Effect of healthcare insurance policy on the quality of life of chronic hepatitis C patients receiving interferon α-2a plus ribavirin therapy

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Abstract. The aim of this study was to evaluate the effect of pegylated interferon α-2a plus ribavirin therapy on the quality of life (QOL) of chronic hepatitis C patients when this treatment was paid for by healthcare insurance. The QOL questionnaire (GQOLI-74) was used to assess patient QOL. A total of 42 cases received 1-year pegylated interferon α-2a plus ribavirin treatment paid for by Guangzhou Medical Insurance (group A), and 30 cases received treatment self-subsidized by the patients themselves (group B). Another 30 patients did not receive interferon therapy (group C). All groups completed the evaluation twice; prior to interferon treatment (T0) and at the end of treatment (T1). There was no statistically significant difference among the three groups (P>0.05). At T1, patients in group A had higher scores for each questionnaire dimension and a higher total score than those of group C (P<0.05). Patients in group B also had higher scores than those of group C (P<0.05), except for material well-being (P=0.305). Compared with group B, patients in group A had higher scores for mental function, material well-being and a higher total score (P<0.05). Patients in group A had higher scores for each dimension and a higher total score at T1 than at T0 (P<0.05), while patients in group B had higher scores for physical function, social function and a higher total score at T1 than at T0 (P<0.05). Pegylated interferon α-2a plus ribavirin treatment is able to improve the QOL of chronic hepatitis C patients. Patients whose treatment was financed by medical insurance exhibited increased improvement in QOL compared to those who paid for their own treatment.

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Introduction

With the gradual improvement of the modern medical model, current evaluation of clinical treatment programs are changing from traditional objective indicators to the comprehensive evaluation approach, including assessment of not only objective indicators, but also subjective factors including quality of life (QOL). Recent data released by the World Health Organization revealed that approximately 123 million people worldwide are infected with hepatitis C virus (HCV), with a prevalence rate of 2% (1). China has an anti-HCV-positive rate of 3.2% among the general population and approximately 38 million anti-HCV-positive patients. Chronic hepatitis C (CHC) patients not only endure physical discomfort, but their QOL decreases significantly compared with that before illness (2). A number of studies have confirmed that pegylated interferon α-2a and ribavirin are the most effective drugs for treatment of CHC (3,4). However, the drugs are expensive, which increases the economic burden of the majority of patients, thus leading to termination or interruption of antiretroviral therapy. Therefore, to enable more patients to receive better treatment, the Guangzhou Municipal Government decided to enroll pegylated interferon α-2a in the basic medical insurance category in February, 2008. Based on this policy, this study assessed results from the QOL questionnaire (GQOLI-74) completed by CHC patients who received pegylated interferon α-2a plus ribavirin treatment, and compared QOL indicators before and after treatment. Comprehensive evaluation of the efficacy of pegylated interferon α-2a plus ribavirin and the Guangzhou basic medical insurance strategy were analyzed from the perspective of QOL in CHC patients.

Patients and methods

Patients. A total of 102 patients with CHC treated at The Third Affiliated Hospital of Sun Yat-sen University, Guangzhou, China between July, 2008 and January, 2010 were enrolled in the study. Among them, 42 patients received pegylated interferon α-2a plus ribavirin which was paid for by the Guangzhou basic medical insurance, including 28 males and 14 females of age range, 18-60 years and mean age, 36.81±10.44 years.

Table I. Patient characteristics of the medical insurance supported, self-financed and no anti-HCV treatment groups.

Characteristics	Medical insurance group (n=42)	Self-financed group (n=30)	No anti-HCV group (n=30)	Statistics
Gender				
Male	28	22	20	χ^2=0.437, P=0.804
Female	14	8	10	
Age (years) (mean ± SD)	36.81±10.44	36.70±11.74	41.02±15.09	F=1.249, P=0.291
Education level				
Primary	2	1	2	χ^2=1.583, P=0.561
Middle	33	24	21	
University and above	7	5	7	

HCV, hepatitis C virus.

A total of 30 patients self-funded their treatment, including 22 males and 8 females, age range, 20-58 years, mean age, 36.70±11.74 years. A further 30 patients did not receive anti-HCV therapy, including 20 males and 10 females, age range, 18-63 years, mean age, 41.02±15.09 years. Diagnosis was in accordance with the 17th Asian-Pacific Liver Research Institute on the diagnostic criteria of CHC (5). The treatment course lasted more than 1 year. Before treatment, HCV-RNA was positively detected by PCR and anti-HCV was also positive. Patients with cirrhosis or hepatitis caused by other viral infections and autoimmune or genetic metabolic liver disease were excluded. Patients included in the study met the following criteria: i) no history of psychological disease, ii) no serious diseases of the heart, lungs, brain, kidneys or diabetes, iii) no hepatic encephalopathy, iv) no administration of sedatives or antipsychotic drugs within 4 weeks, and v) willingness to participate in the psychological test. The differences among the gender, age and education level of the three groups were not statistically significant as revealed by the homogeneity of variance test (P>0.05) (Table I).

