

Health-related quality of life in patients with hepatitis C virus infection in Brazil

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ABSTRACT

Objective. To quantify the health-related quality of life (HRQoL) burden of hepatitis C virus (HCV) infection among a broad sample of adults in Brazil, particularly among those 40 years of age and older.

Methods. This was a retrospective observational study of data from the 2011 Brazil National Health and Wellness Survey, a large (n = 12 000) cross-sectional survey that includes information on medical conditions and health outcomes, including the Medical Outcomes Study Short-form 12 health questionnaire, version 2 (SF-12v2). Respondents who reported a physician diagnosis of HCV infection were compared with those who reported never experiencing HCV on the Mental (MCS) and Physical (PCS) Component Summary scores and SF-6D health utility scores. Unadjusted comparisons were conducted with chi-square tests for categorical variables and t-tests for continuous variables. Regression was used to adjust outcomes for potential confounds. Subgroup analyses were conducted on those 40 years of age and older.

Results. Unadjusted comparisons between respondents infected with HCV (n = 100) and controls (n = 11 694) revealed similar MCS and PCS scores, but HCV patients had lower SF-6D utility scores (0.70 vs. 0.73, P < 0.05). Regressions adjusting for demographic and health characteristics provided similar results to unadjusted comparisons. Subgroup analyses of respondents 40 years of age and older revealed decrements in both MCS (45.95 vs. 49.72, P < 0.05) and SF-6D (0.71 vs. 0.76, P < 0.05). PCS scores were comparable in HCV patients and controls.

Conclusions. HCV infection in Brazil causes significant HRQoL burden, especially among the older population. Prevention measures to curtail the spread of the virus in Brazil should provide societal benefits in terms of quality of life, in addition to preventing morbidity and mortality from chronic infection.

Key words

Hepatitis C; quality of life; Brazil.

Hepatitis C virus (HCV) is a blood-borne illness that affects approximately 160 million people worldwide (1), and

2.5% of the adults in Brazil (2). Historically, the infection has been transmitted primarily through blood transfusions and needle-sharing among injection drug users, though other risk factors have been identified (3). Screening of donated blood has greatly reduced the rate of new infections worldwide, though incidence in Brazil is higher than in

more economically-developed countries, such as the United States, and the virus continues to spread through medical and dental procedures (4).

Since HCV is typically asymptomatic, most new cases go undetected and approximately 75% become chronic (5). Chronic HCV infection greatly increases risk for cirrhosis, liver failure, and

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hepatocellular carcinoma (HCC) (6, 7), and is the most common cause of HCC in Brazil (8). The health consequences of HCV, including cirrhosis and HCC, are more likely as the length of infection increases (9). Consistent with this, clinical research in Brazil has found age to be an important predictor of fibrosis in HCV-infected patients (10).

The burden of HCV infection is not limited to the impact of cirrhosis and HCC. Previous research has found that HCV infection is associated with reduced health-related quality of life (HRQoL), even in the absence of cirrhosis (11–14). The HRQoL burden of HCV infection in the United States has been widely reported, but due to the differences in the two societies, results of those studies may not be applicable to the population of Brazil. There are also differences in population characteristics, such as average age, that may affect the burden of HCV. Notably, the median age in Brazil is estimated at 30 years (15)—considerably younger than in other countries where the HRQoL burden of HCV has been studied—so it is possible that the burden of HCV infection has not yet manifested to the extent that it has in the United States or Japan, where marked decrements have been observed in patient-reported outcomes (12, 14).

Little information has been reported on the patient's perspective of HCV impact in Brazil. The authors are aware of only one study on the impact of HCV infection *per se* in Brazil and it was limited to blood donors (16); it showed that infected donors had lower HRQoL on several scales of the SF-36 than did other donors. However, blood donors are not likely to be representative of individuals with HCV infection, and the researchers did not report analysis of either of the commonly reported component scores. Health state utilities (SF-6D) were also not reported. Other assessments of HRQoL in HCV patients in Brazil have focused on the impact of psychiatric disorders on this population (17) and the impact of response to antiviral treatment (18).

Given that the information on the topic is very limited, the objective of this study was to quantify the HRQoL burden of HCV infection among a broad sample of adults in Brazil, and because the impact is likely to be more severe among older

respondents, a subgroup analysis of older respondents was also planned.

