Title

Direct costs of treatment and catastrophic health expenditure among hepatitis B virus related diseases and the role of public health insurance in Yunnan province of China

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Abstract

Objective: To investigate the medical expenditure on HBV-related diseases states and to identify the effect of health insurance on catastrophic health expenditure in Yunnan province of China

Background: In China, HBV infection is the most common cause of chronic liver disease. More than half a million Chinese people would die annually from end-stage complications in association with huge healthcare costs and socioeconomic burden.

Methods: A cross-sectional study was conducted to estimate the annual total direct costs and catastrophic health expenditure among patients with HBV and liver disease states. Patients’ information was consecutively recorded at one of level three of first-class hospital in December 2012 to June 2013 in Yunnan, China. The total direct costs for four disease states were estimated by questionnaires. The hospital charge, outpatient fees, and the hospitalization fees being reimbursed and household catastrophic expenditure were identified.

Results: The annual direct costs for each disease states were 19,496 Renminbi (RMB) Yuan in HBV without complication, 28,466 RMB Yuan in compensated cirrhosis, 46,061 RMB Yuan in decompensated cirrhosis, and 33,044 RMB Yuan in hepatocellular carcinoma (HCC) patients, respectively. The catastrophic expenditure occurred at each disease states. Health insurance reimbursement released financial burden incurred by medical expense of patients under high level of household economic status. Public health insurance regimes had helped the patients in different extent.

Conclusions: Among patients with hepatitis B infection, the direct costs represent a significant economic burden. Health expenditure and financing systems must be considered to prevent the increase of household catastrophe, particular among the poor.
**Key Words:** hepatitis B; costs; catastrophic; disease state
Background

Worldwide, about 240 million people are chronic carriers of the hepatitis B virus (HBV). About 600,000 people die every year due to the consequences of hepatitis B [1]. The infection can cause acute and chronic liver disease including cirrhosis and hepatocellular carcinoma (HCC). HCC is the third most common cause of cancer mortality in the world. Hepatitis B is endemic in China and other parts of Asia. One-third of worldwide infected with HBV in China, with 130 million carriers and 30 million chronically infected [2, 3].

HBV chronic infected persons will progress to become asymptomatic carriers or more serious consequences; cirrhosis and/or liver cancer [4-6] therefore, HBV infected victims are at high risk of dying from cirrhosis and liver cancer [7]. The most of disease burden associated with HBV infection is persons on progress of the chronic conditions. Some of them can be controlled with drugs such as interferon and antiviral agents. Ultimately, liver transplant may be the best choice for those patients who survive from liver cancer or cirrhosis. Treatment cost of chronic liver diseases in terms of human suffering, hospital charge, and loss of productivity is quite high in developing countries. Following the increasing incidence of HBV, HCC will become an aftereffect issue that occurs in the near future in China. Liver transplant will be a procedure that dramatically increases treatment costs among these patients. Thus, chronic liver diseases constitute a significant financial burden to Chinese people.

Social medical insurance in China included three schemes of public insurance provide to Chinese people, (1) the basic health insurance for urban employees medical scheme (UEM), (2) the basic health insurance for urban residents medical scheme (URM), and (3) the new rural cooperative medical scheme (NRCM). On the basis of the public document “Deepen reform of the medical and health
system work report in Yunnan province” [8], the average social medical insurance applied for reimbursement proportion of UEM and URM under the policy within the scope of hospital expense payment proportion in 2012 were 82.76% and 69.94%, respectively. For NRCM, hospitalization compensation in proportion according to the difference levels of hospital. The compensation proportion at provincial level was 45-55% [9].

The hospital reimbursement procedure was different for different insurance scheme. Under UEM and URM systems, the hospitalization expenses were under the financial clearance with the hospitals and the insurance participants only paid the deductible of hospital charge when they discharged. However, NRCM required patients to go to local cooperative medical management agency or designated medical institution medical insurance reimbursement checkout windows for reimbursement after they discharged.

