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Chronic Hepatitis C in the Elderly: A New Challenge

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Abstract

The growing proportion of patients aged above 65 years in Western countries, rising life expectancy, and the improved health status of most older people, together with the advent of new therapies in Chronic Hepatitis C (CHC) bring us to consider the issue of CHC in that population. This paper aims to review epidemiological data concerning Hepatitis C Virus (HCV) infection, to raise the issue of screening, and to discuss the potential impact of direct-acting antivirals in the elderly. In spite of the paucity of data, there is some evidence to claim that the prevalence/incidence of CHC and its complications (cirrhosis and hepatocellular carcinoma) among the elderly are equal to or even higher than in younger populations. Data on acceptance and feasibility of HCV screening are partial, but both the epidemiology of CHC and its complications, and ethical considerations should lead us to avoid exclusion of the elderly from HCV screening policy. The recent introduction of a series of direct anti-viral agents offers the potential to revolutionize treatment in terms of efficacy and safety in all groups of populations. Inclusion of patients aged above 65 both in clinical trials and cost-effectiveness/benefit analyses should be a priority in terms of public health and ethics.

Keywords: Hepatitis C; Elderly; Geriatrics; Epidemiology; Screening; Cost-Effectiveness

Introduction

Since the emergence of screening tests, infection with Hepatitis C Virus (HCV) has been considered a disease of young and mature adults. However, in most Western countries the elderly population is growing dramatically, its life expectancy is increasing, and its health status is improving. People aged above 65 represented 12.4% of the US population in the year 2000 and are expected to grow to 19% of the population by 2030. Persons reaching age 65 have an average life expectancy of an additional 19.3 years (20.5 years for females and 17.9 years for males) [1]. In most European countries, the aging population is greater. The French National Institute for Statistics and Economical Studies anticipates that in 2050, one third of the inhabitants will be above 60 years, versus one in five in 2005 [2]. In 2013, the life expectancy at age 65 was 18.2 and 22.7 years in male and female respectively in France (versus 17.5 and 21.9 in 2005) [2]. This trend is unlikely to slow down or reverse in the future, and it could spread over most countries.

At the same time, many countries have implemented HCV prevention policies, especially towards drug addicts, and have reported a plateau or a reduction in HCV incidence. In France, 232,196 persons were estimated to be chronically infected with HCV in 2004. The prevalence of HCV-antibodies has decreased among people aged 20-39 years between 1994 and 2004 [3], from 1.3-1.4% down to 0.14-0.31%. Consequently, there was a shift in the mean age of people infected with HCV.

With the advent of new therapies and Direct-Acting Antivirals (DAA) for the treatment of hepatitis C virus infection [4], it follows that strategies to treat HCV infection in the elderly should be reassessed in the light of their efficacy and safety profile. Thus the issue of hepatitis C in the elderly should be clearly considered and discussed.

The aim of this paper is to state the epidemiological situation in a low HCV endemic and aging country such as France, to discuss the specificities of HCV infection screening in the elderly, and to introduce the challenges facing liver and infectious diseases experts in the new era of direct-acting antivirals.

Review of epidemiology and burden of hepatitis C in the elderly

An estimated 7.3–8.8 million people (1.1–1.3%) are infected with HCV in Europe [5]. Estimations via HCV-attributable fractions indicate that HCV caused more than 86,000 deaths and 1.2 million DALYs in the WHO European region in 2002. About one quarter of the liver transplants performed in 25 European countries in 2004 were attributable to HCV [5]. No data are available as regards the age groups above 65.

When searching published papers focused on HCV infection in the elderly, one observes first the paucity of data. A bibliographic search in Pub Med including the keywords "hepatitis C", "epidemiology" and "elderly" (in the title) produced few papers, all of them published before 2010. The prevalence of HCV infection in the elderly varies among different studies and countries [6-15] (Table 1). In the US, the prevalence ranged between 0.9 and 1% in the age groups 60–69 and ≥ 70 in the US [7]. In Italy, among 496 elderly people with a mean age of 79 years, the prevalence of HCV-antibodies was found to be around 11% [10]. A study from Japan revealed an HCV-antibodies seropositivity of 8.8% and 13.1% in hospital and autopsy cases older than 60 years of age, respectively [15]. The identifiable potential risk factors for HCV infection in that population were a history of blood transfusion, war service, a history of contaminated syringes and needles, tattoos, hemodialysis, and being a health care worker; drug use was not included [15].

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Table 1: Seroprevalence of infection with hepatitis C in the elderly.