MATERIALS AND METHODS

This was a retrospective observational study using data from the 2011 Brazil National Health and Wellness Survey (NWHS; Kantar Health, New York, New York, United States) that analyzed a cross-section of 12 000 adults (≥ 18 years of age). The Brazil NHWS captures HRQoL through the Medical Outcomes Study (MOS) Short-form 12 health questionnaire, version 2 (SF-12v2) (19), discussed in detail below, and includes questions about medical conditions, whether these conditions were diagnosed by a physician, any treatment information, health risk behaviors, and health attitudes. All materials were in Brazilian Portuguese. The main body of the NHWS questionnaire was developed in English and translated into Brazilian Portuguese, and then checked for equivalence by another qualified translator. The SF-12v2 employed in this study was the official Brazilian Portuguese version offered by QualityMetric, Incorporated (Lincoln, Rhode Island, United States), which was developed through a process of multiple, independent, forward translations, and a back translation.

Respondents for the 2011 Brazil NHWS were recruited through both Internet-based commercial survey panels, as well as through in-person recruitment. Invitations to participate were sent to members of the online panel through stratified random sampling, with strata based on the age and sex distributions found in the census. Similarly, those recruited in person were selected using quotas based on age and sex. Participants who did not have a computer or were illiterate completed the questionnaire at home with the assistance of a trained interviewer. Inclusion criteria included residing in Brazil, being 18 years of age or older, and the ability to read and write in Portuguese (for Internet interviews) or speak Portuguese (for live interviews). Respondents received a small incentive for participation in the survey. Response rate for the survey was 5%. All subjects gave informed consent and the study was approved by the Essex Institutional Review Board (Lebanon, New Jersey, United States). Identifying information is not present in

the same database as the responses, so the privacy/anonymity of the personal information was guaranteed.

Patients with Hepatitis B virus (HBV) infection or HIV/AIDS were excluded from the analyses to prevent HRQoL burdens associated with these diseases from being attributed to HCV—both conditions being more common among HCV patients than among the general population. Patients who reported suffering from HCV, but who had not received a physician diagnosis of HCV were also excluded.

Measures

Demographic information included age, gender, race, sexual orientation, income, marital status, employment status, and social class. Social class was identified using the classification system developed by the Associação Brasileira de Empresas de Pesquisa (Brazilian Market Research Association, São Paulo, Brazil), which classifies a respondent's status based on a scoring system that considers the number and type of durable goods and conveniences to which the household has access, as well as head-of-household's level of education. This tool has been used to measure socioeconomic status in previous medical research in Brazil (20, 21).

Health characteristics assessed included body mass index (BMI), cigarette smoking, exercise habits, and alcohol use. The influence of comorbid disease was quantified using the Charlson Comorbidity Index (22), which was modified to exclude liver disease.

HRQoL was assessed using the MOS, SF-12v2, a multipurpose, generic HRQoL assessment. The 12 items were selected from the popular SF-36 health survey, and allowed for measurement of the concepts assessed by that instrument (23). This analysis included three metrics calculated from the scale: mental component summary score (MCS); physical component summary score (PCS); and the SF-6D health utility score, a preference-based measure for health using general population values, which allows for health economic evaluations (24). Both the MCS and PCS are standard scores, with a mean of 50 and a standard deviation of 10 in the population of the United States, with higher numbers indicating better HRQoL. Like all stan-

dard scores, they are easily interpretable with regard to whether an individual is above or below average, and measures of effect-size based on standard deviation can be calculated very easily. The standardization also means the two values, or changes in values, can be meaningfully compared to one another.

Norms for different diseases have been published and provide some context for interpretation. For instance, in terms of mental quality of life, among the population of the United States, adults with no chronic conditions have a mean MCS of 52.29, whereas among depressed adults it is 37.40. Similarly, PCS serves as an index of physical health, with an average of 54.30 among adults in the United States with no chronic conditions, compared to 45.48 for those with anemia and 41.52 for those with diabetes (19). The metrics have also been widely used in the HIV literature, where HIV patients show decrements on MCS and PCS compared to population norms (25–27). The metrics are also sensitive to change, as demonstrated by patients enrolled in clinical trials of antiretroviral treatment (ART); for instance, 12 months of ART resulted in MCS and PCS improvements of 1.4 points and 2.5 points, respectively, with the amount of change correlated with both adherence to therapy and virologic outcomes (27). A difference of 3 points in either MCS or PCS is often considered clinically significant.