Because the health insurance does not cover all Chinese residents, some people still encounter catastrophic events. Catastrophic health expenditure is defined as out-of-pocket spending for health care that exceeds a certain proportion of a household’s income with the consequence that households suffer the burden of disease [10]. According to the definition from world health organization (WHO) [11], the catastrophic health expenditure occurs when a household’s total out-of-pocket health payments equal or exceed 40% of household’s capacity to pay. The health insurance is an important tool for providing financial health protection on catastrophic health spending.

Owing to the limited health resource of developing countries, the high cost of HBV-related diseases care remains a major challenge to health authorities nowadays. Under this situation, considering the heavy financial burden on patients with chronic hepatitis B related liver diseases states, the goal of this study was to investigate the financial burden for the above mentioned patients undergoing different
liver diseases treatment courses, as well as to identify the effect of health insurance on catastrophic health expenditure impoverishment from medical expenses in Yunnan, China.

Methods

Study design

In order to obtain the cost of medical care for each case in HBV related liver diseases, a cross-section study was conducted during December 2012 to June 2013. The information in both outpatients and inpatients undergoing treatment protocols for different liver diseases states was consecutively collected at the First Affiliated Hospital of Kunming Medical University in Yunnan province of China, which was the largest comprehensive hospital in Yunnan. It was a level three of first-class hospital which had a liver disease and infectious disease department and was one of the two hospitals in Kunming allowing such patients to be admitted for treatment. Yunnan Province had implemented standardized charges scheme across the province including insurance reimbursement agreement, unified bidding and purchasing drug. For this reason, inpatient hospital costs in the hospitals within the same level were not very different with province-wide.

The study protocol was approved by the Institutional Ethical Committee of the Prince of Songkla University, Thailand, and the First Affiliated Hospital of Kunming Medical University in Yunnan province, China, where the study was carried out.

Patient recruitment

The recruited patients were older than 20 years old and were categorized into four groups, namely (1) chronic hepatitis B (CHB); (2) compensated hepatitis B cirrhosis; (3) decompensated hepatitis B
cirrhosis; (4) HCC based on the International Classification of Disease (ICD) 10\textsuperscript{th} version diagnosis criteria [12]. The diagnosis criteria of above mentioned diseases also dependent on Chinese standard under the guidelines [13, 14] developed by the Ministry of Health of People’s Republic of China and the American Association for the Study of Liver Diseases guideline (AASLD) [15]. The eligible participants considered active in treatment procedures were recruited from the hospital. Those patients with toxic, drug induced, and autoimmune hepatic diseases had been excluded as well as those who could not communicate in Chinese.

Data collection

Outpatients visiting the clinic and inpatients hospitalized during the study period who qualified participation were invited to join the study and to complete questionnaires when they signed the informed consent. We developed a questionnaire to collect information on costs that patients were spent during the course of treatment. The information collected also included the socio-economic and household characteristics, annual household income data. These respondents were asked to fill in the forms about the estimated expenditures in the past one year. An interviewer assisted the patients to fill in the questionnaire if they were illiterate. Some information might also be collected from accompanying relatives. The questions included two types of costs: (1) medical costs (clinic registration, examination, medicine fee, and total hospital expenditure), and (2) non-medical costs (transportation, nutrition supplements, and nursing worker fee). The total hospital expenditure was composed of the hospital charge for each of admissions if the patients have two or more hospital admissions. These two components were assembled and normalized to produce an estimate of an annual medical cost. In addition, patients were requested to contribute more than a single year of data
to get more accurate estimates of the costs.

For inpatients, the basic information (i.e. demographic characteristic, disease condition) was extracted from inpatients electronic medical records database. Same as for outpatients, the other sections of the questionnaire were required the inpatients to fully fill out. And those seriously ill persons who lost ability to answer the questions or were under their family dependent assistance, attending family members were asked to assist finishing the questionnaire. The inpatients’ medical chart reviews were used to capture the cost information on services and special treatments fee after they discharged. All these hospital charge were retrieved from electronic hospital medical database. Epidata software was used for data entry after finished data collection.

