Health gains and costs of HCV treatment: a cost effectiveness analysis of two different health policies scenarios simulated in PITER real life cohort.

L.A. Kondili[1], F. Romano[2], M.Ruggeri[2] S.Rosato[1], M.R. Brunetto[3], A.L. Zignego[4], A. Ciancio[5], A. Di Leo[6], G. Raimondo[7], C. Ferrari[8], G. Taliani[9], G.Borgia [10] P. Blanc[11], T. A. Santantonio[12] G.B. Gaeta[13] A. Gasbarrini[14], L. Chessa[15], E.M. Erne[16], E. Villa[17] D. Ieluzzi[18], F. P. Russo[19] P. Andreone[20], M. Vinci [21], C. Coppola[22] L. Chemello[23], S.Madonia [24], G. Verucchi[25], M. Persico[26], M.Zuin[27] , M. Puoti[28] A. Alberti[29], G.Nardone [30] V. De Maria[31], M Massari[32] G. Montalto[33] G.Foti[34], MG Rumi[34], A. Cichetti[2], A. Craxi' [35] S.Vella[1] on the behalf of PITER Collaborating Group

1 Istituto Superiore di Sanità, Rome; 2Catholic University, Rome 3Azienda Ospedaliero-Universitaria Pisana; 4University of Florence; 5University of Turin; 6University of Bari; 7University Hospital of Messina; 8Azienda Ospedaliero-Universitaria di Parma; 9Sapienza University of Rome; 10 Second University of Naples; 11University of Foggia, 12Santa Maria Annunziata Hospital, Florence, 13Federico II University of Naples, 14Policlinico Universitario Agostino Gemelli , Rome, 15 University of Cagliari, Italy; 16 University of Padua , 17University of Modena and Reggio Emilia, Modena; 18 Azienda Ospedaliero Universitaria di Verona , 19 University of Padua , 20University of Bologna, 21Niguarda Hospital, Milan, 22Gragnano Hospital 23 University of Padua , 24 V.Cervello Hospital Palermo, , 25University of Bologna 26University of Salerno, Italy,27University of Milan, 28Niguarda Hospital, Milan, 29University of Padua, 30Federico II University of Naples, 31Azienda Ospedaliero-Universitaria Catanzaro, 32 ASMN Reggio Emilia, 33University of Palermo, Bianchi Malacrino-Morelli Hospital, Reggio Calabria, 34University of Milan, 35 University of Palermo.

THE AASLD LIVER MEETING® 2016 BOSTON • NOVEMBER 11-15

BACKGROUND

Given that a "life without HCV" is now an attainable goal, it is crucial that health policies that include the cost-effectiveness of access to treatment for all infected individuals be developed. An important step towards creating these policies is to provide indications based on real-life data on individuals who are potentially representative of the HCV-infected population. We evaluated the health gains and costs of two strategies which differed in terms of the start times of DAA IFN-free regimens for treating HCV chronic infection.

AIM

Scenarios of Treatment Policy

The evaluation was performed using a lifetime multi-cohort model of real-life patients with chronic HCV infection considered to be representative of patients in care.

In this study population, access to treatment was defined as: "prioritized", according to the European Association for the Study of the Liver (EASL) 2015 CPG prioritization algorithm.

Two scenarios of policies for treatment were simulated and compared:

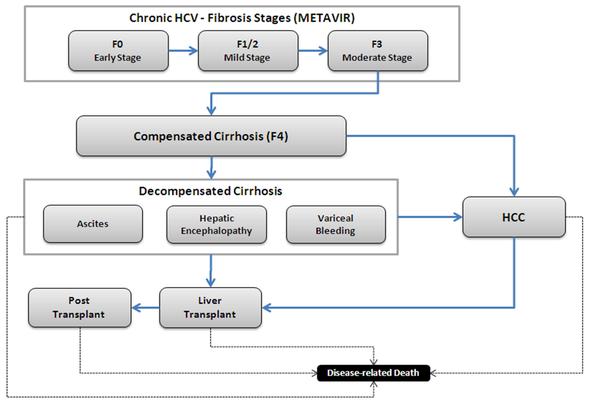
Policy 1: Treat all cohort patients in any stage of fibrosis (F0-F4) with a second-generation DAA regimen (IFN-free treatment); "Universal" treatment

Policy 2: First treat patients in fibrosis stage F3/F4 and those classified as "prioritized"; delay treatment for the remaining patients until they eventually reach the F3/F4 stage. " Delayed" treatment

POPULATION

An ongoing cohort of 8,125 consecutive patients undergoing care for chronic HCV infection in about 100 public clinical centres in the period from May 2014 to December 2015 was considered for the scenario analysis. The definition of the fibrosis stage corresponds to the Metavir stage of liver disease.