Another use of the SF-12 is to generate health state utilities. The SF-6D is a preference-based single index measure for health using general population values, developed using preference weights derived from the United Kingdom's general population and calculated from responses to the SF-12. There are 18 000 potential health states defined by the items included in the SF-6D calculation, and 249 of these were valued by a representative sample of the country's general public using the standard gamble (SG) technique. Regression models were used to extrapolate from the health states assessed in the SG study to define utility values for all of those potential health states. The SF-6D index has interval scoring properties and yields summary scores on a theoretical 0–1 scale, though the lowest possible score is 0.29. A score of 1 indicates ideal health, while a score of 0 indicates the worst possible health state (24). Differences of 0.03 points are

generally considered to be clinically significant (28).

Data analysis

Bivariate comparisons between the HCV group and subjects without HCV infection (controls) were conducted using chi-square tests for categorical outcomes and independent-samples t-tests for continuous outcomes. Multivariate analysis was conducted to adjust the HRQoL values for the influence of covariates. Regression analyses were performed using generalized linear models in IBM SPSS Statistics software, version 19 (SPSS Inc., an IBM company, Chicago, Illinois, United States). These employed maximum likelihood estimation and specified a normal probability distribution and identity function. Covariates included age, gender, BMI, race, income, social class, employment status, marital status, smoking status, having private health insurance, and the CCI. Because of small sample sizes in the HCV group, some of the covariates were reduced into fewer categories: BMI was reduced to obese, overweight, and all else; race to white, pardo, and other; income to above median, below median, and decline to answer; and social class to upper class (A1, A2), middle class (B1, B2), working class (C1, C2), and poor (D, E).

Based on the previous research on chronic HCV infection, older respondents were expected to be more impacted by HCV infection than younger ones. The limited sample size rendered testing for an interaction between age and HCV status unfeasible, so a subgroup analysis of respondents 40 years of age and older was conducted.

RESULTS

After applying exclusion criteria, 11 794 respondents were included in the analysis. A physician diagnosis of HCV infection was reported by 100; the remaining 11 694 served as the control group. As displayed in Table 1, patients with a diagnosis of HCV infection were generally similar to respondents without HCV in terms of demographic characteristics and health habits. There was a significant difference between the two groups regarding the prevalence of cigarette smoking and a trend toward more comorbid health conditions—both

higher among HCV-infected patients. Cirrhosis was more common among HCV patients than among controls (1.0% vs. 0.1%, $P < 0.001$), though complications of HCV were rare in this sample, with only one reported case of cirrhosis and no HCC reported.

Mean HRQoL values are presented in Table 2. Unadjusted comparisons of HRQoL values revealed a significant difference between the groups on mean health utility score, with HCV patients having a 0.03 point decrement on the SF-6D relative to controls (0.70 vs. 0.73, $P < 0.05$). This would be considered a clinically important difference (28). Neither MCS (45.19 vs. 46.88, $P = 0.124$) nor PCS (49.41 vs. 50.50, $P = 0.187$) scores differed by HCV status. A similar pattern was observed after adjusting for covariates. The 0.03 point deficit in health utility remained (0.70 vs. 0.73, $P < 0.05$), while the adjusted MCS (45.32 vs. 46.85, $P = 0.138$) and PCS (48.60 vs. 49.42, $P = 0.293$) scores were similar in HCV-infected patients and controls.

Because most of health consequences of HCV manifest in middle life or later, analyses were also conducted on the subsample of respondents who were 40 years of age and older ($n = 5 437$). This included 57 HCV-infected patients and 5 293 controls. The demographics and health characteristics of these respondents are presented in Table 3. In this group of patients, compared to control respondents, HCV-infected patients were younger, more likely to be employed, less likely to be of African descent, less likely to decline to report income (all $P < 0.05$). Prior to adjustment for covariates, HCV-infected patients had lower health utilities (0.69 vs. 0.76, $P < 0.05$) and also had lower MCS scores (44.59 vs. 49.70, $P < 0.001$). PCS scores were comparable in HCV and control groups (48.33 vs. 48.89, $P = 0.645$). Multivariate analyses revealed a pattern of results similar to the comparisons using unadjusted numbers; health utility scores were lower among those infected with HCV than controls, with the average score of those infected being lower by 0.05 points (0.71 vs. 0.76, $P < 0.05$). HCV infection was also associated with reduced MCS scores (45.95 vs. 49.72, $P < 0.01$). There was no relationship between HCV status and PCS. Regression-adjusted means for MCS, PCS, and SF-6D are presented in Figure 1.

