PHARMACOECONOMIC CONSIDERATIONS AND QUALITY OF LIFE ASSESSMENT IN HEPATITIS C PATIENTS

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Abstract

Background: Gradual liver damage occurs due to hepatitis C virus (HCV) that may result in liver fibrosis and even cancer. Pakistan is a developing country with the second highest prevalence 4.5-8% of hepatitis C. The main purpose of this study was to estimate the quality of life of people affected with hepatitis, to create general awareness about the disease and to determine pharmacoeconomic considerations of hepatitis C treatment.

Methods: It was a cross-sectional study conducted in village Wali Pur Bura of District Nankana sahib, Punjab, Pakistan. Sample size determined by Daniels equation was 100, both male and female participants were included this study. The data was collected to assess the health status data of study population through validated questionnaire and a urdu version of tool EuroQol 5D-5L, comprising of five (5) questions covering the various aspects of health. Data were analyzed through SPSS version 16. Paired sample statistics for comparing two attributes of the study and frequencies were calculated.

Results: In current study, majority (70 %) of patients were belong to the lower class and only 39% patients were aware of Punjab Government's participation in hepatitis free treatment plan. 60% patients showed marked reduction in quality of life and the reason behind was painful interferon therapy. Poor quality of life is observed due to the extra hepatic symptoms of HCV including depression. According to the health scale of 60 participants out of 100 was having below Average health status, 21 participants possessed Average Health while 19 participants had Excellent Health.

Conclusion: Hence, concluded that due to hepatitis C, health as well as socioeconomic and family life is badly affected. Majority of the participants were having poor quality of life. Costly treatment is beyond the reach of majority of rural population that increases the incidence of depression among patients and their families.

Keywords: Hepatitis C, quality of life, socioeconomic, rural areas.
Introduction
Gradual liver damage occurs due to hepatitis C, which results in cancer of liver cells and liver fibrosis. Globally more than 185 million people have been infected with HCV, out of them 3,500,000 die every year (1). Globally, Pakistan is at the second number who has high prevalence of hepatitis C (4.5% to 8.0) (2). HCV is a hepatotropic RNA virus and belongs to the flaviviridae family (3). HCV infected person is the main carrier for the transfer of hepatitis C. In present, most widely spread blood borne disease is hepatitis C. It is calculated that the cases of HCV will increase in the future and it will be a main cause of hepatocellular carcinoma (4). HCV patients have multiple signs and symptoms of disease, which ranges from the lack of clinical manifestation to the presence of entire body symptoms, which includes loss of appetite and tiredness. At advance stage, abnormal accumulation of fluid in the abdominal cavity occurs other complications include hepatic encephalopathy and jaundice (5). It is not only a hepatic disorder but also a psychosocial disease (6). 20%-40% patients with chronic hepatitis C develop liver fibrosis or hepatocellular carcinoma that leads to the eventual liver failure and ultimately death. The chances of liver cancer in patients with CHC reaches 1%-4% each year (7). Test for hepatitis C diagnosis divided into two categories: serological assays that determine anti-HCV antibodies and molecular assays that discover, represent or quantify HCV RNA genomes. For screening of anti-HCV serological assays are used like, the Recombinant Immunoblot Assay (RIBA) and the enzyme immunoassay (EIA) (8).

Quality of life of Hepatitis C patients
According to different studies, all patients affected with Hepatitis C, don’t have compromised quality of life and other chronic symptoms associated with the disease. (9). While on contrast some other studies indicated have a reduced HRQOL in HCV patients (10). Even patients who did not show any signs of cirrhosis, confronted different psychological and physical problems (10). Extra hepatic symptoms of HCV infection including anxiety ,myalgia, gastrointestinal disturbances, depression and fatigue may exacerbate the quality of life (11). Gender difference is important factors in HCV infection as number of studies shows that women have more worse quality of life than men. Reduced quality of life is due to the somatic side effects associated with interferon based therapy. Relapse HCV is also associated with poor quality of life (12). The high cost of treatment also disturbs the patient psychologically (11).The poor quality of life is also due to non-viral factors, such as psychiatric disturbance associated with previous IV drug use(10). Patient's negative perception about his or her disease is also alter the quality of life. They believe that their disease is responsible for disconnecting them from social activities that leads them towards social loneliness. HCV can cross BBB and cause mood changes, depression, is also one of the major factor which reduces the patient's quality of life (11).

Pharmacoeconomic considerations of Hepatitis C
A large number of individuals having HCV infection are unaware about their disease (13). Benefit from the treatment can be identified by screening. Mass screening for HCV infection has significant economic concerns which are linked with different additional diagnostic tests such as liver biopsies and also with the cost of screening test using different assays (14).

HCV executes a high economic burden globally. In 2012, the healthcare cost of HCV infection was 6.5 billion dollars and it is estimated that the cost will be reach at 9.1 billion dollars by the year 2024 (15). In developed countries treatment of Hepatitis C with boceprevir or telaprevir and pegylated interferon/ribavirin has been estimated as cost-effective (16). Treatment cost are estimated to be in the range of US$24,000-39,000 lifetime disease costs, for liver transplant and for the treatment of decompensated cirrhosis , other than antiviral therapy (17, 18).

