

THE PRINCIPLES OF BIOETHICS IN THE NOWADAYS THERAPY OF HEPATITIS B AND C

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Abstract

Chronic hepatitis with viruses B and C represents a health problem all over the world, due to the great number of infected individuals, the serious complications and the progression of the disease, as well as the arsenal of drugs we have. The most important bioethical aspect anywhere in the world is the decision of choosing the person from a great number of patients on the waiting list who shall benefit from a costly therapy, under the circumstances of limited material resources. From the point of view of the infectious diseases specialist, the solution would be the most correct identification of the patients eligible to get the antiviral medication and the choice of the most appropriate medication scheme, suitable to the individual's clinical-biological context, under the circumstances of respect for the principles of bioethics.

Key words: *chronic hepatitis, antiviral therapy, bioethics.*

The development of sciences, in general, and of the medical science, in particular, in respect of the mankind progress, has unavoidably led to some problems of modern ethics in the medical practice.

Bioethics studies the human behavior in the fields of science, life and health seen from the perspective of moral values

and of two fundamental principles: the principle of the respect for life and the principle of a person's self-determination.

All individuals have the right to live and their life is sacred and it must be defended and protected as part of a whole, the society where all people must be treated with the same consideration

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and no harmful effects, be it physical, verbal or mental.

Actually, the convergent guiding ideas of bioethics are:

- not to harm;
- to do good;
- respect for the autonomy of a person;
- equality of people.

In practice, these principles reflect a society in its diversity, where the behavior should be guided by the mutual respect and the benefits, as well as their absence, should have a balanced distribution.

Chronic viral hepatitis B and C is a worldwide challenge for epidemiologists, who are trying to stop this phenomenon through specific means, for the clinicians treating diseases with a slow but sure progress towards an end marked by serious complications such as hepatoma, cirrhosis and hepatic insufficiency, and last but not least, for the pharmacological research in its attempt to present a more and more adequate drug arsenal.

The infectious disease doctor often faces issues of bioethics when starting the therapy for chronic hepatitis B and C, with the observation of the clinical, biological and immune-virusologic results so as to respect the criteria of treatment inclusion and exclusion.

In principle, the patient must display an eligible value of the viral load, cytolytic activity, an increased ALAT, and the hepatic-biopsy puncture must prove the degree of fibrosis and cellular dysfunction. We are going to present objective and succinct data in which the principles of bioethics should be applied with modulation.

The B hepatitis virus which belongs to the family of Hepadnaviridae is a DNA virus and is remitted parenterally, especially in drug users who inject

themselves, by sexual intercourse in people with multiple partners, and is also remitted vertically from infected mothers, in most cases perinatally.

It is estimated that there are 360 million infected people worldwide with a disease caused mortality of approx. 400,000 /year.

The evolution towards the ill-fated end can be hastened by an overinfection or coinfection with a variator which replicates only in the presence of virus B-virus D.

The drug resources are represented by two categories of pharmacological agents:

- interferons - pegylated interferon alpha;
- nucleoside agents - lamivudine, adefovir, emtricitabine, etc.

The patient is monitored throughout the therapy period, clinically, biologically and virusologically. (4; 5)

In Romania, a 24-week therapy scheme is approved.

Its success mainly depends on the viral genotype, the patients being responders, with a rate of the therapy success and prolonged viral suppression only in a ratio of 40%. (4; 10; 13)

Responders are considered to be the patients with an undetectable viral load after the 12th administration, who continue the therapy up to 24 weeks and who, beginning with the 6th month from the interruption of the therapy have an undetectable viral load.

The costs of the therapy per year per patient are:

- interferon alpha = 250 million/year
- pegylated interferon = 380 million/year
- lamivudine = 38 million/year
- entecavir: - with the "naive" / the ones who have not get any other

kind of therapy before = 112 million/year;

- with the “experienced”/ the ones who have received other kinds of therapy before, 240 million/ year

The therapy is affected by adverse effects which sometimes can be very serious and can lead to the interruption of the treatment - leucopenia, thrombocytopenia, the addition of other drug agents such as erythropoietine in circumstances of severe anemia, asthenia, weight loss, nervous breakdown, suicidal propensity. (13)

Fortunately, the specific prophylaxis with the hepatitis vaccine B is handy, with good vaccine protection and coverage. (3; 6; 7)

One cannot say the same about viral hepatitis C, which is generally diagnosed in the chronic stage.

It is caused by an ARN virus which belongs to the family of Flaviviridae and displays obvious symptoms, asthenia, anorexia, light transitory increase of ALAT, with no prophylaxis specific to vaccination (8).

The diagnosis is tardy and the hepatic-biopsy puncture shows the degree and the severity of the histological damage.

The therapy consists not only in the administration of pegylated interferon, but also in Ribavirine, which brings the costs to 500 million / year/patient. (9; 12; 14)

Under the circumstances of very high costs and a limited budget for each country and implicitly, for each hospital, the following question, regarding the ethical aspect of the therapy, comes

naturally: “Who is it addressed to ?”; “Who is eligible ?”; “From the eligible ones, who is going to get the therapy sooner ?”. We have to mention that the therapy costs are supplemented by the costs of the investigations and repeated hospitalization for the observation of the evolution of the disease for a year – the viral load, biochemical and hematologic samples, ecography, the histopathological tests.

The National Committee for the evaluation of patients with chronic hepatitis have devised an algorithm for including them in the drug programme and, as any algorithm, it has its own limits.

One of these limits is the elusion of the corrugating aspect of the cytolysis, reflected in the increase of ALAT, with long remission periods, but during which the viral load exists and can be very heavy. (1; 2; 11)

A moment of cytolytic “calmness” may take away the chances of the patient to start the therapy by changing his/her position on a long waiting list.

The answers to the above questions will certainly come by means of common efforts meant to identify the eligible patients, to improve the criteria in order to give a chance to as many patients as possible, under the circumstances of scarce economic resources.

It is a high responsibility of the infectious diseases specialist who have to follow the golden standards and principles of bioethics, for the best distribution of chances and raise the possible benefits.

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