

HCV – Estimation of the number of diagnosed patients eligible to the new anti-HCV therapies in Italy

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Abstract. – OBJECTIVE: The present research wants to take a picture of the current epidemiological scenario regarding HCV infection in Italy. Studies used to estimate HCV burden of illness in Italy were so far local and performed a number of years ago, not mirroring the state of the art. EpaC wanted to provide a real number of diagnosed patients, eligible to new anti-HCV therapies.

PATIENTS AND METHODS: EpaC is the most important Italian NGO for hepatopathic patients. A number of sources were cross-checked. Starting from all regional data regarding HCV-related exemptions, a correction/integration was performed with online questionnaire to associated patients (from which we derived patients cured and also other/no exemptions); survey to all prescribing centers in Italy (from which we derived the percentage of ineligible patients); prevalence of particular subpopulations was also collected (prisoners and HIV/HCV coinfecting); calculations of new diagnosed, dead and cured patients in 2015. Excluded patients were illegal immigrants and active drug addicts (subpopulations currently rarely cured).

RESULTS: A total of 221,549 patients were derived from regional exemptions databases and the mean national prevalence was 0.364%. Adding patients without exemptions/other exemptions, total was 308,624. We deducted the yearly deaths, cured and not eligible patients and, last, integrated with coinfecting and prisoner special groups. Prevalence was also estimated at regional level, highlighting a reduction of the typical North-to-South prevalence gradient. Applying the above-mentioned corrections/integrations, total diagnosed and eligible HCV patients in Italy who can be immediately cured are supposed to range 163,148-187,756.

CONCLUSIONS: This is a research aimed at filling an informative gap able to provide useful actual information in terms of HCV patients real-life management and future resource allocation. These data may be considered the basis for policy- and decision-makers to plan and man-

age patients ready to be cured. The research does not provide information on patients not yet diagnosed.

Key Words

NHCV, hepatopathic patients, Regional exemptions.

Abbreviations

HCV, Hepatitis C Virus, EpaC, Italian Liver Patient Association.

Introduction

HCV affects an estimated number between 130 million and 210 million people worldwide. According to the European Centre for Disease Prevention and Control, Italy has the highest number of HCV-positive patients in Europe and the highest rate of death from cirrhosis and HCC⁽¹⁾. Nevertheless, studies used to estimate HCV burden of illness in Italy were so far local and old (performed in 1990s), not mirroring the current state of the art. The Italian epidemiological scenario has changed significantly over the last 20 years. It is important to quantify patients eligible to the new anti-HCV therapies in Italy; however, there are no reliable sources of information on hepatopathic patients prevalence at regional and national level. Two key aspects still recognized as true from old studies were 1) the North-to-South gradient of prevalence (3.9% in Veneto-16.2% in Campania) and 2) an age-related increasing prevalence (from lower values in teenagers and young adults to higher values in adults aged over 60 years) (Figure 1).

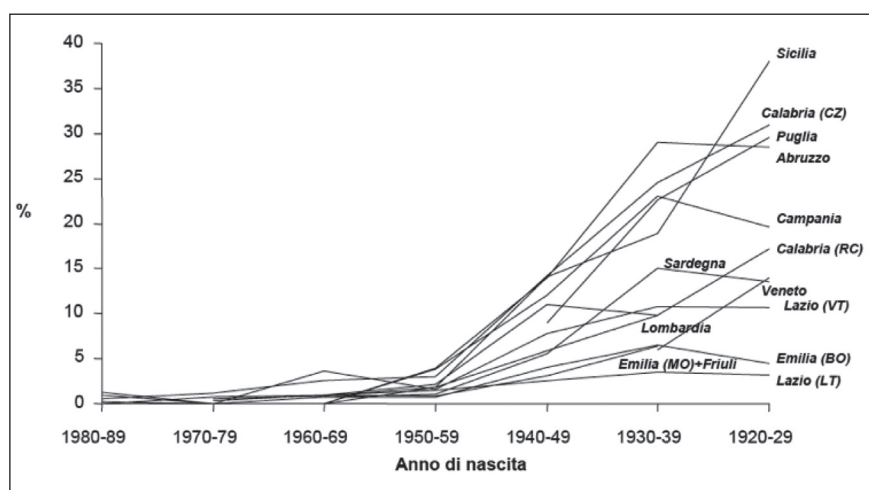


Figure 1. HCV age-related prevalence in different Italian regions².

EpaC is the most important NGO for hepatopathic patients, actively involved in the Italian environment, producing data with the direct collaboration of patients, clinicians and Institutions.

Objectives

The present research aims at taking a picture of the up-to-date epidemiological scenario regarding HCV infection in Italy. EpaC wanted to provide Institutions with a real number of diagnosed patients, eligible to the new anti-HCV therapies, as basis for taking aware decisions concerning future HCV eradication strategies and evidence-based budget allocation.

Patients and Methods

A number of Institutional sources were cross-checked. Starting from all regional data regarding HCV-related exemptions (code 016.070.54), a correction/integration was performed with online proforma questionnaire to associated patients (from which we derived patients cured and also other/no exemptions); survey to all prescribing centers in Italy (from which we derived the percentage of patients ineligible to new antiviral treatment); prevalence of particular subpopulations was also collected (prisoners and HIV/HCV coinfecting); calculations of new diagnosed, dead and cured patients in 2015. Illegal immigrants and active drug addicts (subpopulations currently rarely cured) were excluded from calculations.

Table I. Adjustments on 016 exemption macrocode, applying the national average of subcodes.

