

NEW ANTIVIRAL DRUGS FOR HEPATITIS C IN ITALY: WILL IT BE A TREASURE HUNT?

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BACKGROUND

Despite Italy has a large HCV infected pool (1.500.000 estimated), the novel Direct Antiviral Agents (DAAs) to treat hepatitis C genotype 1 in triple therapy have experienced very long approval times. As the estimated budget to cover all eligible patients could be ten-fold higher, limitations or patient selections could be applied. The patients' information is still scarce and fragmentary, and most of them do not know the risks, benefits and related costs and other basic information useful in making the decision to undergo antiviral treatment or wait for new interferon-free therapies. EpaC Onlus, the largest and most representative Italian association of HCV patients, has raised the problem of how to bring the needs, desires and expectations of patients in workshops with Institutions and scientific societies. The best way to represent patients is asking them an opinion on topics considered to be of primary importance. For this reason we decided to take a "snapshot" on patients' perceptions on access to new drugs in a "pre-marketing" period.

OBJECTIVES

The study purpose is to obtain the patients' point of view about associated costs, sustainability, possible scenarios related to the lack of economic resources, and to subsequently use these results to legitimize the positions taken by the association and bring the voice of patients to institutions.

METHODS

An anonymous web-based questionnaire was published on the association website www.epac.it. It was composed of multiple choice questions and was preceded by a scenario aimed at informing patients about the possible mean drug cost per patient per course of 25.000-35.000 €, the availability of interferon-free monotherapy DAAs drugs in the next future, different reimbursement possibilities (payment-by-results, expenditure thresholds...). In this preface, EpaC did not express any influencing opinion and tried to faithfully reproduce the state of the art of various stakeholders' debates. Participants were required to answer in order to provide the association the best conditions to represent their point of view.

RESULTS

Number of participants - 763. Valid forms: 727.

Participants profile - Sex: Female 237 (33%), Male 490 (67%) (Fig.1). Age: 75% of participants are aged 18-60, 25% 60-80. (Fig. 2) Geographical provenience: all Italian regions (Fig.3). Health state: 94% suffer from chronic hepatitis C, 3% are coinfecting (HBV or HIV), 3% are recurrent liver-transplanted. (Fig. 4)

Fig.1 Sex

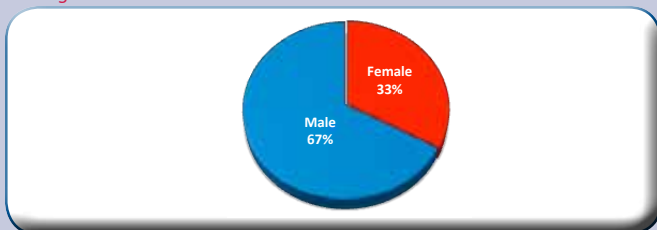


Fig.2 Age

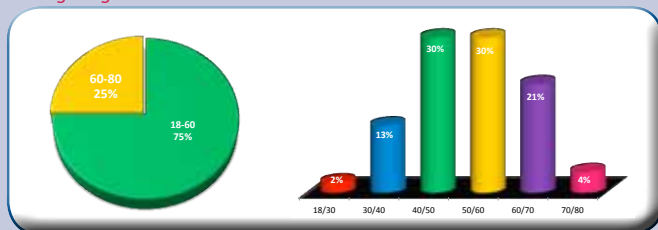


Fig.3 Geographical provenience

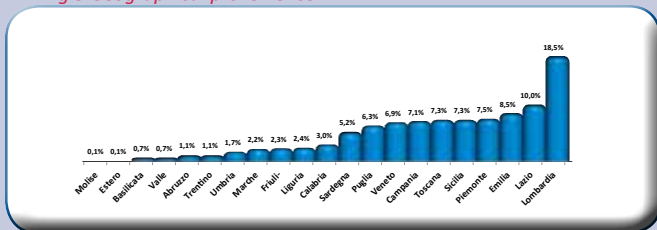
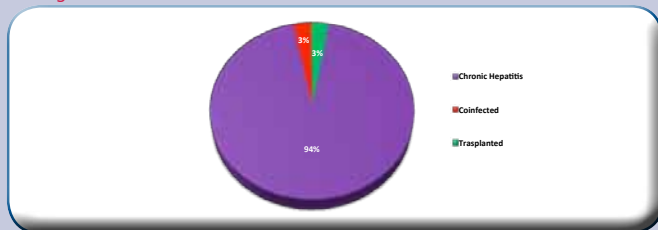


Fig.4 Health state



Fibrosis: 53% have a medium-advanced (F3-F4) fibrosis grade, 47% have mild-to-moderate-to-absent fibrosis (F0-F1-F2) (Fig. 5). Genotype: 77% have HCV genotype 1 infection, 6% do not know, the remaining are infected by genotype 2, 3 or 4 (a small percentage of patients aware not to be eligible to the triple therapy). (Fig. 6)

