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Public Health

Prevalence of Hepatitis C Virus in the Population of Albania for the Period 2007-2010

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Abstract

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Key words: *Hepatitis C Virus*; HCV-RNA; prevalence; Cobas-Amplicor; Albania.

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BACKGROUND: Hepatitis C is a blood-borne, infectious, viral disease that is caused by a hepatotropic virus called *Hepatitis C virus* (HCV).

AIM: The aim of this study is to determine the prevalence of active HCV infection (HCV-RNA) in the cases that were anti-HCV positive.

MATERIAL AND METHODS: Plasma of 301 high-risk for HCV infection consecutive from University Hospital Centre "Mother Theresa" Tirana-Albania, during January 2007 to December 2010 was included in this study. To identify the presence of HCV RNA, the samples were examined by Cobas Amplicor HCV test (qualitative method).

RESULTS: From 301 samples analyzed in total, 214 of them resulted positive for the presence of HCV-RNA's, corresponding to a prevalence of 71.1%, with 95% CI interval [65.8 - 75.9] for value of $\chi^2 = 52.7$ p value <0.0001. Divide by the sex 56% were males and 44% females, with statistically significant difference between them for value $\chi^2 = 4306$ p value=0.0380. Among the age groups the highest prevalence was observed in the age groups > 25 years with a significant difference with other age groups for p value <0.001.

CONCLUSION: Among tested samples, 71.1 % were confirmed to be positive for HCV -RNA infections. The prevalence of male was highest compared to female. For males and females infected the prevalence was highest in the age group of > 25 years.

Introduction

Human hepatitis C is an infectious disease affecting the liver of humans and chimpanzees, caused by the Hepatitis C Virus (HCV) [1]. HCV is the only known member of the *Hepacivirus* genus in the family *Flaviviridae*. It is single stranded 50 nm positive sense RNA virus with six major genotypes causing hepatitis C in the whole of the world [2, 3]. It is reported that approximately 15-40% of persons infected with HCV clear the virus from their bodies during the acute phase of infection and the 60-85% of patients infected with HCV develops chronic hepatitis C [4], which progresses to liver cirrhosis with an elevated risk of the development of hepatocellular carcinoma [2, 5, 6]. The infection is often asymptomatic especially in its early stages but once established, it can progress to advanced liver diseases such as liver fibrosis and ultimately cirrhosis.

These liver diseases can further lead to other complications such as liver failure and liver cancer [7].

Albania, a developing nation with about 3 million people has alarmingly rate of outbreaks of hepatitis C virus that need for proper survey and genotyping. Prevalence studies of anti-HCV antibodies in the general population of Albania have been recorded as about 1%. In the healthy population (200 samples) more the 15 years old the prevalence result 0.99% [8]. For the blood donor population in Albania the prevalence of Hepatitis C result to be 0.7% [9].

HCV-infection was never investigated at molecular level for presence of active infection in Albania so for this reason we did this study to determine the prevalence of active HCV infection (HCV-RNA) in the cases that were anti-HCV positive.

Materials and Methods

Patients and blood sampling

Plasma of 301 high-risk for HCV infection consecutive from different departments of University Hospital Centre "Mother Theresa" Tirana-Albania during January 2007 to December 2010 was included in this study. Patients comprise 169 men and 132 women from different age groups (1-73 years of age). This plasma was examined for Hepatitis C to Molecular Biology Laboratory, Institute of Public Health, in Tirana. Patients belong to different groups from politransfusion persons, blood donation centers, and persons from Unit of Gastrohepatology and Infection Disease. Each individual duly signed a proforma containing information about his/her previous exposure to a risk factor like age, sex etc. The blood sample 5 ml of each patient was collected in EDTA-tubes and immediately was transported to Molecular Biology Laboratory, Institute of Public Health, for plasma isolation. Plasma samples aliquot were stored at -70°C until use.