Currently the annual costs of acute HCV infection and CHC is nearly 600 million US dollar (19), and it will be expected to be 184 billion US dollar in the period 2010-2019 (20), sofosbuvir-based treatment cost for one patient in the US is $50,000 (21). In Canada the costs are estimated to be 150 million canadian dollars annually until 2040 (22).

Methodology
A cross sectional study based on questionnaire was conducted in village Wali Pur Bura, Nankana sahib, Punjab, Pakistan.

Sample Size
Sample size determined through Daniels equation for our study was 100.

Informed consent
As study was conducted in a village (Nankana Sahab, Punjab Pakistan) where most people were illiterate due to that reason informed consent was taken orally.

Inclusion Criteria
Both males and females having HCV infection, individuals who have had been received treatment against Hepatitis- C, and age above 18 years.

Exclusion Criteria
Pregnant women, individuals having others infectious diseases including Hepatitis A, AIDS and hepatitis B, children are excluded, individuals that are under 18 and alcoholic.

Data Collection Tools
Validated EuroQol 5D-5L urdu version questionnaire tool comprising of five (5) questions covering the various aspects of health was used to assess the health status data of study population. Health status data was further graded up using health scale developed by EuroQol Foundation with due permission.

Data Analysis Tools
Data were analyzed through SPSS version 16 by applying paired sample statistics for comparing two attributes of the study and frequencies were calculated. Patient's quality of life was analyzed through predesigned EU-QOL 5D which includes questions comprising different factors like self-care, mobility, usual activities, depression, pain/discomfort.
Out of participants 70% patients were belong to the lower class and having monthly income less than 20,000 and 39% families having more than 5 members and that causes burden on the expenses (Table 2). In developing countries treatment cost of hepatitis is much high (23) and life time health care cost of HCV infected person is much high as compare to healthy person (24). Due to these factors unaffordability of treatment is much common in Pakistan. Due to the poor economic conditions and high treatment cost of HCV 58% patients took loan to get the costly treatment of HCV.

Out of 100 only 39% patients know Punjab Government is providing free treatment (Table 1) but most of them said Government providing medicines only to those who have reference and mostly low quality medicines are dispensed and it is also a time consuming process. More than half of population is unaware of this program. 53% patients were compliant with their treatment this rate is lower because of lack of knowledge. Virologic response of medicine can only be achieved through medicine adherence in noncompliance. It can lead to reduce outcome of therapy and different side effects. Patient motivation is required to optimize therapy outcome (25). Approximately 37% patients were also taking conventional treatment along with allopathic. Out of these many patients were having firm believe that they were cured by conventional treatment.

Table 3: Study parameters of HCV patient related to treatment

| Parameters | n=100 |
|------------|-------|
| Age Group  | 45    |
| Gender     | 62    |
| Occupation | 78    |
| Education  | 90    |
| Marital Status | 100 |

Quality of life of people, suffering from Hepatitis C, is badly affected by the. Muscular or joint pains, fatigue, depression and other psychological problems are most commonly associated with this chronic disease (26). Fatigue, either mental or physical, is the most frequently documented complaint of HCV infected patients (27). About 35% patients had severe problem in walking due to poor health condition during HCV infection. 33% had moderate problem in walking. 43% patients had moderate problem in washing or dressing while 23% patients had severe problem while doing dressing. Due to HCV infection 34% patients had severe problems while performing their usual activities. Many patients had lost their job due to this disease and suffer from severe financial crisis. 47% patients had extreme pain in HCV infection. That was due to extra hepatic symptoms of HCV infection as well as painful interferon therapy. According to findings of present study HCV patients were found suffering from depression. Out of 100 patients 59% were extremely depressed. It has been reported that HVC have capability to cross blood brain barrier thus leads to mood swings and depression (28) and anti-viral drugs also disturb the psychological health of the patients (27). Irritability and loss of interest associated with HCV patient has a negative impact on their interpersonal relationships that results into to visible change in behavior of HCV patients. That shows significantly compromised or reduced quality of life of HCV patients. This poor quality of life is due to the extra hepatic symptoms of HCV including depression. The above mentioned symptoms e.g. impaired mobility, fatigue and depression disturb the person's working ability all together (29). The high cost of treatment also disturbs the patient's financial life which has impact on patient's quality of life.

Conclusion

There is a marked decline in the quality of life of patients suffering from hepatitis C. This decline is mainly due to the extra hepatic effects and common symptoms of this disease. Interferon therapy is another reason of compromised health status. Financial status of hepatitis C patients usually declines because the treatment of hepatitis C is not cost-effective. Costly treatment is beyond the reach of majority of rural population that increases the incidence of depression among patients and their families.

Recommendations

Patient compliance can be improved by informing the patients regarding potential side effects of interferon, before starting the interferon therapy. Prevalence of hepatitis C can be decrease in rural areas by providing easy access of Punjab government free treatment plan of hepatitis C to common people.

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