TABLE 1. Characteristics of survey respondents (n = 11 794) by hepatitis C virus (HCV) status, adults 18 years of age and older, Brazil, 2011

Variable	HCV group (n = 100)		Control group (n = 11 694)		P value ^a
	No.	%	No.	%	
Female	45	45.0	5 883	50.3	0.290
Sexual orientation					
Heterosexual	88	88.0	10 764	92.0	0.137
Homosexual	5	5.0	371	3.2	0.300
Bisexual	4	4.0	286	2.4	0.318
Decline to answer	3	3.0	273	2.3	0.661
Income					
Above median	46	46.0	4 666	39.9	0.215
Below median	45	45.0	5 633	48.2	0.528
Decline to answer	9	9.0	1 395	11.9	0.368
Race					
White	69	69.0	7 802	66.7	0.630
Black	3	3.0	836	7.1	0.108
Pardo	23	23.0	2 571	22.0	0.807
Amarelo	4	4.0	284	2.4	0.311
Indigena	0	0.0	71	0.6	0.434
Decline to answer	1	1.0	130	1.1	0.915
Married/living with partner	56	56.0	5 913	50.6	0.279
Employed	75	75.0	7 815	66.8	0.084
Social class					
Upper class (A1, A2)	17	17.0	1 519	13.0	0.235
Middle class (B1, B2)	62	62.0	6 433	55.0	0.162
Working class (C1, C2)	21	21.0	3 357	28.7	0.090
Poor (D, E)	0	0.0	385	3.3	0.065
Body Mass Index					
Obese	24	24.5	2 040	17.7	0.079
Overweight	33	33.7	3 880	33.6	0.993
Normal	39	39.8	5 230	45.3	0.273
Underweight	2	2.0	386	3.3	0.474
Decline to answer	2	2.0	158	1.4	0.576
Has private health insurance	53	53.0	6 263	53.6	0.911
Currently smokes	33	33.0	2 200	18.8	0.000
Currently exercises	50	50.0	6 487	55.5	0.273
Currently drinks alcohol	64	64.0	7 052	60.3	0.452
Cirrhosis	1	1.0	8	0.1	0.001
Age (years)	41.16 ^b	12.57 ^c	40.69 ^b	15.80 ^c	0.712
Number of non-liver comorbidities	0.42 ^b	0.77 ^c	0.29 ^b	0.73 ^c	0.083

^a P values for frequencies are from X² test; P values for equality of means are from independent-samples t-tests.

^b Mean.

^c Standard deviation.

TABLE 2. Health-related quality of life by hepatitis C virus (HCV) status among adults 18 years of age and older (n = 11 794), Brazil, 2011

	HCV group (n = 100)		Control group (n = 11 694)		P value ^b
	Mean	SE ^a	Mean	SE	
Unadjusted					
MCS ^c	45.19	0.95	46.88	0.10	0.124
PCS ^d	49.41	0.84	50.50	0.76	0.187
Health utility	0.70	0.01	0.73	0.00	0.012
Adjusted					
MCS	45.44	1.06	46.85	0.19	0.177
PCS	48.64	0.79	49.42	0.14	0.317
Health utility	0.70	0.01	0.73	0.00	0.042

^a Standard error of the mean.

^b P value of unadjusted comparisons are from independent-samples t-test; P value of adjusted values refers to the coefficient for diagnosed Hepatitis C in a regression incorporating sociodemographics and other health characteristics.

^c Mental component summary score.

^d Physical component summary score.

DISCUSSION

To the authors' knowledge, this is only the second study to assess the impact of HCV infection on HRQoL in Brazil, and the first using a survey of the general population. Respondents diagnosed with HCV infection had lower health utility scores than those without HCV, both in the unadjusted comparison, as well as in multivariate regression adjusted for demographic differences and the influence of comorbid illnesses. This finding is especially impressive when one takes into account the young, average age of the sample and its lack of liver complications—only one respondent had diagnosed cirrhosis and none reported HCC. As would be expected, the findings were stronger when analysis was limited to the subsample of older patients, whose deficits in mental HRQoL and health utilities were both statistically and clinically significant.