Note: the samples taken from politransfusion group included three categories: persons with Thalassemia, persons who have undergone process of dialysis and those who have hospitalized in oncology unit.

HCV qualitative test

The samples were subjected for molecular analysis. In this study we have identify the presence of HCV RNA by Cobas Amplicor HCV test, Roche Diagnostics GmbH, Mannheim, (qualitative method) that realizes the extraction of RNA from patient samples. This test is based on five major processes: specimen preparation; reverse transcription of the target RNA to generate complementary DNA (cDNA); PCR amplification of target cDNA using HCV specific complementary primers; hybridization of the amplified product to oligonucleotide probes specific to the target; and detection of the probe-bound amplified products by colorimetric determination according to the manufactures instruction by Roche [10].

The method of data analysis

Standard methods of statistical analysis SPSS 16 were used to assess the association between the study variables. Categorical variables were explored by using table 2x2 and chi-square. Observations for missing values were not included in the testing. Continuous variables were explored using Student t test two-way and one-way, OR with 95% CI waste oils and tailored for each model is reported. The level of significance is: $\alpha \leq 0.05$

Results

From 301 cases analyzed for HCV-RNA 56% of them were income from Gastro-Hepatology and Infection Disease Unit. In second place was the center of hemodialysis with 16.7% of cases, followed by center of thalassemia with 11.7% of cases (Table 1).

Table 1: Number of cases divided by source of samples.

Source of samples	Number of cases	Percentage
Blood donors	17	5.60%
Child's home	1	0.30%
Prison	1	0.30%
Hemodialysis	50	16.70%
Pediatric	26	8.70%
Drug users	2	0.70%
Thalassemia	35	11.70%
Gastrohepatology and Infection Disease Unit	169	56.00%
Total	301	100%

From 301 samples analyzed in total, 214 of them resulted positive for the presence of HCV RNA's, corresponding to a prevalence of 71.1%, with 95% CI interval [65.8 - 75.9] for value of $\chi^2 = 52.7$ p value <0.0001 (Figure 1).

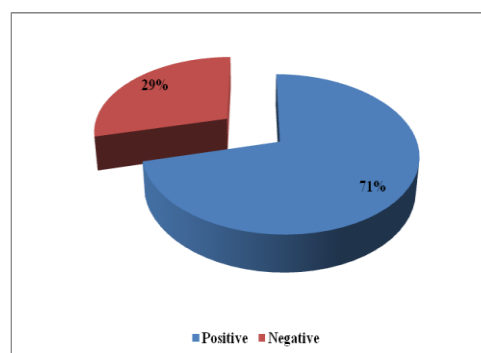


Figure 1: Number of positive/negative cases in total.

In this study, 56% (169) of cases were males and 44% (132) females. Men make up majority of the sample, with statistically significant difference with women. For value $\chi^2 = 4306$ p value = 0.0380. In this study the prevalence to men was highest compared to female. For male prevalence was 58% (124) while for female was 42% (90) cases. There were a significant value was show between the positive cases divided by sex. For value $\chi^2 = 0.74$ p value <0.049 (Figure 2).

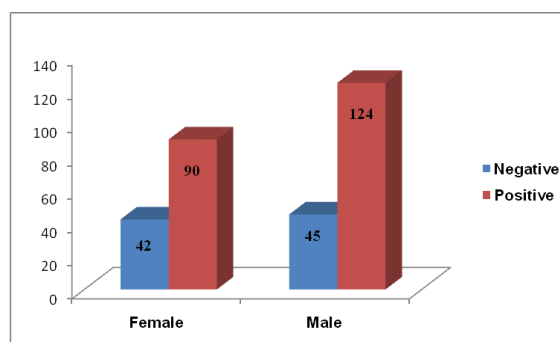


Figure 2: Positivity of cases divided by sex.

