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Full Length Research Paper

Morbidity risk in an Italian cohort of HCV and HBV patients

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We aimed at evaluating the HBV and HCV epidemiology and the corresponding hospital admissions, as well as morbidity risk. We analysed one Hospital's database, located in a city with a population of 57,891 foreign residents out of 378,376 as at 12.31.2012. We evaluated the HBV and HCV hospital admissions from 2000 until 2012 for liver cirrhosis using the International Classification of Diseases. 2,697 hepatitis cases were reported (1,237 HBsAg and 1,460 HCV RNA positive patients). HBV and HCV occurred more often in males (63% and 59%) than in females (37% and 41%). 1,270 (87%) in the HCV group and 492 (40%) in the HBV group had at least one hospital admission. HBV hospital admission was detected in 1% of people aged 15-30; 10% in those aged 31-45; 50% among those aged 46-60; 39% in people over 61; HCV hospital admission was detected in 1% of people aged 15-30; 6% among those aged 31-45; 48% among those aged 46-60; 45% among those over 61. We found a high rate of hospital admissions for HBsAg and HCV RNA positive patients. This suggests that in the next future chronic hepatitis will have a high impact on health care costs.

Keywords: HBV, HCV, epidemiology, hospital admissions, chronic hepatitis, International Classification of Disease.

INTRODUCTION

In April 2014, WHO for the first time produced guidelines for the screening, care and treatment of people affected with hepatitis C virus (HCV) (WHO, 2014).

These guidelines are primarily addressed to policy-makers in ministries of health working in low- and middle-income countries which formulate country-specific guidelines for treatment. In May 2014, a new resolution urged WHO Member States to develop and implement a national strategy for preventing, diagnosing, and treating viral hepatitis based on the local epidemiological context (WHO, 2014).

Even though the introduction of an effective vaccine against hepatitis B virus (HBV) has reduced its prevalence and its health and economic impact in industrialized countries (WHO, 2001), WHO estimated that more than 2 billion people were infected with the virus and 350 million were chronic carriers. Every year there are more than 4 million clinical cases of acute HBV infection (WHO, 2002). In Italy, HBV incidence has been progressively decreasing from 1991 to 2005, because in 1991 vaccination became mandatory for infants and adolescents.

As far as HCV is concerned, even though the screening of donors" blood introduced in the early „90s has reduced the spread of the virus, WHO estimates that 150 million people, about 3% of the world population, are chronically infected with HCV and at risk of developing liver cirrhosis and hepatocellular carcinoma (WHO, 2014). Currently, therapies for HCV are rapidly evolving and several drugs are in various stages of development. It

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has also been shown that these new molecules would be able to treat more than 90% of people with HCV infection and would be effective against genotypes that were previously difficult to be treated (WHO, 2014).

Recent studies also demonstrated that treatment of patients with compensated cirrhosis is cost-effective (Cammà et al., 2013; Obach et al., 2014).

Therefore, this study aimed at evaluating the HBV and HCV epidemiology in Florence (Tuscany, a region in central Italy) in 2012 and the hospital admissions of these patients at least once, as morbidity risk, from 2000 until 2012.

PATIENTS AND METHODS

We analyzed the Laboratory Information System with a universal identifier of the University Hospital Careggi in Florence reported in 2012. HBV patients were identified on the basis of the presence of antigene surface – HBsAg – . HCV patients were identified on the basis of the presence of HCV RNA; limit of detection: 15 IU/mL. Serum samples were stratified into the following age groups: 0-14, 15-30, 31-45, 46-60, over 61.

We retrospectively evaluated the hospital admissions of these patients for “chronic liver disease and cirrhosis”, “fibrosis and cirrhosis of the liver”, “bleeding from oesophageal varices”, using the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) and 10th revision (ICD-10) from 2000 until 2012.

RESULTS

The analyzed hospital‟s database was located in a city with a population of 57,891 foreign residents out of 378,376 total residents as at 12.31.2012.

A total of 2,707 HBV and HCV hepatitis cases were reported, of which 1,237 HBVsAg and 1,460 HCV RNA positive cases (table 1).

The risk of contracting the infection

The risk of contracting the HCV or HBV infection was 1.3 times (OR: 1.3, CI: 1.23 to 1.45) and 1.7 (OR 1.7, CI: 1.57 to 1.99) higher for males, respectively. The comparison Italian/foreign cases shows foreigners at greater risk of contracting HBV (OR: 4.6, CI 4.06 to 5.35), while Italians have a higher risk of contracting HCV (OR: 1.6, CI: 1.36 to 1.97).

Patients

When we consider the single access to the laboratory for blood exam we found that 523 (2,1%) were HBsAg positive patients and 575 (2.3%) were HCV RNA positive patients.