Country	Year	Population	Age	Prevalence of HCVanti-bodies	Reference
USA	1999-2002	Community	> 60	0.9%	Armstrong [6]
		Community (White)	60-69 70	0.9% 1 %	
	1988-1994	Community (Non-Hispanic Blacks)	60-69	2.5 %	Alter [7]
			70	2.8 %	
Italy	1999	Nursing Home	(mean age 79)	4.5%	Chien [8]
	1990	Blood Donors	> 60	2.5%	Sirchia [9]
	2000	Nursing Home	(mean age 79)	11%	Baldo [10]
	1998	Community	> 60	3.3%	Monica [11]
	2003	Community	68-77	2%	Mazzeo [12]
Corea	1992	Community	70-79	5.7%	Kim [13]
	1993	Blood Donors	> 50	3.9%	Yano [14]
Japan	1999	Hospital Autopies	> 60	8.8%	Sawabe [15]
				13.1%	
France	2004	Community	> 65	1%	InVS [16]
			75-80	1.38%	

In 2002, France was classified in the group of countries of the WHO European region with the highest death rates for HCV-related liver cancer (>3 per 100,000 deaths) and for HCV-related liver cirrhosis (6-8 per 100,000) [5]. In 2004, the prevalence of HCV antibodies was estimated at 0.84 % of the French population, i.e. 367,055 people aged 18-80. Of this number, two thirds were HCV-RNA positive [16]. A quarter of HCV-infected people were aged above 65, including 6.1% aged between 75 and 80, with an HCV prevalence around 1% and 1.38% in these two age groups. The age groups45-49 and 55-60 were the most affected with HCV (prevalence of 1.78% and 2.28%, respectively). After adjustment for sex, place of birth, health insurance coverage, injecting and nasal drug use, tattooing, age above 60 was the strongest risk factor (ranking 3rd after injecting drug use and birth in a high-endemic country) [16]. In spite of these data, people aged above 65 have never been targeted by French HCV health programs.

In 2004-2011, 161,387 patients were hospitalized in France with Chronic Hepatitis C (CHC) [17]. CHC prevalence in French hospitals decreased from 0.45% to 0.33% between 2004 and 2011; 21,164 CHC patients died in hospitals. Liver complications were diagnosed in 60.2% of cases. Between 2004 and 2011, mortality increased in CHC hospitalized patients from 4.6% to 10.6%; meanwhile, the mean age of patients hospitalized with HCV increased from 52 to 56 [17]. Among patients hospitalized for HCV-related liver cirrhosis in France in 2009, 24.5% were aged 70 and above (including 8.3% > 79); as regards HCV-related Hepatocarcinoma (HCC), 38.4% were aged 70 and above (including 12.8% >79) [18].

The natural history of hepatitis C in the elderly and the aging process of the liver remain partially unknown. Several studies brought some evidence that the speed of fibrosis process increases with age [19]. More advanced age (≥50 years), obesity and serum ALT>20 IU/L were associated with severe fibrosis in patients with chronic HCV [20]. Risk factors associated with death in patients with HCV complications were: male sex, being hospitalized in home medical care, age ≥ 50 years, diagnosis of alcohol addiction, HCC, HIV co-infection and non-Hodgkin lymphoma [17]. Together with alcohol intake and HCV genotype, age has been recognized as a risk factor for liver cirrhosis and HCC in HCV patients [21]. Age is a major risk factor of death in CHC patients. While the adjusted survival-time ratio was 0.45 among patients aged 50-59, it was 0.25 and 0.13 among those aged 70-79 and above 79, respectively [17].

Due to the natural history of HCV infection and trends in HCV epidemiology, we must think beyond the mere prevalence of HCV antibodies and consider the complications of HCV infection, that is, liver cirrhosis and hepatocellular carcinoma. Even if the prevalence data for HCV infection and its complications in the elderly are scarce, they converge to underline the elderly as a major topic in HCV epidemiology research.

Screening HCV in the elderly

If we acknowledge concern about HCV in the elderly, we must acknowledge also that the issue of screening HCV infection in this population group remains unanswered: Should we screen? How to screen? The decision to screen an infectious disease must be based upon three major criteria: (1) limiting the spread of the virus, (2) being feasible and acceptable by patients and society, (3) managing the disease as early as possible.

While the risk of spreading the virus C through injecting/nasal drug use is doubtful in the elderly, the likelihood of transmitting it through other routes, such as surgical procedures, could be non-negligible because of age-related comorbidities and access to multiple sources of health care and surgical procedures. In 2012, one third of French hospital stays were attributed to people aged above 65 while the proportion of this age group within the total population was 16.5% [22]. Although the health policy to prevent nosocomial infections has been substantially improved during the last twenty years and has most likely reduced the risk of HCV transmission through medical procedures, this route of transmission should not be neglected. The likelihood of HCV infection was multiplied by 11.6 and 5.7 in patients with a history of invasive radiological procedure or digestive endoscopy, respectively [23]. Sexual transmission of HCV has been considered to occur rarely. However, recent data indicate that sexual transmission of HCV can occur, especially among HIV-infected persons [24]. Surveillance data from the US Centers for Disease Control demonstrate that 10% of persons with acute HCV infection reported contact with a known HCV-infected sex partner as their only risk for infection. HCV transmission by sex has been estimated at 0.07% per year or approximately one per 190,000 sexual contacts. No specific sexual practices were related to HCV positivity among couples making possible unambiguous and reassuring counseling messages [25]. Thus, although sexual life in the elderly is often a taboo subject, sexual transmission of hepatitis C in that population group should be considered.

