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Anti Hcv Antibody Merits Proper Interpretation

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1. Abstract

1.1. Introduction: Chronic Hepatitis C Virus (HCV) infection, a leading cause of liver cirrhosis, causes significant morbidity and mortality and has become an important indication for liver transplantation all over the world. The initial treatment was with Pegylated Interferon and Ribavarin but later on wide availability of oral Directly Acting Antiviral (DAA) drugs has led to attainment of high Sustained virological response (SVR), as evidenced by absence of HCV virus from blood after 12 weeks of completion of treatment. The anti HCV antibody can remain positive for many years even after attainment of SVR which are analyzed wrongly by many patients, relatives and physicians as failed treatment.

1.2. Aims and Objectives: To determine prescence of anti HCV antibody in blood after atleast three years of attainment of sustained virological response in chronic hepatitis C patients.

1.3. Materials & Methods: This was a prospective study done at Medical Gastroenterology Department, PGIMS,Rohtak on confirmed cases of chronic hepatitis C who successfully completed their treatment and attained SVR from 31.08.2013 to 31.08.2019.

1.4. Results: Out of total 2500 patients in our study group who have already attained SVR after successful completion of treatment, majority i.e. 2470 patients (99.8%) had anti HCV antibody positivity, atleast three to seven years after attainment of SVR. Only 30 patients (1.2%) has become anti HCV antibody negative after three to seven years of SVR.

1.5. Conclusion: The anti HCV antibody can persist for very long period after attainment of SVR and should be interpreted wisely to avoid any confusion regarding successful treatment and future course of action.

2. Introduction

Hepatitis C Virus (HCV) infection is a pan global problem with approximately 71 million patients already been infected with this deadly virus and chronicity can lead to liver cirrhosis, hepatic decompensation and/or hepatocellular carcinoma which are associated with high morbidity and mortality [1,2]. The antiviral treatment aims at achieving complete viral eradication defined as undetectable HCV RNA 12 weeks after the end of antiviral treatment (sustained virological response, SVR) thus leading to reduction of its complications [3] and result in normal life expectancy in patients who already have developed advanced liver fibrosis [4] and also improves health-related quality of life [5-8]. The availability of Direct-Acting Antiviral (DAA) has revolutionized the treatment, being more effective, shorter duration of treatment, lesser side effects and can be used in those groups of patients for whom Interferon (IFN) therapy was contraindicated i.e. in decompensated cirrhosis or in presence of significant comorbidities. The anti HCV antibody can remain positive for many years even after attainment of SVR which are analyzed wrongly by many patients, relatives and physicians as failed treatment. There are very limited number of studies available in literature on this, hence need of doing the same.

3. Aims and Objective

To determine prescence of anti HCV antibody in blood after atleast three years of attainment of sustained virological response in Chronic Hepatitis C patients.

4. Materials & Methods

This was a prospective study done at Medical Gastroenterology Department, PGIMS,Rohtak on confirmed cases of chronic hepatitis C who successfully completed their treatment and attained SVR from

31.08.2013 to 31.08.2019, were enrolled in the study after proper consent. Patients who were found HCV antibody positive on rapid card test or Enzyme linked immunoassay test & confirmed on Polymerase Chain test for HCV RNA quantitative test and were put on oral antiviral treatment for the same. In this prospective study, HCV patients who visited the Medical Gastroenterology Department in last nine years, and consented for enrollment in the study, their detailed records were collected. The patients who had attained SVR 12 weeks, atleast three years back were tested for prescence of anti HCV antibodies.

5. Stastical Analysis

Statistical analysis was performed by the SPSS program version 25.0. Continuous variables were presented as mean ± SD or median (range), and categorical variables were presented as absolute numbers and percentage.

6. Observation

Total 2500 patients who were monoinfected with HCV and attained SVR after completition of treatment were enrolled in this study. Out of these, 400 patients were treated with pegylated Interferon and Ribavarin and rest 2100 were treated with oral DAA. On analyzing sex distribution, there was clear cut male predominance i.e. 1675 (67%) and 825 (33%) were females. In this total pool of 2500 patients, 1700 (68%) were non-cirrhotic and 800 (32%) were cirrhotic. Majority of patients belong to rural area (villages), 1750 patients (70%) in comparison to urban area (township), 750 patients (30%). All 2500 patients had sucessfully completed thier treatment and achieved SVR, atleast three years prior to enrollement in the study (Figure 1-3) and (Table 1 and Table 2).