Region	016 exemptions (n)	Prevalence
Lombardy	54,430	0.546%
Puglia	20,714	0.506%
Campania ¹	27,245	0.464%
Liguria	6,338	0.398%
Tuscany	14,889	0.397%
Emilia-Romagna	16,292	0.366%
Friuli Venezia Giulia ²	3,959	0.322%
Basilicata ²	1,862	0.322%
Sardinia ²	5,358	0.322%
Abruzzo ³	4,295	0.322%
Piedmont	14,084	0.317%
Molise	979	0.311%
Aosta Valley	400	0.311%
Veneto	15,104	0.307%
Lazio	16,315	0.278%
Calabria ^{4,5}	5,381	0.272%
P.A. Trento	1,448	0.270%
P.A. Bolzano	1,259	0.244%
Marche	3,684	0.237%
Umbria	2,049	0.228%
Sicily ⁶	5,464	0.107%
TOTAL	221,549	0.364%

¹Adjusted applying the average regional rate of 6 out of 7 Local Health Authorities (LHA) to the lacking LHA (Caserta).

²Adjusted applying the national average of subcodes, excluding areas with subcodes (0.322%).

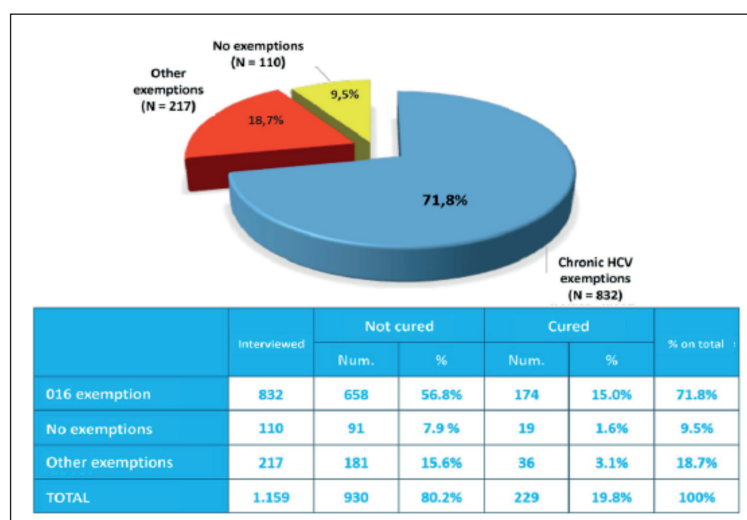
³Adjusted applying the national average of subcodes, excluding areas with subcodes (0.322%) – probable overestimate.

⁴Partial data (4 out of 5 LHAs – lacking Reggio Calabria).

⁵Adjusted applying the average rate of 2 LHAs (50% of the total regional population) to the other 3 LHAs with macrocodes (data missing from Reggio Calabria).

⁶Probable underestimate due to the use of other exemptions.

Figure 2. *Upper panel:* patients distribution (with or without exemptions). Data collected through online survey. *Lower panel:* patients % distribution (with or without exemptions).



Results

A total of 221,549 patients were derived from regional exemptions databases and the average national prevalence was downsized to 0.364% (Table I). Adding patients without exemptions/other exemptions derived from the online survey (Figure 2), total was 308,624. We deduced the yearly deaths, cured and not eligible patients and, last, integrated with coinfecting and prisoners special groups (data not shown). Prevalence was also estimated at regional level, highlighting a reduction of the typical North-to-South prevalence gradient. Applying the abovementioned corrections/integrations, total diagnosed and eligible HCV patients in Italy who can be immediately cured are supposed to range 163,148-187,756 (Table II).

Discussion

The present research has tried to fill an information gap at national level, which may be of precious help for decision- and policy-makers in defining future therapeutic strategies and budget allocation decisions. In fact, the research provides important information regarding the current HCV epidemiological situation in Italy, which has undergone major changes over the past 10-15 years. According to the results regarding eligible patients, an eradication plan seems to be feasible and applicable in the next few years, also considering the likely price reductions of drugs (about 12,500.00 euros for patient treated, starting from 2018), already estimated by recent studies³.

We hereby recognize the limits of our research, in particular concerning the estimated numbers co-

Table II. Estimate of patients diagnosed and eligible to anti-HCV treatment at 1 January 2016.

Features	Parameter	Subjects	Pts estimate
Total HCV subjects (cured or not)	–	308,624	308,624
Cured subjects (with or w/o exemption)	25.0%	-77,156	231,468
Not eligible pts	15.0%	-34,720	196,748
New acute infections in 2015	0.23 x 100,000 on Italian population	+1,400	198,148
Cured/on treatment pts in 2015	–	-25,000	173,148
Pts died in 2015	–	-10,000	163,148
Total treatable pts (Jan 1 2016)		MIN	163,148
Prisoners	7.4%	+3,968	167,116
Coinfected pts		+20,640	187,756
Total treatable pts (Jan 1 2016)		MAX	187,756

ming from the survey to prescribing centers and the online proforma questionnaire administered to patients. Specifically, we are aware of possible underestimation of HCV patients with a different exemption code, patients without any exemption, ineligible patients and cured patients without exemptions.

Another important issue to be considered is the current attitude of certain patients cured with generic drugs self-provided through health travels e.g. to India. The number of these “health travellers” seems to be increasing according to recent information come to EpaC’s attention.

We intend, therefore, to perform a new research in 2017, which will consider all the above mentioned limits, trying to overcome them and give more precise results.

Conflict of Interest

The Authors declare that they have no conflict of interests.

References

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