These results are a meaningful extension of previous research on the HRQoL impact of HCV in Brazil, which had previously been limited to blood donors (16) or the effect of treatment with pegylated interferon (18). These results are largely consistent with the results of those studies. Though blood donors with HCV showed decrements on many subscales of the SF-36, decrements among the patients without biopsy (those most likely to be similar to the current sample) were significant on the mental health, role emotional, and social functioning scales, all of which load onto the MCS score. Likewise, response to pegylated interferon was shown to increase MCS scores, but not PCS scores.

Study limitations

There are some limitations of the current analysis that warrant mention. First, the sample of respondents with HCV was small, limiting statistical power. It follows that the respondents included in this analysis may not be representative of adult HCV patients in Brazil. The NHWS is a patient-reported survey, and so diagnosis of HCV could not be confirmed. The absence of HCV in the control group also could not be confirmed. Indeed, HCV is almost certainly present in the control group, as a recent review of the epidemiology of HCV in Brazil estimated that only 10%

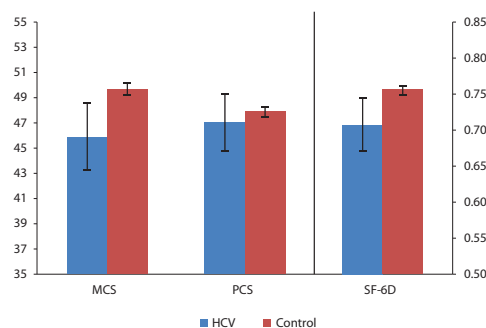
TABLE 3. Characteristics of the sample (n = 5 494) 40 years of age and older by hepatitis C virus (HCV) status, Brazil, 2011

Variable	HCV group (n = 57)		Control group (n = 5 437)		P value ^a
	No.	%	No.	%	
Female	26	48.1	2 605	49.2	0.876
Sexual orientation					
Heterosexual	48	88.9	4 956	93.6	0.157
Homosexual	1	1.9	121	2.3	0.832
Bisexual	2	3.7	86	1.6	0.232
Decline to answer	3	5.6	130	2.5	0.146
Income					
Above median	28	51.9	2 081	39.3	0.061
Below median	25	46.3	2 566	48.5	0.749
Decline to answer	1	1.9	646	12.2	0.020
Race					
White	42	77.8	3 731	70.5	0.242
Black	0	0.0	398	7.5	0.036
Pardo	10	18.5	1 018	19.2	0.895
Amarelo	1	1.9	80	1.5	0.839
Indigena	0	0.0	26	0.5	0.606
Decline to answer	1	1.9	40	0.8	0.358
Married/Living with partner	33	61.1	3 159	59.7	0.831
Employed	41	75.9	3 158	59.7	0.015
Social class					
Upper class (A1, A2)	9	16.7	772	14.6	0.667
Middle class (B1, B2)	35	64.8	2 767	52.3	0.066
Working class (C1, C2)	10	18.5	1 505	28.4	0.108
Poor (D, E)	0	0.0	249	4.7	0.103
Body Mass Index					
Obese	14	25.9	1 082	20.7	0.349
Overweight	19	35.2	2 060	39.5	0.521
Normal	20	37.0	1 991	38.1	0.867
Underweight	1	1.9	86	1.6	0.907
Decline to answer	0	0.0	74	1.4	0.382
Has private health insurance	27	50.0	2 682	50.7	0.922
Currently smokes	19	35.2	1 213	22.9	0.033
Currently exercises	27	50.0	2 640	49.9	0.986
Currently drinks alcohol	33	61.1	2 890	54.6	0.339
Cirrhosis	1	1.9	6	0.1	< 0.001
Age	50.63 ^b	8.06 ^c	55.08 ^b	11.68 ^c	< 0.001
Number of non-liver comorbidities	0.54 ^b	0.84 ^c	0.33 ^b	0.78 ^c	0.081

^a P value for frequencies are from X2 test; P values for equality of means are from independent-samples t-tests.

^b Mean.

^c Standard deviation.