**Statistical analysis**

The R software (version 3.0.1) was used to perform data analysis [16]. Descriptive statistics for characteristics of patients were conducted. The significance level for all analyses was set at alpha of 0.05, and all tests were two-sided.

The annual estimated cost of health expenditure was determined by clinic costs, hospital-based costs, additional costs, transportation costs and other costs during hospital stay. The clinic costs included registration, examination, and medicine expense. Hospital-based costs included all hospital charge: admission, bed, examination, and medical and nurse charges. Additional expenses included buying drugs from outside the hospital. Transportation costs were the expenses of both patients and their companions while travelling to and from hospital for the purpose of those aforementioned diseases regardless of visiting clinic or hospitalization. Other costs were considered as supplemental nutrition fee and nursing workers if occurred during the period of hospitalization.
The total annual direct fee as the proportion of annual household income was used to compare across various disease states. The variables on expenses were not normally distributed, median and interquartile range (IQR) were selected as parameters for sample distribution. Nonparametric statistical tests were used in most of the settings where normality of the distribution of variables did not achieved. Multivariate analysis of covariance (MANCOVA) method was used to find the effects of insurance schemes on the deductible of hospital charge adjusted for demographic variables such as patients' age and occupation in the four groups of patients. The comparison was done among those who bought one kind of insurance regime. Since age was a continuous variable, mancova was an appropriate way to adjust its effect on the statistical models. Anova function with type III sum squared in car package was used to determine the P-values [17].

**Catastrophic measurement**

The annual household income was divided into three levels based on the household income tertiles. Information on the household income and health payments derived from data was used to estimate the catastrophic expenditures. The cut-point for catastrophic expenditure was determined by the ratio between total direct costs and annual household income being equal to and exceeding 40%. In the light of the total direct expense before and after reimbursement, the median proportion of expense decline after reimbursement was calculated. The number and percentage of people with catastrophic expense in each household income tertile group were computed for different liver disease groups.

**Results**

**Descriptive results**
A total of 940 HBV infected cases were consecutively sampled for this study, 520 were cases with HBV without serious consequences, 91 with compensated cirrhosis, 198 with decompensated cirrhosis, and 131 with HCC. The demographic characteristics of these cases are shown in Table 1. The mean age for all participants was 44 and the range was from 20 to 82 years old and the age increased with increasing severity of disease. The male to female ratio in HBV group was around 2:1. The male to female ratio was exceeding three times in other liver disease groups. Most of them accepted middle school education in all groups. For all respondents, the Han nationality and being married were the majority. The proportion of those with no insurance was higher in HBV group compared to those HBV with serious complication groups. When patients got severe disease state, decompensated cirrhosis and HCC, they tended to use similar insurance schemes, high usage of UEM and NRCM.

The median estimated monthly household income was 4,000 RMB Yuan for all samples and Kruskal Wallis test gave no statistically significant difference among disease states. The individual income was 2,000 RMB Yuan for all participants and varied at different group, namely 2,000 RMB Yuan in HBV, 2,200 RMB Yuan in compensated cirrhosis, 2,350 RMB Yuan in decompensated cirrhosis, and 2,000 RMB Yuan in HCC patients. The difference among the four groups was statistically significant by Kruskal Wallis test.

The estimated annual direct costs

The annual costs estimated by each liver disease state are shown in Table 2. A different pattern was observed in the direct expense among those diseases. The annual total direct fee included the direct medical fee and direct non-medical fee. The median of the estimated direct cost for decompensated cirrhosis patients were the highest, being 46,061 RMB Yuan, followed by HCC and compensated
cirrhosis, 33,044 and 28,466 RMB Yuan each. The lowest was in the HBV without serious consequence group, being 19,496 RMB Yuan. The annual total direct medical fee accounted for a high proportion of the total direct fee at different disease states. There was diverse number of direct medical expense along with the variation of disease states. Similarly, the median direct medical fee and no-medical fee possess the consistent sort with the total fee by four disease groups. The median cost of direct medical fee and non-medical fee in the decompensated cirrhosis patients was the highest among the four groups, 44,744 and 573 RMB Yuan, respectively.