Scale recording and conversion method. This study used the general QOL questionnaire (GQOLI-74 for adults) created by Li and Yang (6). There are 20 factors in GQOLI-74; each factor reflects a specific aspect of QOL. Among these, factors 1 to 19 are classified into four dimensions, including physical function, psychological function, social function and material well-being. The 20th factor is the overall evaluation of the QOL. The QOL status of the patients was determined through comprehensive analysis of the four dimensions and the total score. As a comprehensive assessment questionnaire of QOL of the chronic patients, the GQOLI-74 scale has good reliability, validity and sensitivity (7). All questionnaires were completed by the patients. Explanations from the investigator were given to those patients with low educational levels who could not understand the meaning of the issues without prompting. A total of 204 questionnaires were distributed; the completion rate was 100%. The scale used scores on various dimensions, the total score was calculated, and the standard formula was used to convert the scores (8).

The general QOL questionnaire (GQOLI-74) was used to measure QOL in 72 patients with CHC who were treated with pegylated interferon α-2a (PEGASYS; Roche; 180 μg, subcutaneous, once a week), plus ribavirin capsules (Chengyi Pharmaceutical Industry Co., Ltd., Dongping, China; production; oral, 1000-1200 mg/day). The treatment duration was 1 year. Of the 72 patients, 42 received treatment paid for by Guangzhou basic medical insurance (group A) and 30 patients self-funded their treatment (group B). Another 30 patients who did not receive interferon antiviral therapy were selected as the control group (group C). All groups completed the evaluation twice; prior to the interferon treatment (T0), and at the end of treatment (T1). QOL differences were compared between any two of the groups at the same time and between T0 and T1 in each group.

Statistical analysis. SPSS 13.0 statistical analysis was used. The t-test, analysis of variance or the Mann-Whitney test were used to measure the data. Information regarding the three groups was first compiled with the Rank Cases, and then the Student-Newman-Keuls (SNK) method was selected to carry out multiple comparisons of variance analysis. Count data were analyzed by χ^2 test. P<0.05 indicated a stastically significant difference.

Results

QOL before interferon treatment (T0). Each dimension of the GQOLI-74 scale and total score were compared at T0. The results demonstrated that there was no statistically significant difference among the three groups (Z=-0.377 to -1.177; P>0.05) (Table II).

QOL at the end of the interferon treatment (T1). At T1, the differences among the three groups for GQOLI-74 scales in each dimension and total scores were statistically significant (Z=-2.274 to -5.222; P=0.000-0.008) (Table III). Upon paired comparision of the three groups, we found that patients in group A had higher scores for each dimension and a higher

Table II. Comparison of QOL among the three groups prior to interferon treatment (T0).

Group	Physical function	Psychological function	Social function	Material well-being	Total score
Group A (n=42)					
Median	55.33	58.75	61.88	60.63	58.45
Quartile	50.2, 64.9	50.8, 66.7	55.6, 71.9	52.0, 67.6	52.6, 70.7
Group B (n=30)					
Median	57.50	60.44	61.06	55.22	58.27
Quartile	53.0, 65.6	52.5, 68.5	55.6, 68.1	49.8, 65.9	52.0, 68.0
Group C (n=30)					
Median	58.63	60.25	57.50	54.82	56.38
Quartile	46.9, 62.7	54.8, 66.9	49.3, 63.3	40.9, 61.7	46.7, 64.6
Z-value	-1.177	-0.846	-1.062	-0.377	-1.085
P-value	0.239	0.398	0.288	0.706	0.278

Group A, patients whose treatment was paid for by the Guangzhou Medical Insurance; group B, patients whose treatment was self-funded; group C, patients who did not receive interferon antiviral therapy; QOL, quality of life.

Table III. Comparison of QOL among the three groups at the end of interferon treatment (T1).

Group	Physical function	Psychological function	Social function	Material well-being	Total score
Group A (n=42)					
Median	67.13	76.38	68.13	70.09	72.63
Quartile	54.5, 75.3	58.2, 79.3	61.6, 73.5	52.4, 78.1	57.6, 79.6
Group B (n=30)					
Median	65.06	65.00	69.63	56.30	64.30
Quartile	55.7, 68.1	58.6, 68.9	57.8, 73.9	51.0, 61.4	49.2, 71.8
Group C (n=30)					
Median	54.56	54.00	53.31	57.53	54.64
Quartile	46.3, 58.1	50.8, 62.5	45.8, 58.1	48.0, 67.6	43.4, 59.8
Z-value	-2.274	-3.211	-2.725	-2.795	-5.222
P-value	0.008[a]	0.003[a]	0.006[a]	0.005[a]	0.000[a]

[a]P<0.05 indicates significant difference. Group A, patients whose treatment was paid for by the Guangzhou Medical Insurance; group B, patients whose treatment was self-funded; group C, patients who did not receive interferon antiviral therapy; QOL, quality of life.

Table IV. Paired comparison of QOL among the three groups at different times.