The Euro Hepatitis Index 2012 shows France to be the country with the best hepatitis care delivery in Europe [26]. Part of the French viral hepatitis strategy includes an annual mass-media campaign targeted at the general public (not considering age and sex as specific targets) as well as specific campaigns to raise awareness among health-care workers and groups at high risk. French national hepatitis programs

have resulted in effective screening campaigns since the early 1990s, very good access to treatment, and enhanced hepatitis surveillance systems. In spite of these good results, only 57.4 % of patients with HCV antibodies were estimated to know their serological status in 2004 [16]. The awareness of serological status varies dramatically according to risk factors. Among HCV patients with a history of drug use, 93.2% knew their HCV seropositivity; among HCV patients with a history of blood transfusion before 1992, 66.5% knew their seropositivity; only 25.6% of those without history of drug use or blood transfusion knew their status [16]. Insofar as they are likely to belong to these two last groups, elderly persons should be considered a target group for HCV screening.

Opportunities to offer HCV screening are plentiful in most Western countries because of the high number of contacts of the elderly with the health care system. After the age of 55, more than 85% of the French population benefit from at least one consultation per year in a general practice, and the mean number of consultations per year for this age group is 6.3 and 7.2 [27]. In spite of these opportunities, we should ask whether the elderly, if targeted by screening programs, would accept an offer of HCV screening. Acceptance of screening for HCV was high (90%) among patients undergoing colonoscopy for colorectal cancer screening in Canada (median age 56); willingness to be tested was not related to age [28]. However, this result measured only a declared acceptance of HCV screening by patients engaged in preventive care and potentially more likely to accept and complete anti-HCV treatment than other target screening populations. The above figures are close to a UK survey in a high-risk urban population that reported that 90% of participants would still want to be tested even if they were unable to receive HCV treatment [29]. The relationship between age, awareness of HCV status, and willingness to screening has not been studied and data is lacking. Barriers to screening HCV could arise from attitudinal and cognitive issues in patients, but also could be system-centered (costs and accessibility of screening services) and physician-centered (negative reinforcement and patient stereotyping). These topics deserve further investigation.

Another issue is the frequency of competing risks in the elderly, and therefore the uselessness of screening because of the difficulty/impossibility of treatment and the low expected benefit for these patients. Should we target only patients without comorbidity? In the same way, should we eliminate injecting drug users or HIV-HCV co-infected patients from policy screening on the pretext that the benefit could be low? Given that the life expectancy of patients at age 65 in 2008-10 in the European Union was 16.5 years for men and 20.1 years for women, and 18.7 and 23.2 years in France [30], not considering the elderly in a national public-health policy would be clearly unfair. Beyond individual considerations, the social acceptability of HCV screening should be discussed. The combination regimes of Interferon (IFN) and the antiviral drug ribavirin have been shown to be able to reduce morbidity and mortality by HCV infection, and to be cost–effective [31,32]. HCV screening in at-risk groups has also been demonstrated to be cost-effective [33]. However, the advent of new and expensive therapies must lead us to reassess the cost-efficiency and cost-benefit ratio of HCV screening, including aging and life expectancy as major variables. Sensitivity analyses of economic models must include aging as a compulsory parameter. It should be borne in mind that every decision to screen and treat any disease implies the possibility of losing human and financial resources that could be used for other patients.

The paucity of data should encourage decision-makers (1) to think beyond focusing prevention policy on drug users and on reducing the likelihood of HCV transmission through surgical procedures and risky behaviors such as tattooing; (2) to support research and debate on HCV screening in the elderly as well as other at-risk groups.

Treating HCV in the elderly

Until the recent advent of Direct Anti-viral Agents (DAAs), the treatment of HCV depended on combination regimes of Interferon (IFN) and ribavirin. These regimes required regular injections, generally for a minimum of 12 weeks, and the use of IFN often caused serious side effects (thrombocytopenia, leukopenia and depression). Of the common HCV genotypes, genotype 1 responded relatively poorly to these regimes (50-60% viral clearance), while most (80% plus) of genotype 3 patients responded with sustained viral clearance. Patients with severe liver disease (decompensated cirrhosis) tolerated these regimens very poorly and often their liver function deteriorated [34]. The advent of oral DAAs expected with no (or less) major side effects offers the potential to revolutionize treatment, particularly in genotype 1 patients and those with advanced liver disease [35]. Will this revolution also take place for the elderly?