METHODS & RESULTS



	Costs	QALYs	Incremental Costs	Incremental QALYs
Strategy 1	€ 271.366.854	90.926	€ 31.083.475	3.495
Strategy 2	€ 240.283.379	87.430		
ICER			€ 8.893	

Base case analysis

At the IFN-free price level of € 15,000, the strategy 1 costs € 271,366,854 and returns 90,926 QALYs. On the other hand, the strategy 2 costs € 240,283,379 and returns 87,430 QALYs. As a result, the incremental costs are equal to € 31,083,475 and incremental QALYs are 3,495. The ICER is € 8,893 per QALY. The incremental cost-effectiveness ratio therefore is cost effective compared to the threshold value generally taken into account by National Institute for Clinical Excellence (UK agency) which ranges to € 20,000–40,000/QALY.

Multivariate probabilistic sensitivity analysis

The results of the Monte Carlo simulation are summed up in Fig. 2 and Fig. 3. Most of points on the cost–effectiveness plot (Fig. 2) are distributed in the northeast quadrant so strategy 1 is thus associated with higher costs and greater benefits than strategy 2. The curves in Fig. 3 display how ICERs remain below € 40,000/QALY in 91 % of the scenarios assumed.

Scenario analysis regarding the DAA price.

A fixed based price of €15,000 was applied for patients with moderate to severe liver disease (F3-F4 decompensated cirrhosis), whereas discounted prices were applied for patients with lower stages of fibrosis(Figure 4).

Figure 2 Incremental CE Plane

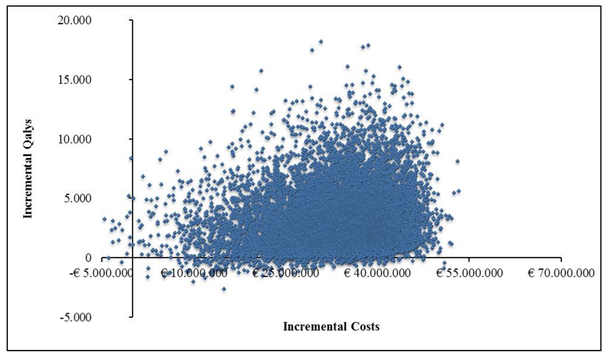


Figure3 Cost- Effectiveness Acceptability Curve

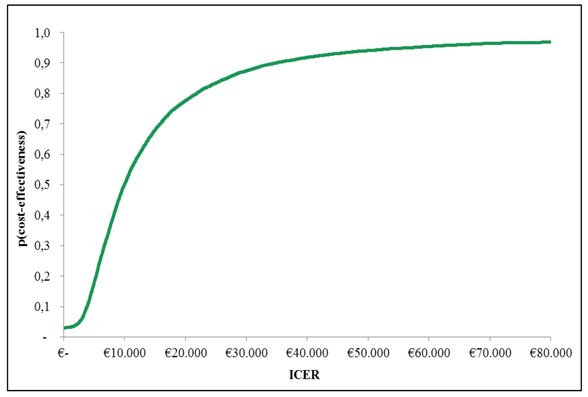
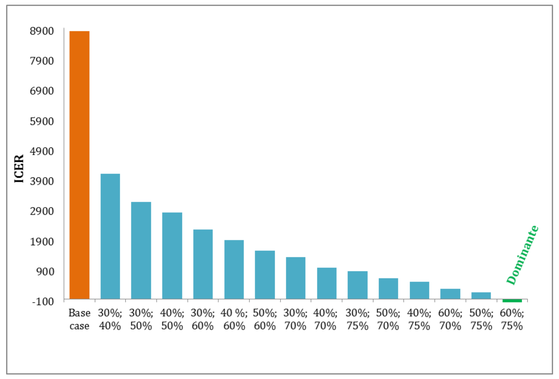


Figure 4 Scenario analisys of DAA price



The ICERs continued to decrease with decreasing price levels of the treatment regimens in patients with F0 fibrosis, until reaching dominance, meaning lower costs and higher benefits in terms of QALY for Policy 1 compared to Policy 2. For discounts of the base price of at least 75% applied in patients with F0-F2 fibrosis, Policy 1 became dominant

CONCLUSIONS

Treating HCV infection at early stages of fibrosis appeared to improve health outcomes and to be cost-effective. Cost-effectiveness increased significantly when varying the price of treatment regimens in early stages of fibrosis. For the price levels less than 75% of the base price applied in patients with F0-F2 fibrosis stage, Policy1 "Universal DAA treatment" vs Policy 2 "Delayed treatment" become cost saving (less cost greater benefit)

The scenario analysis of differentiated drug price discounts according to the fibrosis stage, as applied in this study, could serve as a model to be further developed and as a health policy tool for many payers in price negotiation and in planning possible screening strategies. In the near future, market or political forces could significantly drive drug costs down, which would allow patients with a slow progression of HCV infection to be treated at a lower cost.

ACKNOWLEDGEMENTS

Authors wish to thank all clinical centers which are involved in the study on a voluntary basis.

The PITER platform has been supported by "Research Project PITER2010" RF-2010-2315839, of Italian Ministry of Health, by Istituto Superiore di Sanità funds for start-up studies and by an un-conditioned partial support from Bristol-Myers Squibb, and Merck (MSD Italia).

Contact information

Loreta A. Kondili MD, PhD
Istituto Superiore di Sanità Viale Regina Elena 299; 00161 Rome Italy
Tel: +39 0649903816/Fax:+39 0649902012 email: loreta.kondili@iss.it