work impairment (48.3% vs. 9.67% work time missed or impaired), and more hospitalizations in the past 6 months (0.81 vs. 0.13) (all p<.05).

CONCLUSION: Anemia and depression are common tolerability issues among those with HCV in Brazil and are associated with significantly worse health outcomes. More tolerable treatments could have significant patient and societal benefits.

INTRODUCTION

- The hepatitis C virus (HCV) is a chronic blood-borne disease, which is the leading cause of liver cirrhosis and hepatocellular carcinoma (HCC) globally. [1] The prevalence rate of HCV in Brazil has been estimated to be 1.50%, higher than most other countries in the Americas and Europe. [2]
- The Ministry of Health in Brazil recommends the use of pegylated interferon (PEG-IFN) and ribavirin (RBV) for the treatment of chronic HCV genotype [1], with the addition of either telaprevir or boceprevir for patients with advanced fibrosis or compensated liver cirrhosis. [3-4]
- Despite the effectiveness of these PEG-IFN-based regimens, they are associated with a number of tolerability issues including anemia, depression, and flu-like symptoms, among others. [5]

OBJECTIVE

- To assess the prevalence of tolerability issues among HCV patients and their association with health outcomes.

METHODOLOGY

Data Source

- Data were obtained from the 2011/2012 Brazil National Health and Wellness Survey (N=24,000), an Internet-based health survey administered to a representative sample of the Brazilian adult population.
- Patients who reported a diagnosis of HCV and reported being treated or having treatment experience were included.

Measures

- **Tolerability issues**
  - Only anemia and depression were included as tolerability issues, as they were the only ones assessed in the NHWS. Anemia was defined as a self-reported diagnosis of anemia in the past 12 months. Depression was defined as either a self-reported diagnosis of depression in the past 12 months or scoring a 5 or higher on the Personal Health Questionniaire-9 (PHQ-9), which is associated with a positive screen for depression.
- **Demographics and health history**
  - Age, sex, education, employment, and household income were included for all patients. Patients also reported their current alcohol use, smoking habits, exercise behavior, and height and weight (which were used to calculate a body mass index (BMI) category). The Charlson comorbidity index (CCI) was calculated based on the presence of self-reported comorbidities. Patients also reported the number of years they had been diagnosed with HCV.
- **Health outcomes**
  - The Short Form-36 version 2 (SF-36v2) was used to measure health status, the Work Productivity and Activity Impairment-General Health (WPAI-GH) version was used to measure impairment in daily activities (all patients) and work-related impairment (for those employed). The number of all-cause physician visits, ER visits, and hospitalizations in the past six months were self-reported by patients.

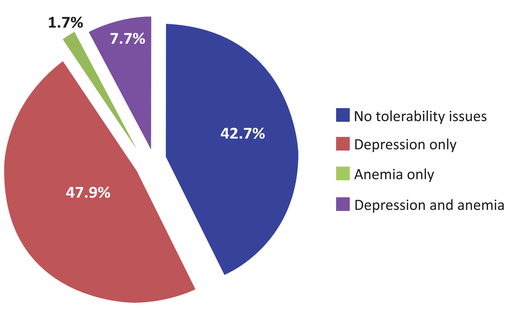
Analysis

- Patients with tolerability issues (anemia and/or depression) and without tolerability issues were compared with respect to health outcomes (SF-36v2, WPAI-GH scores, and healthcare resource use) using generalized linear models, controlling for age, sex, CCI, and years diagnosed.

RESULTS

- N=197 patients reported a diagnosis of HCV. Of these, N=117 (53.9%) were currently using treatment (77.8% using either RBV and/or PEG-IFN) or had been treated in the past.
- 57.3% of patients (N=67) experienced a tolerability issue, with the most common tolerability issue being depression (47.9%; see **Figure 1**).

Figure 1. ***Distribution of Tolerability Issues Among Patients with HCV Treatment Experience***



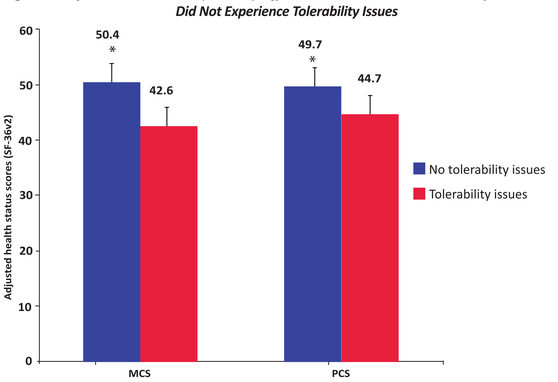
- Patients who experienced a tolerability issue had been diagnosed more recently compared with patients without a tolerability issue (13.4% vs. 6.0%, respectively, were diagnosed <5 years ago; p<.05). No other demographic and healthy history differences were observed (see **Table 1**).