Question 1. Novel DAAs access: which stand should EpaC publicly take? 83% answered EpaC should always ask for fund raising to guarantee therapies to all eligible patients, despite the severity of the disease. (Fig. 7)

Fig.5 Fibrosis

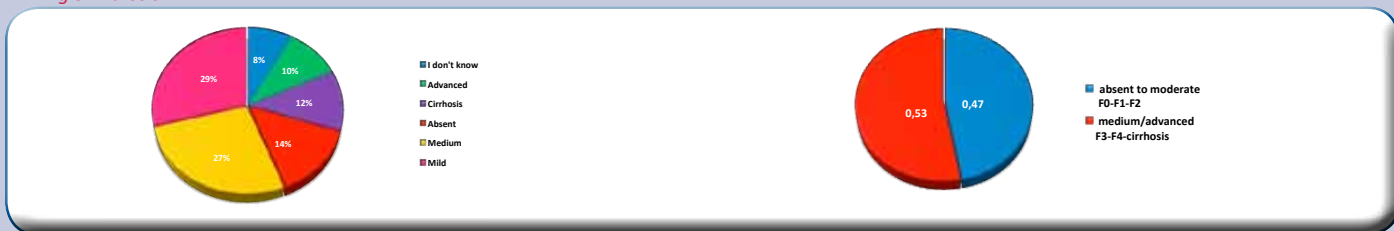


Fig.6 Genotype

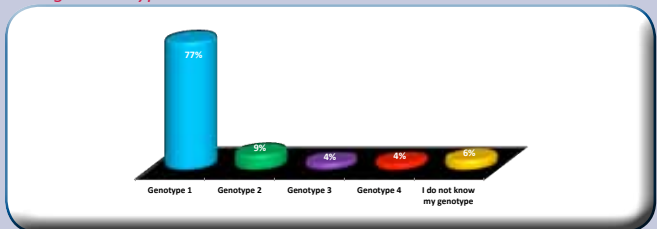
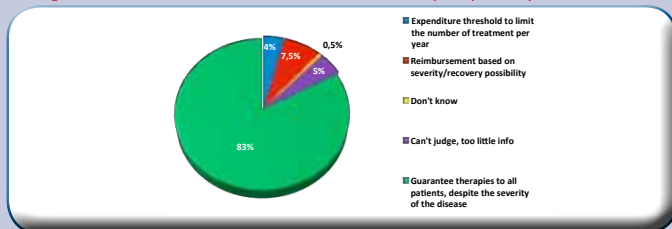


Fig.7 Novel DAAs access: which stand should EpaC publicly take?



Question 2. Therapeutical shift: are you prone to postpone your treatment of 4-5 years? 35% answered they want to be cured soon; 20% have an advanced disease and need to block the evolution of the pathology; 31% are prone to wait because of a mild/moderate disease; 4% can wait despite an advanced disease (Fig. 8). A subanalysis of the answer "I want to be cured soon" reveals a high percentage (>78%) of patients with mild-to-moderate-to-absent fibrosis (F0-F1-F2), which shows that the wish to be cured is not only based on the severity of the disease, but also other social implications need to be considered. (Fig. 9).

Question 3. Who should be treated: without money to cure all patients, do you think it is fair to give priority to patients with advanced disease? 40% of participants declare their intolerance for this hypothesis; 37% find this unfair, but think it is the best solution; 21% find it fair. (Fig. 10)

Fig.8 Therapeutical shift: are you prone to postpone your treatment of 4-5 years?

Fig.9 Subanalysis of the answer "I want to be cured soon"

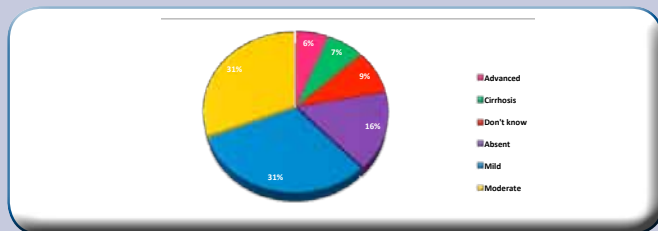
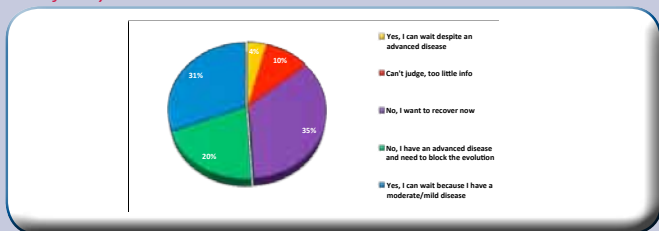
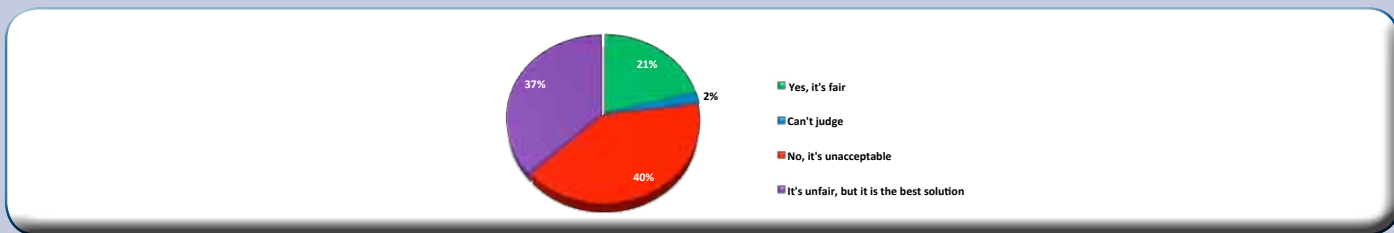