HBsAg occurred more often in males (63%) than in females (37%). HCV occurred slightly more often in males (59%) than in females (41%).

When we divided all patients into five age groups, HCV prevalence among the different groups was 2% among those aged 15-30, 10.9% among those aged 31-45, 36.7% among those aged 46-60, and 50.4% among those over 61 years of age. HBsAg prevalence among the different groups was 3.2% among those aged 15-30 years, 13.9% among those aged 31-45, 30.40% among those aged 46-60, and 52.5% among those aged over 61 years.

In the HCV group 1270 (87%) had at least one hospital admission, while in the HBV group 492 (40%) did. When we divided the HCV patients into 5 age groups, hospital admission was detected in 1% of people aged 15-30; 6% of people aged 31-45; 48% of people aged 46-60; 45% of people aged over 61 (Figure. 1); HBV hospital admission was detected in 1% of people aged 15-30; 10% of people aged 31-45; 50% of people aged 46-60; 39% of people aged over 61 (Figure. 2).

Considering hospital admissions from 2000 to 2012, we found that the mean for HBV was 5.1 and for HCV were 5.2.

DISCUSSION

This study shows a different prevalence of HBV patients compared to Stasi, Silvestri et al. (2014), when we divided the patients by age groups. In fact, in the previous study, we found a prevalence of 27% in the 15-30 age group compared with 3.2% in this latter study. This could confirm the hypothesis that it is due to the immigration of people not entirely covered by HBV infant vaccination. In fact, in Florence the Chinese population, subjected to different vaccination programs, was less numerous (1.2%) than in Prato (3.7%).

Cozzolongo et al. (2009) showed a seroprevalence of HCV of 2.6% in a Southern Italian town and Fabris et al. (2008) in Northern Italy, showed an increased seroprevalence in people over 75 years old. Actually, the most effective preventive measures are screening and testing of donors‟ blood and organ, good infection control, and safe injection practices in healthcare settings.

For each patient we found about 5 hospital admissions. Moreover, the rate of these increased gradually with the patients‟ age. Annual costs for disease progression in compensated cirrhosis are € 479.07 (lower limit = 383.24, upper limit = 574.89), in decompensated cirrhosis they are € 4994.28 (lower limit = 3995.76, upper limit = 5993.64) (Cammà et al., 2013). Recently in Italy, the triple therapy with Peg-interferon, ribavirin, and boceprevir or telaprevir was the standard treatment for patients

Table 1. Characteristics of study population positive for viral hepatitis

	Gender	0-14	15-30	31-45	46-60	Over 61	Total
anti HBc (total)	M		22	160	270	323	775
anti HBc (total)	F		44	90	118	166	418
anti HBc IgM	M			1	4	4	9
anti HBc IgM	F				1		1
anti HBe	M		11	72	109	82	274
anti HBe	F		27	40	53	49	169
HAV IgM	M				1		1
HAV IgM	F		3				3
HBeAg	M		4	22	18	14	58
HBeAg	F		5	1	2		8
HBsAg	M		38	188	293	265	784
HBsAg	F		61	88	138	166	453
HCV IgG	M	4	15	76	227	269	591
HCV IgG	F	2	10	60	107	359	538
HCV RNA	M		30	129	499	208	866
HCV RNA	F		21	82	200	291	594
HDV Ig total	M			8	15		23
HDV Ig total	F		2		4	1	7
HDV IgM	M			1	2		3
HEV IgG	M				4	1	5
		6	293	1018	2065	2198	5580

