**ABSTRACT**

OBJECTIVES: The hepatitis C virus (HCV) is one of the most common blood-borne viral infections in Brazil and associated with various negative outcomes 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 Brazilian National Health and Wellness Survey (NHWS), 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 (PHQ-9) 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: NHWS patients reported a diagnosis of HCV in 9.6% (N=977; 66868 in total), with the addition of either ribavirin (RBV) or peginterferon (PEG-IFN) to the treatment of chronic HCV genotype 1b, with 77.8% using either RBV and/or PEG-IFN. Anemia and depression were diagnosed more recently compared with patients without a tolerability issue (13.4% vs. 6.0%, respectively). 57.3% of patients (N=67) experienced a tolerability issue, with the most common tolerability issue being depression (47.9%; see Table 1). The presence of tolerability issues was associated with significantly worse health outcomes. More tolerable treatments could have significant patient and societal benefits.

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 improve patient care and reduce healthcare costs.

**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. The prevalence rate of HCV in Brazil has been estimated to be 1.5%, higher than most other countries in the Americas and Europe.

The Ministry of Health in Brazil recommends the use of pegylated interferons (PEG-IFN) and ribavirin (RBV) for the treatment of chronic HCV genotype 1, with the addition of either ribavirin or peginterferon for patients with advanced fibrosis or compensated cirrhosis.

Despite the effectiveness of REG-IFN-beta regimens, they are associated with a number of tolerability issues including anemia, depression, and the like symptoms, among others. 1

**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 Brazilian National Health and Wellness Survey (NHWS), an internet-based health survey administered to a representative sample of the Brazilian adult population.

- Patients who reported a diagnosis of HCV and were 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 or scoring a 5 or higher on the Personal Health Questionnaire-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 were asked about their current smoking status, regular exercise habits, alcohol consumption, 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 were also asked the number of years they had been diagnosed with HCV.

- **Health outcomes**
  - The Short Form 36 (SF-36) version 2 (SF-36v2) was used to measure health status, the Work Productivity and Activity Impairment questionnaire (WPAI) was used to measure impairment in daily activities (all patients) and work-related impairment (for those employed).

- **Analysis**
  - Patients were classified into two categories (anemia and/or depression) and without tolerability issues were compared with respect to health outcomes (SF-36v2, WPAI-SF scores, and healthcare resource use) using general linear models, controlling for age, sex, and years diagnosed.

**RESULTS**

- Of the 977 patients reported a diagnosis of HCV in the NHWS, 97 (6.0%) were currently using treatment (77.8% using either RBV and/or PEG-IFN) or had been treated in the past (See Table 1).

- 57.3% of patients (N=67) experienced a tolerability issue (47.9%; see Figure 1).

- Patients who experienced a tolerability issue had been diagnosed more recently compared with patients without a tolerability issue (13.4% vs. 6.0%, respectively). Depressed patients were diagnosed more recently compared with patients without a tolerability issue (13.4% vs. 6.0%, respectively). 57.3% of patients (N=67) experienced a tolerability issue, with depression (47.9%) being the most common tolerability issue. 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 or scoring a 5 or higher on the Personal Health Questionnaire-9 (PHQ-9). The presence of tolerability issues was associated with significantly worse health outcomes and decreased work productivity and activity impairment, and increased healthcare resource use.

**DISCUSSION**

- **Limitations**
  - NHWS was self-reported and could be subject to recall bias.

  - The NHWS is a broad representative with respect to key demographic characteristics but the HCV subgroup may be different from the entire HCV population (i.e., the HCV population in Brazil may be older, less 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 improve patient care and reduce healthcare costs.

**REFERENCES**


7. National Health and Wellness Survey. 2011/2012. NHWS is broadly representative with respect to key demographic characteristics but the HCV subgroup may be different from the entire HCV population (i.e., the HCV population in Brazil may be older, less educated, have higher household income, etc.). This could affect the generalizability of the findings.

8. The prevalence of HCV in Brazil has been estimated to be 1.5%, higher than most other countries in the Americas and Europe.

9. Patients were asked about their current smoking status, regular exercise habits, alcohol consumption, 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 were also asked the number of years they had been diagnosed with HCV.

10. The Short Form 36 (SF-36) version 2 (SF-36v2) was used to measure health status, the Work Productivity and Activity Impairment questionnaire (WPAI) was used to measure impairment in daily activities (all patients) and work-related impairment (for those employed).

11. The presence of tolerability issues was associated with significantly worse health outcomes and decreased work productivity and activity impairment (See Figure 1).

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

13. Patients who experienced a tolerability issue had been diagnosed more recently compared with patients without a tolerability issue (13.4% vs. 6.0%, respectively). Depressed patients were diagnosed more recently compared with patients without a tolerability issue (13.4% vs. 6.0%, respectively). 57.3% of patients (N=67) experienced a tolerability issue, with depression (47.9%) being the most common tolerability issue. 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 or scoring a 5 or higher on the Personal Health Questionnaire-9 (PHQ-9). The presence of tolerability issues was associated with significantly worse health outcomes and decreased work productivity and activity impairment, and increased healthcare resource use.

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