Table 1. ***Demographic and Health History Differences Between Patients Who Experienced and Did Not Experience Tolerability Issues***

Variables	No tolerability issues (N=50)	Tolerability issues (N=67)	P-Value
Age (Mean ± SD)	40.92 ± 13.82	39.90 ± 14.38	0.699
Male (%)	35 (70.00%)	35 (52.24%)	0.053
University degree (%)	21 (42.00%)	28 (41.79%)	0.982
Currently employed (%)	36 (72.00%)	46 (68.66%)	0.696
Household income			0.654
R$ <2,000 (%)	15 (30.00%)	14 (20.90%)	
R$ 2,000 to <6,500 (%)	16 (32.00%)	24 (35.82%)	
R$ 6,500+ (%)	14 (28.00%)	19 (28.36%)	
Declined to answer (%)	5 (10.00%)	10 (14.93%)	
Body mass index (BMI)			0.146
Underweight (%)	0 (0.00%)	4 (5.97%)	
Normal weight (%)	29 (58.00%)	27 (40.30%)	
Overweight (%)	15 (30.00%)	24 (35.82%)	
Obese (%)	6 (12.00%)	10 (14.93%)	
Decline to provide weight (%)	0 (0.00%)	2 (2.99%)	
Regularly consume alcohol (%)	32 (64.00%)	39 (58.21%)	0.526
Regularly exercise (%)	28 (56.00%)	36 (53.73%)	0.807
Smoking habits			0.333
Never smoked (%)	22 (44.00%)	28 (41.79%)	
Former smoker (%)	10 (20.00%)	21 (31.34%)	
Current smoker (%)	18 (36.00%)	18 (26.87%)	
Charlson comorbidity index (CCI) (Mean ± SD)	1.60 ± 1.47	2.48 ± 4.04	0.146
Years diagnosed with HCV			0.049
0-4 years (%)	3 (6.00%)	9 (13.43%)	
5-9 years (%)	3 (6.00%)	10 (14.93%)	
10-14 years (%)	11 (22.00%)	10 (14.93%)	
15+ years (%)	33 (66.00%)	33 (49.25%)	
Unknown (%)	0 (0.00%)	5 (7.46%)	

- Controlling for demographics and health history variables, the presence of tolerability issues was associated with worse health status (see **Figure 2**). Health utilities were significantly worse among those with tolerability issues (0.63 vs. 0.75, p<.05).

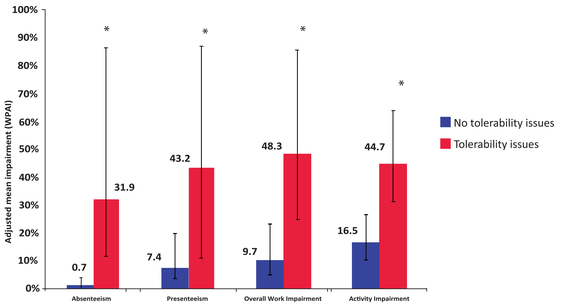
Figure 2. ***Adjusted Health Status (SF-36v2) Differences Between Patients Who Experienced and Did Not Experience Tolerability Issues***



Note: *p<.05 between tolerability and no tolerability groups

- The presence of tolerability issues was also associated with a significantly greater level of work impairment and activity impairment (see **Figure 3**).

Figure 3. ***Adjusted Work And Activity Impairment (WPAI-GH) Differences Between Patients Who Experienced and Did Not Experience Tolerability Issues***



Note: *p<.05 between tolerability and no tolerability groups

- Although no differences were observed between physician visits and ER visits, patients who had experienced tolerability issues reported more hospitalizations in the past 6 months (0.81 vs. 0.13) (p<.05).

DISCUSSION

Limitations

- All data were self-reported and could be subject to recall bias.
- The NHWS is broadly representative with respect to key demographic characteristics but the HCV subsample may differ from the entire HCV population (e.g., the HCV population in NHWS may be more educated, have higher household income, etc.). This could affect the generalizability of the findings.

CONCLUSION

- Anemia and depression are common tolerability issues among those with HCV in Brazil and are associated with significantly worse health outcomes.
- More tolerable treatments could have significant patient and societal benefits.

References

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