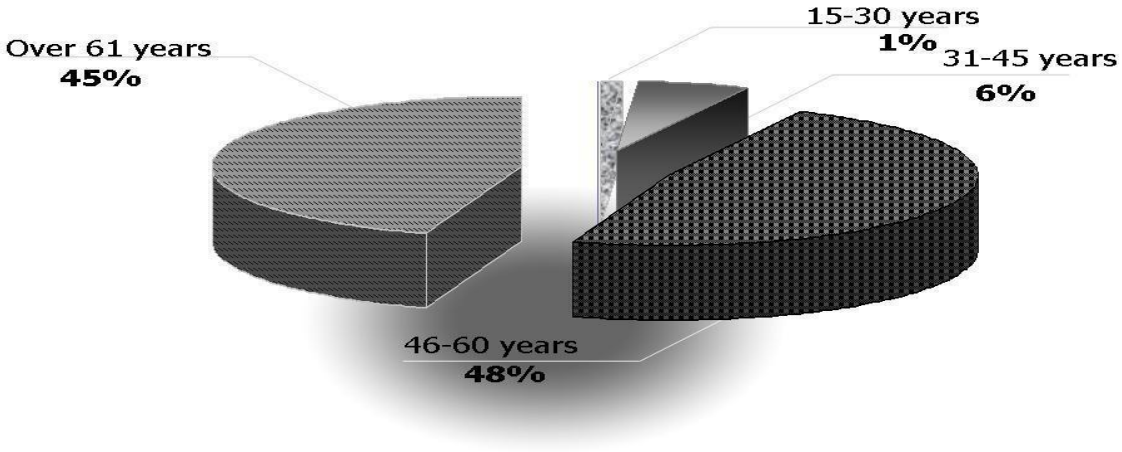

Figure 1. Age distribution in HCV hospital admissions

with a previous treatment failure of dual therapy with Peg-interferon and ribavirin. For relapsers to dual therapy, triple therapy should be initiated as soon as possible in patients with severe fibrosis (F3-F4, Metavir classification) and it

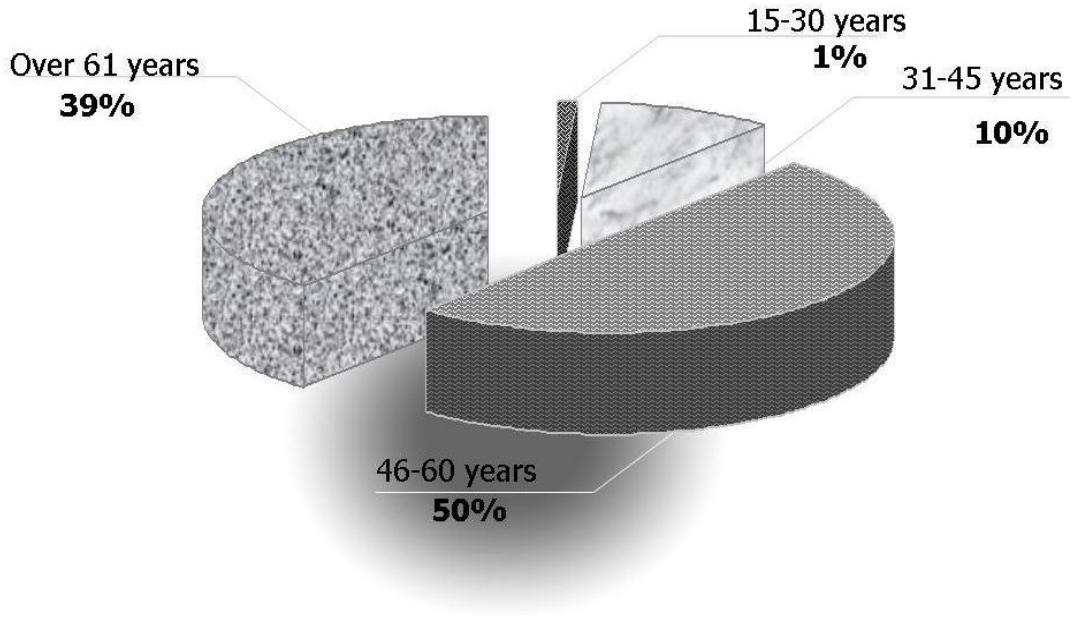

Figure 2. Age distribution in HBsAg hospital admissions.

was indicated for patients with moderate fibrosis (F2). The Italian Association for the Study of the Liver recommended discussion on a case by case basis for patients with minimal lesions (F0- F1). For naïve patients with genotype 1 negative predictors of response to pre-treatment (genotype CC IL28B or fibrosis F3-F4), triple therapy should be introduced as first-line therapy (AISF et al., 2014).

Cammà et al. (2013) showed that the first generation protease inhibitors (boceprevir and telaprevir) was highly cost-effective compared to no therapy in relapser and partial responder genotype 1 chronic hepatitis C patients. Currently, new interferon free therapeutic options now available in Italy.

Mennini et al. (2014) predict three different scenarios, based on epidemiological data, in order to evaluate the impact of future anti-HCV treatments on the burden of disease. The first scenario (new treatment in 2015 with SVR = 90% and same number of treated patients) was associated with a significant reduction in direct health care expenses, corresponding to € 11.1 million. The second scenario (increase in treated patients to 12,790) produced a decrease equal to € 18.4 million. In the third scenario (treated patients = 16,770) the net direct health care cost was estimated as € 44.0 million. This could produce a quasi eradication of HCV.

In conclusion, our results show a high rate of hospital admissions for HBV and HCV. Therefore, in the next future either new treatments or hospitalizations for the consequences associated with the disease will have an impact on health care costs easy to compute but probably difficult to sustain.

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