The total expense was stratified into the outpatient and inpatient fee. The highest median cost of direct cost for clinic fee was in the HBV infection group, 7,650 RMB Yuan, due to a large number of hepatitis B patients needed treatment as outpatient. And the lowest was the HCC group, being 615 RMB Yuan. The hospital charge became the main cost for various diseases states. The median direct fee for hospitalization was the highest for decompensated cirrhosis patients (33,464 RMB Yuan) and the lowest for hepatitis B patients. We noticed that the median of 0 for total hepatitis B patients without serious consequence because of many of them had no hospital charge since they were treated as outpatients. Then we separated HBV patients into those with and without hospital charge to observe the variation of hospitalization fee. Finally, this median fee for hospital among those who need admission changed to 16,121 RMB Yuan. However, the hospital charge was higher than outpatient fee among the four liver disease states.

Table 3 presents the median annual total direct costs estimated before and after insurance reimbursement under various types of insurance scheme, as well as the ratio of the costs compared to the annual household income. It was obvious that the extent of reimbursement in noncomplicated HBV infection group was lower compared to the severe liver disease groups. The proportion of decrease in
total direct expense after reimbursement were 30.0%, 42.4%, 40.7%, 36.1% at noncomplicated HBV infection, compensated cirrhosis, decompensated cirrhosis, and HCC patients, respectively. The median percentage for the ratio of the total direct costs to the annual household income had decreased after insurance reimbursement. The median total direct fee declined from 31.9% down to 26.9% in noncomplicated HBV infection, from 58.1% to 27.7% in compensated cirrhosis, from 85.8% to 41.1% in decompensated cirrhosis, and from 61.9% to 38.8% in HCC patients, respectively. With Wilcoxon test, the decline in median total direct fee in all groups was all statistically significant. Even though the medium proportion of reduction of total direct costs after reimbursement cost reached 40.75%, the direct fee was still large (41.1%) for decompensated cirrhosis patients in terms of the ratio compared to household income. It implied that this group of patients was vulnerable to catastrophic. The similar phenomenon also existed in HCC group.

Impact of catastrophic expense on household income

Table 4 reveals the impact of catastrophic expense before and after insurance reimbursement on different tertile levels of household income undergoing medical payments. The proportion of households facing catastrophic payment from health expenses varied among the four HBV-related liver disease groups, from 42.7% to 37.1% in noncomplicated HBV infection, from 67.0% to 36.3% in compensated cirrhosis, from 77.8% to 51.0% in decompensated cirrhosis, and from 65.6% to 49.6% in HCC patients groups.

Table 4 also shows that the rich (the third tertile) got more benefit from insurance reimbursement than the poor (the first tertile) among the severe manifestation groups of HBV infection. However, only in the decompensated cirrhosis group, the richest group got more benefit than the poorest tertile with
statistically significant (p<0.05). In comparison against the HBV infection without severe complication, the compensated cirrhosis group had got more benefit with statistical significance. The benefit was true among the richest people in all categories of complicated HBV infection groups against those without complication.

The health insurance in compensated group showed the highest capacity to salvage of those patients with heavy financial burden, with 54.1% of reduction of catastrophic events. After reimbursement it could save more than 50% of patients not undergoing catastrophic payment. While it only contributed 13% in HBV groups and the magnitude of improvement in decompensated and HCC groups were about 34% and 24%, respectively.

From MANCOVA (Table 5), different types of insurance were significantly associated with catastrophic expenditure in four disease states after adjustment for demographic characteristics. NRCM was the health insurance scheme that gave the lowest reimbursement rate and it was used as the reference to compare with other insurance regimes. In an imaginary condition where reimbursement had not in place, catastrophic expenditure would occur in all disease categories at the same rate. In the real condition where reimbursement had been implemented by health insurance schemes, UEM and URM had relieved the burden better than NRCM, especially when occupation and age had been adjusted in the MANCOVA model. Occupation was another significant variable in the final model in all disease states. These catastrophic expenditure was also significantly influenced by sociodemographic factor such as patients’ employment status in HBV (p<0.001) and HCC (p=0.01) groups and marginally significant in compensated cirrhosis group (p=0.06) while patients’ age was not (not shown in the table).