Compared groups	Physical function	Psychological function	Social function	Material well-being	Total score
Group A/C at T1	0.006[a]	0.003[a]	0.006[a]	0.005[a]	0.000[a]
Group B/C at T1	0.008[a]	0.021[a]	0.004[a]	0.305	0.024[a]
Group A/B at T1	0.352	0.004[a]	0.759	0.008[a]	0.039[a]
Group A T1/T0	0.019[a]	0.006[a]	0.031[a]	0.005[a]	0.002[a]
Group B T1/T0	0.027[a]	0.075	0.025[a]	0.066	0.043[a]
Group C T1/T0	0.231	0.082	0.256	0.242	0.754

[a]P<0.05 indicates significant difference. Group A, patients whose treatment was paid for by the Guangzhou Medical Insurance; group B, patients whose treatment was self-funded; group C: patients who did not receive interferon antiviral therapy; T0, before interferon treatment; T1, end of interferon treatment; QOL, quality of life.

total score than those of group C (P=0.000-0.006). Patients in group B also had higher scores than those of group C (P=0.004-0.024), except for material well-being (P=0.305). Compared with group B, group A had higher scores for mental function, material well-being and a higher total score (P=0.004-0.039). Patients in group A had higher scores for

each dimension and a higher total score at T1 than at T0 (P=0.002-0.031), while those of group B had higher scores for physical function, social function and a higher total score at T1 than at T0 (P=0.025-0.043) (Table IV).

Discussion

Various studies have demonstrated that QOL is decreased in patients with CHC (3,9). Based on this observation, there have been attempts to improve the QOL of these patients through intervention with psychological counselling, diet, exercise and rest, drugs and other techniques (10,11). In the present study, GQOLI-74 was used to assess the QOL of 72 patients who received 1-year pegylated interferon α-2a plus ribavirin antiviral treatment, including 42 cases whose treatment was paid for by Guangzhou Medical Insurance (group A), and 30 cases who self-funded their treatment (group B). Another 30 CHC patients who did not receive interferon antiviral therapy were selected as the control group (group C). The results demonstrated that at T1, patients in group A had higher scores for each dimension and a higher total score than those of group C (P<0.05). Patients in group B also had higher scores than those of group C (P<0.05), except for material well-being (P>0.05). Patients in group A had higher scores for each dimension and a higher total score at T1 than at T0, while patients in group B had higher scores for physical function, social function and a higher total score at T1 than at T0. This indicated that pegylated interferon α-2a plus ribavirin therapy not only improved the physical function of the patients, but also improve the QOL of CHC patients involving a number of aspects. This result is in accordance with previous studies (12,13).

It is worth considering that at the end of interferon therapy, patients in group B had no improvement in material well-being compared with those of group C during the same period or compared with before treatment (P>0.05). This was probably due to the high cost of completing the 1-year course of pegylated interferon α-2a treatment, which contributed to a financial burden on the patients, and thus affected their material well-being.

Data has revealed that since 2005, the number of reported hepatitis C cases has increased each year in Guangzhou City (14). The majority of patients are infected with HCV for several years before they receive hospital treatment. Certain patients are unable to receive standard full-course anti-HCV treatment due to poor economic conditions, or they may resort to obscure folk prescriptions. Certain other patients are likely to develop cirrhosis or liver cancer in the future. Therefore, the Guangzhou Municipal Government decided to include the pegylated interferon α-2a injection for CHC in the clinical specific project of basic medical insurance category in February, 2008. Pegylated interferon α-2a treatment costs approximately 5,000 RMB a month. Currently, the policy provides the insured individual a proportion of 80% of out-patient treatment costs; the monthly maximum payment is 3,500 RMB. The excess cost is paid for by the individual. Thus, the health insurance policy may substantially reduce the economic burden of CHC patients.

Following the initiation of the policy, through evaluation of the GQOLI-74 scale of CHC patients treated with pegylated interferon α-2a plus ribavirin, the study demonstrated that compared with group B, patients in group A had higher scores for mental function, material well-being and a higher total score (P<0.05). This suggests that after the pegylated interferon α-2a injection was included in the basic medical insurance coverage in Guangzhou, patients whose treatment was financed by the Guangzhou City health insurance demonstrated a better QOL status than patients who self-funded their treatment. This was probably due to the reduced economic burden and psychological stress, thus QOL status was greatly improved. The policy also ensures that the insured patient with CHC enjoys an individualized health plan for 6 months. For those insured patients who require clinical continued use of pegylated interferon α-2a injection, a maximum of another 12 months of treatment is confirmed by a designated medical specialist agency. This fully guarantees the integrity of pegylated interferon α-2a treatment in patients with CHC.

An important obstacle of prevention and treatment of CHC patients was removed after CHC entered the clinical specific scope of the Guangzhou basic medical insurance project. However, a number of patients are still unable to be admitted to a hospital for standard anti-HCV treatment. Every effort should be made to identify this subgroup of patients in order to allow them to receive treatment at qualified hospitals. Medical insurance coverage should become an essential feature of the prevention and treatment of CHC patients.

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