FIGURE 1. Adjusted means and 95% confidence intervals for health-related quality of life indicators among respondents 40 years of age and older with and without physician-diagnosed hepatitis C virus (HCV) infection, Brazil, 2011

Notes: Error bars indicate standard error of the mean; MCS: Mental Component Summary; PCS: Physical Component Summary; SF-6D: health utility score. The figures on both axes represent the scores of the measure instruments.

of those with HCV are diagnosed (2). Consistent with this, the prevalence of HCV reported in the NHWS was less than the 2.5%, with slightly fewer than 1% of respondents reporting a physician diagnosis of HCV. However, the inclusion of unidentified HCV patients in the control group would make the analysis more conservative. Another potential limitation is that additional variables not included in the regression could explain the decrements in HRQoL among HCV patients, though many of these factors were accounted for in the regressions and the respondents reporting HCV infection were overall quite similar to the non-HCV sample. Finally, it is unclear how survey respondents

may differ from those who did not respond; and although the low response rate may have impacted the results, it is not expected that such a bias would be responsible for the differences observed across HCV infection status.

Conclusions

HCV infection has a substantial impact on the HRQoL of patients in Brazil, in addition to its documented role in liver disease and HCC, though these may not manifest until middle age. Prevention measures to curtail the spread of the virus in Brazil would provide societal benefit in terms of quality of life, in addition to preventing the mor-

bidity and mortality otherwise caused by the cirrhosis and HCC that result from chronic infection. Public health officials, physicians, and patients should also consider the impact of HCV infection on HRQoL when considering treatment strategies.

Conflict of interests. This analysis was conducted by Kantar Health (Princeton, New Jersey, United States) and funded by Merck & Company (Horsham, Pennsylvania, United States of America). At the time of the manuscript's drafting, AEK was employed by Merck & Company, and GP was a consultant to the same. JV is an employee of Kantar Health.

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Calidad de vida relacionada con la salud en pacientes infectados por el virus de la hepatitis C en el Brasil

RESUMEN

Objetivo. Cuantificar la carga de la infección por el virus de la hepatitis C (VHC) en cuanto a calidad de vida relacionada con la salud (CVRS) en una amplia muestra de adultos del Brasil, particularmente en los de 40 años de edad o mayores.

Métodos. Se llevó a cabo un estudio retrospectivo y de observación de los datos de la Encuesta Nacional de Salud y Bienestar del Brasil del 2011, una amplia encuesta transversal ($n = 12\,000$) que aporta información sobre trastornos médicos y resultados en materia de salud, e incluye el cuestionario de salud denominado Estudio de los Resultados Médicos, en la versión 2 de su forma abreviada de 12 ítems (SF-12v2). Los entrevistados que notificaron un diagnóstico médico de infección por el VHC se compararon con los que afirmaron que nunca habían padecido esta infección en cuanto a las puntuaciones resumen de las componentes mental (MCS) y física (PCS) y las puntuaciones de utilidad en salud del SF-6D. Se llevaron a cabo comparaciones no ajustadas mediante pruebas de ji al cuadrado para las variables categóricas y pruebas t para las variables continuas. Se empleó un modelo de regresión para ajustar los resultados en cuanto a confusiones potenciales. Se realizaron análisis del subgrupo de adultos de 40 años de edad o mayores.

Resultados. Las comparaciones no ajustadas entre los entrevistados infectados por el VHC ($n = 100$) y los controles ($n = 11\,694$) mostraron puntuaciones de MCS y PCS similares, pero los pacientes infectados por el VHC obtuvieron puntuaciones de utilidad del SF-6D inferiores (0,70 frente a 0,73, $P < 0.05$). Las regresiones de ajuste de las características demográficas y de salud proporcionaron resultados similares a los de las comparaciones no ajustadas. Los análisis del subgrupo de entrevistados de 40 años de edad o mayores mostraron disminuciones tanto en la MCS (45,95 frente a 49,72, $P < 0.05$) como en el SF-6D (0,71 frente a 0,76, $P < 0.05$). Las puntuaciones de la PCS fueron comparables en los pacientes infectados por el VHC y los controles.

Conclusiones. La infección por el VHC en el Brasil causa una carga significativa en cuanto a CVRS, especialmente en la población de mayor edad. Las medidas preventivas para reducir la propagación del virus en el Brasil deben proporcionar beneficios sociales en cuanto a calidad de vida, además de prevenir la morbilidad y la mortalidad causadas por la infección crónica.

Palabras clave Hepatitis C; calidad de vida; Brasil.