Some authors discussed the benefits expected from antiviral therapies in the elderly [36-38]. Older age would be an independent factor associated with a lower likelihood of being considered for antiviral therapy [38]. Older adults would be less likely to accept antiviral treatment and discontinuation of therapy and dose reductions would be more frequently required in this age group compared with younger adults [38]. These limitations have not been identified by Mindikoglu and Miller [39]. Furthermore sustained virological response rates following combination therapy with standard interferon and ribavirin would be similar in individuals older than 60 years of age and those younger than 60 years of age [38]. Ikeda et al. have shown that, beyond age 60, treated patients with HCV liver cirrhosis experienced a reduction in mortality and in incidence of HCC [40]. In a recent meta-analysis, the sustained virological response to a combination regimen of interferon and ribavirin was lower in patients aged 65 and above [41]. In a cohort of patients who failed to respond to a previous therapy, the efficacy of a tritherapy, including telaprevir or boceprevir, was not significantly different before and after age 65. These advances, and those to come, raise the hope that physicians may overcome the barriers created by the relatively poor efficacy and tolerability of peg interferon alfa plus ribavirin, and become able to treat patients aged 65 and above more efficiently and safely. However the median age of patients in the most recent trials on DAA was around 50: these trials included large ranges of patients 18-69 yet they did not consider the issue of efficacy and safety in older people and did not compare patients before and after age 65 [42-46].

The low number of the elderly in clinical trials and the rare comparisons of efficacy and safety according to age are not specific to HCV infection. Unlike the case of pediatrics, there is no specific legal requirement for the development of medicines for geriatric use. The International Conference on Harmonization of Technical

Requirements for Registration of Pharmaceuticals and the European Medicines Agency have clearly stated that the use of drugs in older people requires special consideration due to the frequent occurrence of underlying diseases, concomitant drug therapy, and the consequent risk of drug interaction. CHC should be approached as in oncology: as requiring elderly-specific data including at least 100 older people and stratifying data; as including comorbidities, concomitant therapies and frailty in the study design; and as tackling the issue of specific adverse events, age-related efficacy endpoints, and pharmacokinetics [47]. As in oncology, standardized geriatric assessment before any therapy decision should be promoted in order to provide equal opportunity to older people who could benefit from the recent advances in HCV therapy.

Besides the issue of antiviral therapies, there remain those of treating HCV-related liver cirrhosis and HCC, and of liver transplant in the elderly. While data on the management of liver cirrhosis in the elderly, including that related to HCV, is lacking, data on HCC is more extended. The mean age of HCC patients has been progressively increasing over the last decades and the ageing of these patients is becoming a real challenge in everyday clinical practice. International guidelines on HCC management do not address this problem exhaustively and do not provide any specific recommendation [48]. Available data seem to indicate that in elderly patients the outcome of HCC is mostly influenced by liver function and tumor stage rather than by age and that age by itself should not influence treatment allocation. Available data suggest that in either elderly and younger patients alike, treatment is a main predictor of outcome, and a fatalistic attitude among physicians leading to under treatment or non-treatment of aged patients should no longer be justified [48].

As regards liver transplant, the European Foundation for Liver Transplant reported that cirrhosis and cancer of the liver were the two major causes leading to liver transplant in patients aged 60 and above, 61% and 27% respectively [49]. The rate of patients newly registered for liver transplant by the French Agency for Biomedicine has increased by 28.2% during the last five years. The number of transplant patients aged above 65 has increased from 21 to 115 in 11 years (+450%); this category represents 6% of patients first registered for liver transplant in 2013. The number of patients newly registered for liver transplant because of hepatocarcinoma increased by 39% between 2007 and 2013 [50]. Available data did not show different results according to age [51,52]. Actually physiological age should be more significant than demographic age in liver transplantation. It follows that geriatric assessment should precede any medical decision. Last, guidelines on management of patients not eligible for liver transplant are needed.

Conclusion

In spite of the paucity of data, there is evidence to support the claim that the prevalence/incidence of CHC and especially its complications (cirrhosis and hepatocellular carcinoma) among the elderly are equal to or even higher than in younger populations. Data on acceptance and feasibility of HCV screening are partial, but both the epidemiology of CHC and its complications, and ethical considerations should lead us to avoid exclusion of the elderly from HCV screening and monitoring programs. The recent introduction of a series of Direct Anti-viral Agents (DAAs) offers the potential to revolutionize treatment, in terms of efficacy and safety, in all groups of populations. Inclusion of patients over age 65 both in clinical trials and cost-effectiveness/benefit analyses should be a priority in terms of public health and ethics.

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