Discussion
Rely on the results from the analysis of the estimated annual total direct costs, this study found that the treatment on decompensated cirrhosis patients took the largest share of the annual total direct costs of the four disease groups (Table 2). The hospital expense accounts for a larger proportion in the annual total direct costs regardless of the above mentioned liver disease stages. The results revealed that HBV and its liver disease complication resulting in the chronic hepatitis B had appeared significant economic consequences because the compensated cirrhosis, decompensated cirrhosis, and liver cancer are costly due to the need of hospitalization and expensive medication and procedures. This result is consistent with another study conducted in Shangdong [18]. The total direct expense in other studies [18-20] also increased with the increasing severity of liver disease. However, the expense for HCC patients was lower than decompensated cirrhosis patients in this study. The possible explanation is that patients with HCC treatment period are limited by short survival (Jung KW, 2013), in addition, there are a number of patients abandoned treatments. In China, some patients diagnosed as advanced liver cancer might give up treatment when they balanced the expense for high cost treatment and limited survival time. Some of them might prefer dying at home instead of hospitalization at the end of life. Some patients might be reluctant to receiving treatment leading to reduction of their quality of life from side-effects of the treatment.

The costs of HBV-related illness appear comparable to other countries. In the United States of America (USA) 2004, the average annual costs order for patients at different disease states was similar with this study. While the expenses were as follows: CHB 761 USA dollar (USD); compensated cirrhosis 227 USD; decompensated cirrhosis 11,459 USD; and HCC 7,533 USD [19]. In both Hong Kong and Singapore 2004, the CHB costed 810 USD in Hong Kong and 410.37 USD in Singapore. Compensated
cirrhosis costed 1,321 USD in Hong Kong and 671.62 USD in Singapore. Decompensated cirrhosis costed 7,490 USD in Hong Kong and 8,794.19 USD in Singapore. HCC costed 15,618 USD in Hong Kong and 7036.59 USD in Singapore [20].

This study indicates that the direct cost is tremendous for all patients having HBV infection in various stages of disease, providing the availability of social medical insurance reimbursement to the majority of hospital costs. However, the diverse insurance coverage is a major hurdle in the financial burden of HBV-related disease patients as the insurance schemes provided markedly different reimbursement rates.

The degree of use of and benefit from insurance regimes among Chinese HBV infected patients seems to be dependent on the stage of disease course. Under the existing system of medical reimbursement, reimbursement in all health insurance schemes was mainly aimed at hospitalization costs. When patients were treated as outpatients, reimbursement procedures in view of current insurance regimes were unlikely to lessen the clinical costs. Hence, under this situation, patients who predominantly required outpatient therapy were forced to be dependent on their household socioeconomic status. On the other hand, patients requiring hospitalization, i.e. those with compensated and decompensated cirrhosis, the usage of insurance regimes was obvious as shown in Table 1. The benefit of different insurance schemes among these four groups was different. In summary, NRCM had the poorest performance to these patients while UEM and URM did significantly decrease the deductible much better than NRCM (Table 5). The fact that patients occupation were significantly associated with deductible amount of hospital charge in the four disease states might be due to the insurance regime they could obtained was closely related to their occupation. To be noted that most of the patients in the
HBV group did not require hospitalization and only 150 patients who need hospitalization contributed in this comparison.

From the report of Cui Y et al. in China 2013, it is estimated that 120 million people with surface antigen carried and around 300,000 of them died of liver cirrhosis and HCC yearly [21]. In terms of such a huge population, most of them were in the form of outpatient medical treatment and the total direct fee for clinic in the four groups is shown in Table 2. The annual total direct costs after reimbursement which assembled both outpatient fee and hospital expense, the last 2 rows of Table 2, more accurately reflected the financial expenditure year-round. Those who did not have any serious liver damage paid a larger amount of total direct fee for clinic and they did not covered by any public health insurance. It might happen that some patients pursue unnecessary hospital treatment in order to reduce the economic burden on them and it would lead to decline the use of the limited medical resources efficiency.

