Epidemiological and economic evaluations according to DAA treatment access: an interim evaluation based on PITER cohort data

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\textbf{BACKGROUND}

Hepatitis C virus (HCV) is a leading cause of liver-related morbidity and mortality worldwide; Italy has the highest prevalence of HCV in Europe and the highest death rate for HCC and cirrhosis. Each year more than 20,000 chronic liver disease complicated deaths are reported and, in more than 65% of them, HCV is the main etiological factor of chronic liver disease. Considering the morbidity and mortality impacts expected by the DAAs therapy, due to their very high efficacy in eradicating HCV and in improving the liver related clinical outcomes, different consequences in the economic burden according to the access to therapy could also be expected.

\textbf{AIM}

The aim of this work is to describe the changes in the epidemiologic pattern of HCV patients in care in Italy from the DAAs introduction (2014) to the universal access (2017) and to evaluate the net payback period to recover the initial investment on DAAs treatment from the National Health System (NHS) perspective.

\textbf{METHODS}

A multistate Markov model of HCV liver disease progression was developed (Figure 1). Fibrosis stage distribution, treatment efficacy and direct costs according to each health state were derived from PITER cohort data (Figure 2, Table 1). PITER is an ongoing cohort of 10,520 consecutively enrolled patients from 90 hospital centers across Italy linked to care for chronic HCV infection in the period May 2014 to September 2017, who are not on HCV treatment at time of enrolment. The payback period was defined as the number of years required to recover the NHS investment on DAA treatment. A 20-year time horizon for three different enrolment periods DAA treatment access (2014/2015, 2016 and 2017) in Italy were considered.

\textbf{RESULTS}

Of 5282 patients enrolled and evaluated for the access to DAA therapy (coming from 30 clinical centers distributed all over Italy), 2657 (51\%) had undergone a DAA therapy from January 2015 to December 2017. Mean age: 58 ±12 years, 55\% were male and genotype 1b was prevalent (62-67\%). Standardising the real-life data of the three enrolment periods for 1000 patients, the investment on DAAs was considered equal to € 25 million during 2014-2015, € 15 million during 2016 and 9 million euros in 2017 (Figure 3). For the first enrolment period (2014-2015), the complete return on investment will not achieved due to the severity of the treated patients and the high costs of treatment: For 2016 and 2017 the estimated payback periods were 6.6 and 6.2 years respectively. The total cost saving after 20 years was 50.13 and 55.50 million euros for 1000 patients treated during 2015 and 2017, respectively (Figure 3). The DAA shows that the SW and health medical costs are the inputs with the major impact on the break even point (Figure 4a). A specific sensitivity analysis on the transition probabilities of chronic liver disease progression reported from other studies has been conducted demonstrating the robustness of the results (Figure 4b).

\textbf{CONCLUSION}

The epidemiologic pattern of patients in care in Italy has changed following the universal access to DAA treatment. This study could be a useful tool for public decision-makers in understanding how HCV epidemiological profiles influence the HCV liver disease economic burden.

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\textbf{REFERENCES}