Fig.10 Who should be treated: without money to cure all patients, do you think it is fair to give priority to patients with advanced disease?



Question 4: What is the longest distance you are disposed to cover to get the triple therapy? 40% of patients would go everywhere; 14% further than 100 km; 8% 60-100 km; 8% 40-60 km; 14% 20-40 km; 16% 0-20 km (Fig. 11). A subanalysis of the first group points out no geographical and disease severity differences. (Fig. 12 a-b). That is there are many patients disposed to do everything in order to be cured.

Fig.11 What is the longest distance you are disposed to cover to get the triple therapy?

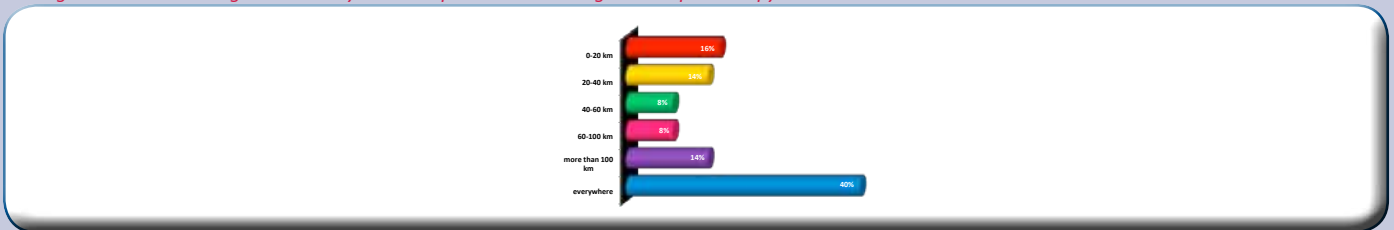
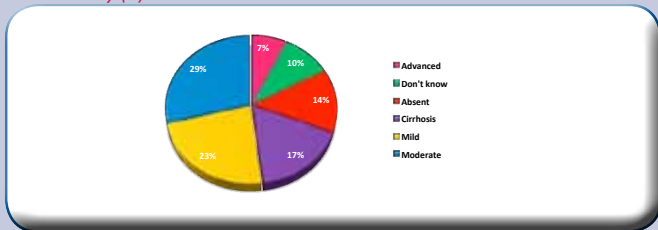
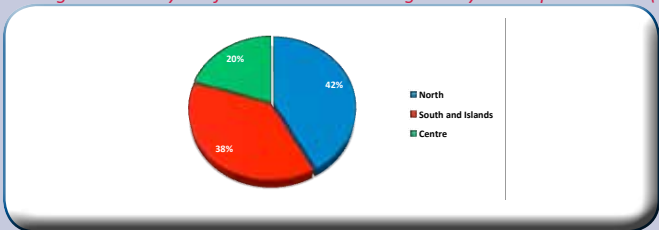


Fig.12 Subanalysis of the answer "I would go everywhere": provenience (a) and disease severity (b)



CONCLUSIONS

This was a unique and the largest survey on Italian patients about this topic and its results express patients' determination in looking for specialized structures having funds for cures, which could lead to important internal and external migration flows. Patients expect from EpaC to raise awareness in the policy-makers and to bring on a campaign of novel therapies equity of access with all Institution independently from the severity of disease stage.

DISCUSSION

There is no doubt that surveys directly administered to patients are a useful and powerful tool for associations that represent patients and need to debate with other stakeholders.

Advantages. Representativeness and democracy are guaranteed and protected, limiting individualism and personal opinions. In addition patients are personally involved and invited to express themselves about their future or to take responsibility, albeit theoretical. Noteworthy, they are informed about what to expect and this puts them in a decision-maker position, rather than a purely passive one. Finally, the information collected by patient associations on patients may have a significant predictive value and be useful to decision-makers and the scientific community to reflect on some choices about the management of innovative drugs access.

Limitations. The consulted population is made up of a range of patients with specific characteristics (eg more informed about their disease, a higher level of education than average, proficient with computer tools, etc.), which may not necessarily represent the views of the whole community. In addition, the choices and the views expressed in response to some questions can vary considerably after the patient performs an interview with the doctor, with particular reference to the possibility of postponing therapy for several years. In other words, more information for patients and greater experience of doctors in handling the new molecules will allow patients, over time, to gain insights maybe different from those now provided.