As a shorter course of disease with high mortality [22], the total direct costs in HCC group was not the highest among the four groups and were lower than that of the decompensated cirrhosis which also required hospitalization and had longer survival time. Some imported drugs for HCC were not incorporated into the scope of hospital medical expenses and the indication for reimbursement was very restricted and patients needed to pay for their treatment by themselves. Thus in the present study it could explain that even though HCC patients predominant the inpatients, there are still not been significantly improved on the most catastrophic expenditures after the medical insurance reimbursement.

The level of household income played a key role in catastrophic expenditures, even in the same disease
Catastrophic expenditure in this study was defined as annual medical expense equal and excess 40% of the annual household income, then under the same medical cost and reimbursement system, financial gap emerged between catastrophic expenditure and different household economic status would be distinct from each other. The healthcare reimbursement system could only released those patients at a middle and high household socioeconomic status from the financial burden caused by the treatment (Table 4).

On the patients’ perspective of economic income, the middle and high-income group had more opportunity to obtain economically significant improvement from medical insurance reimbursement than lowest income group. Thus depart from the rank of catastrophic expense situation. Based on the condition, current health care reimbursement system could be developed depend on variety of diseases. The results revealed that for middle and high income household, the current health care reimbursement scheme could provide the assists in those families out of financial hardship.

**Limitation and conclusion**

According to the design of study, the information on annual healthcare costs were estimated on patient memory rather than prospective assessment at 12-month cross-sectional periods, thus, the recall and report biases were inevitably existed in this study. To minimize the effect of the possible bias, research team members had been well trained on explaining the objectives of this study and promised maintaining the privacy of personal information confidential, and had patiently interviewed the subjects under a questionnaire with in depth details as much as possible.

Despite the limitation of the available data, this study has made a significant contribution on our understanding of health resources used for treating HBV-related liver diseases in China. However, the
economic barriers to treatment should be considered in health system strategies to mitigate the financial burden toward patients with above mentioned diseases. Meanwhile, understanding the financial burden associated with HBV-related liver diseases is important for policy setting and decision makers to estimate the further burden of the disease.

The results from this study hint that current medical insurance regime should be develop appropriate medical claims aimed to the costs for patients with liver disease states, as well as strengthen efforts in outpatients treatment costs reimbursement system. As for the diverse household socioeconomic situations, healthcare system should pay attention to provide support to low-income families on the premise of fairness.
List of abbreviations

HBV, hepatitis B virus;

HCC, hepatocellular carcinoma;

RMB, Renminbi;

UEM, urban employees medical scheme;

URM, urban residents medical scheme;

NRCM, new rural cooperative medical scheme;

WHO, world health organization;

ICD, International Classification of Disease;

AASLD, American Association for the Study of Liver Diseases guideline;

MANCOVA, Multivariate analysis of covariance;

IQR, interquartile range;

USA, the United States of America;

USD, USA dollar;
Competing interests

The authors declare that they have no competing interests.

Authors’ contributions

Cheyanhua conceived of the study, performed the analysis and interpretation of data and drafted the manuscript. Hutcha Sriplung has participated in the design of the study and revised the manuscript. Virasakdi Chongsuvivatwong had made substantial contributions to conception and design. Youjing had contribution to acquisition of data. Lili helped coordination. Wangyeying participated in the analysis and interpretation of data. Yanyuanzhi, Masijia, Zhangxiaoli, Zhangruyi, Shenting, Chenhemin, Raoshaoefeng participated in the data collection with the help of Youjing. All authors read and approved the final manuscript.

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Additional files provided with this submission:

Additional file 1: table.doc, 111K
http://www.biomedcentral.com/imedia/6774227751136460/supp1.doc