For 19 patients the data of age are missing. Age less taken in the study is <1 year, while the oldest age obtained in the study is 73 years. For this sample the average was 32.3 years, while the median is 30.5 years. Value 95% CI for age group observed is [30.1-34.5] (Figure 3).

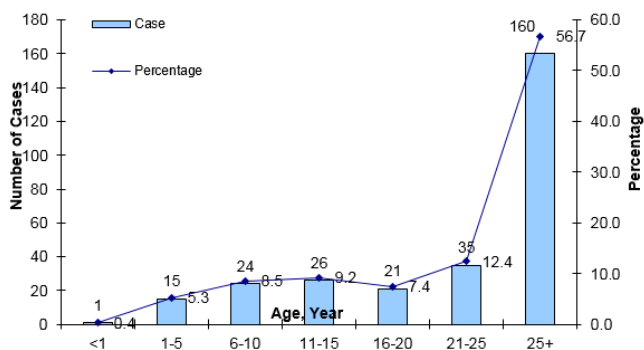


Figure 3: Distribution of cases divided by groups-age.

Discussion

WHO estimated the global prevalence of Hepatitis C as 3% [11]. Moreover, around 3 to 4 million individuals are diagnosed as new cases every year [12]. Anti-HCV assays have several disadvantages, such as a high rate of false positivity, a lack of sensitivity of detection in the early window period of 45 to 68 days after infections, the inability to distinguish between acute (ongoing active, viremic), past (recovered), and persistent (chronic) infections, and a possibility of false negativity with samples from immunocompromised patients, who may have an adequate antibody response [13, 14, 15, 16]. PCR has emerged as a powerful molecular diagnostic tool for the detection of active infection which is manifested by the presence of HCV RNA in the blood of the infected person. Until now no study had earlier been conducted to figure out the prevalence of anti-HCV antibodies especially for HCV-RNA among the general population of Albania. We for the first time conducted our study to find out prevalence of active HCV infection.

Our study is descriptive and consisted in the collection of microbiological data from 2007 to 2010 for 301 patients presenting to visit or hospitalized in the politransfusion persons, blood donation centers, and persons from Unit of Gastro-hepatology, Pediatric, and Infection Disease etc. Patients belong to a different status socio-economic, urban or rural residence. We note that all cases analyzed for HCV-RNA were positive for anti-HCV, tested by immunoassay ELISA method. 56% of patients were income from Gastro-Hepatology and Infection Disease. Patients who manifest clinical signs like Hepatitis infection first of all went to Gastro-hepatology and Infection Unit. For this reason we observed a significant difference between sources of

samples (Table 1).

From 301 anti-HCV positive only 214 of them resulted positive for the presence of HCV RNA's, corresponding to a prevalence of 71.1%. A difference between the cases of anti-HCV positive by ELISA and HCV-RNA positive cases and connects with sensitivity and higher specificity molecular methods and/or the spontaneous viral clearance of the virus. Following acute infection the overall rate of spontaneous viral clearance is estimated to be 25%, but appears to be dependent on the route of transmission and other host and pathogen-related characteristics (17-20).

In this study 56% of cases were males and 44% females. Men make up majority of the sample, with statistically significant difference with women. Such a significant difference is observed in a study conducted in the years 1999-2002 (21) (Figure 2). The least incidence of HCV in females could be attributed to low exposure to HCV risk factors due to male dominating society of the area and also the estrogens hormone in females is considered to play a role in the spontaneous clearance of HCV infection (22-24).

Most patients belong to the age group > 25 years. This groups present a significant difference with other age groups for p value <0.001. Higher prevalence in this age group may be linked to a sexually active age or/and almost of them have done surgical intervention or have done blood transfusion (Figure 3).

In conclusion, the prevalence of active HCV (presence of HCV-RNA's) recorded to different ages and gender groups show to be 71.1% and has increased with the increase of ages. The prevalence of active HCV to male was highest compared to female. In this study the prevalence results to be highest for the age group > 25 years.

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