Epidemiological and economic evaluations according to DAA treatment access in Italy based on real life PITER cohort data

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INTRODUCTION

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 DAA 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.

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.

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 1-2). 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.
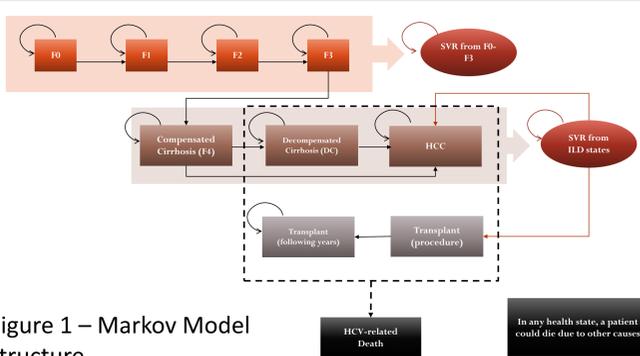
Figure 1 – Markov Model structure

Figure 2 – Patients distribution per disease stage
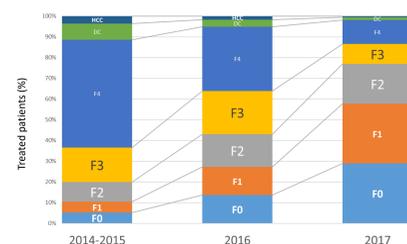
Table 1 – Patients distribution per genotype

Genotype Distribution in treated patients	2015 N 1390 (%)	2016 N 553 (%)	2017 N 665 (%)
G1	938 (67%)	352 (64%)	415 (62%)
G2	186 (13%)	100 (18%)	135 (20%)
G3	154 (11%)	61 (11%)	65 (10%)
G4 and Other	112 (8%)	40 (7%)	51 (8%)

Table 2 – Economic parameters

Cost of treatment	Base-case	Min c	Max c	Sources
Treatment 2014-2015	€ 25.000	€ 20.000	€ 29.000	Assumption
Treatment 2016	€ 15.000	€ 12.000	€ 17.400	Assumption
Treatment 2017	€ 9.000	€ 7.200	€ 10.440	Assumption
Other direct medical costs	Base-case	Min	Max	Sources
F0	€ 234	€ 176	€ 292	Kondili et al 2017; Marcellusi et al 2016
F1	€ 234	€ 176	€ 292	Kondili et al 2017; Marcellusi et al 2016
F2	€ 234	€ 176	€ 292	Kondili et al 2017; Marcellusi et al 2016
F3	€ 617	€ 292	€ 942	Kondili et al 2017; Marcellusi et al 2016
F4	€ 876	€ 397	€ 1.354	Kondili et al 2017; Marcellusi et al 2016
Decompensated Cirrhosis (DC)	€ 6.626	€ 4.385	€ 8.868	Kondili et al 2017; Marcellusi et al 2016
HCC	€ 12.896	€ 5.792	€ 20.000	Kondili et al 2017; Marcellusi et al 2016
Transplant (procedure)	€ 73.774	€ 62.648	€ 84.900	Kondili et al 2017; Marcellusi et al 2016
Transplant (following years)	€ 2.365	€ 0	€ 4.729	Kondili et al 2017; Marcellusi et al 2016
SVR	€ 0	€ 0	€ 0	Kondili et al 2017; Marcellusi et al 2016
SVR from ILD states	€ 1.388	€ 397	€ 2.483	Assumption from Cortesi 2015

The deterministic sensitivity analysis shows that the SVR 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-d).
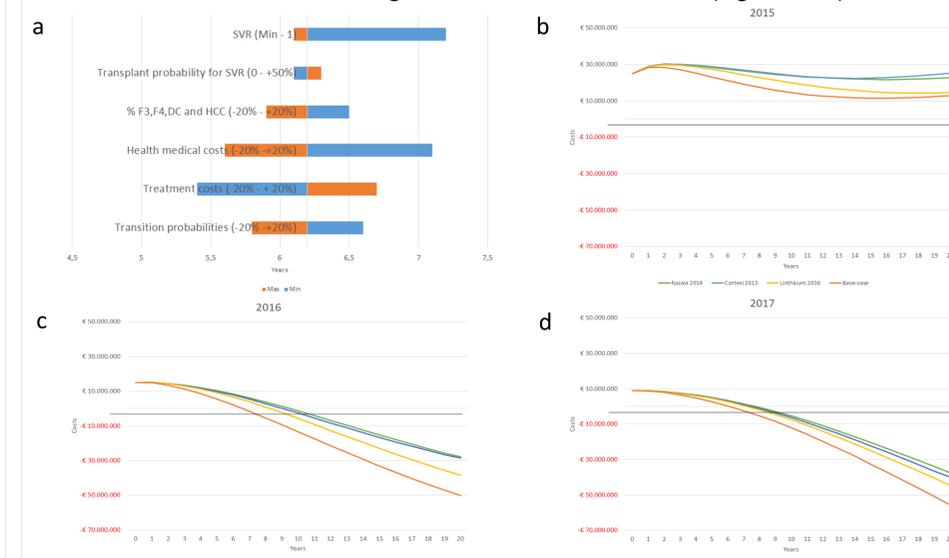
Figure 4 – Deterministic sensitivity analysis per 1000 HCV treated patients

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 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 2016 and 2017, respectively (Figure 3).
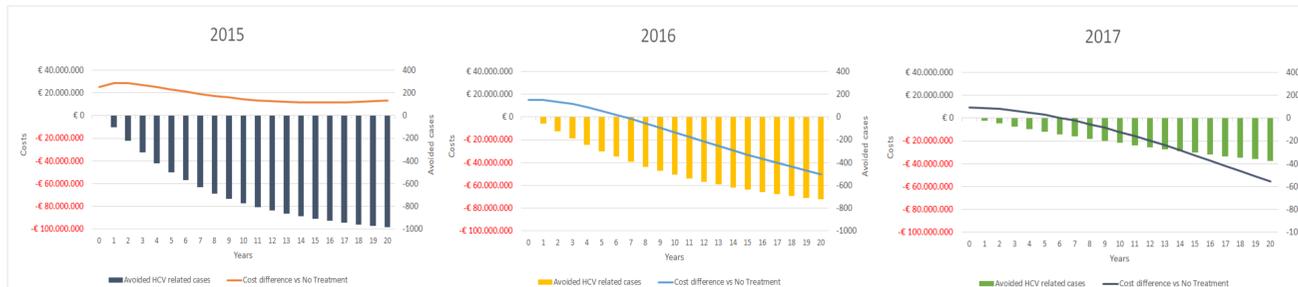
Figure 3 – Avoided HCV related cases and cost due to DAAs treatment per 1000 HCV treated patients

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.

ACKNOWLEDGEMENTS

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DISCLOSURES

Nothing to disclosure

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