Table 1: Showing Anti HCV Antibody Positivity / Negativity in SVR Achieved Chronic HCV Patients

Total Patients	Full Course Of Treatment Completed	Sustained Virological Response Achieved	Anti HCV Antibody Positive after Three Years	Anti HCV Antibody Negative after Three Years
2500	2500	2500	2470 (98.8%)	30 (1.2%)

Table 2: Showing Distribution of Anti HCV Antibody Negative On Basis of Duration

Total Patients	Anti HCV Antibody Negative after Three-Four Years of SVR	Anti HCV Antibody Negative after Four-Five Years of SVR	Anti HCV Antibody Negative after Five-Six Years of SVR	Anti HCV Antibody Negative after Six-Seven Years of SVR
2500	6 Patients	7 Patients	7 Patients	10 Patients

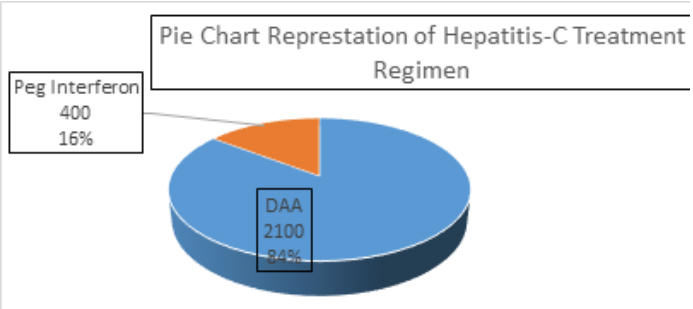

Figure 1: Showing Distribution on Basis of Treatment Regimen

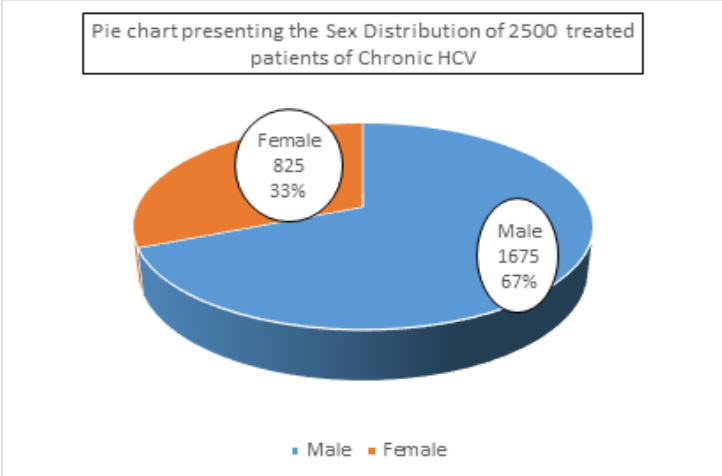

Figure 2: Showing Sex Distribution of Treated Chronic HCV Patients

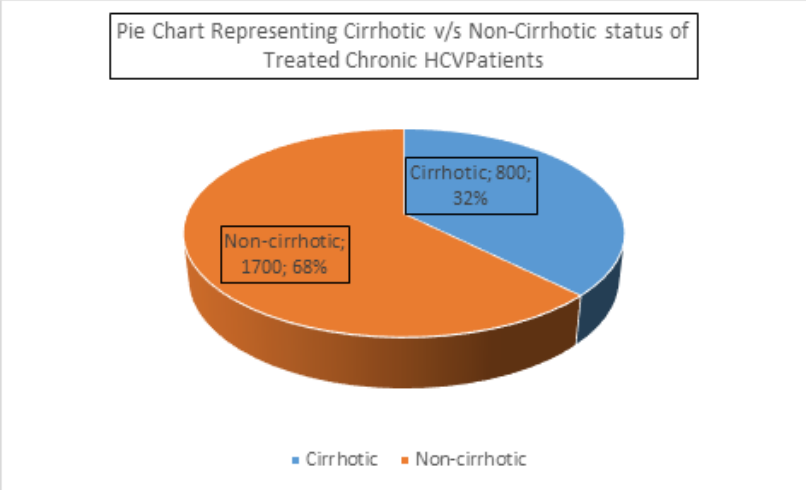

Figure 3: Showing Cirrhotic/Non cirrhotic Distribution of Chronic HCV Patients

7. Discussion

The initial test for identifying whether anyone is having HCV infection is HCV antibody test [9] and is most commonly done with a 3rd-generation Enzyme Immunoassay (EIA) which has a sensitivity of approximately 99% even when used in low-prevalence populations [10]. The HCV RNA test is done which provides confirmation or exclusion of active infection. Rapid, point-of-care HCV antibody screening tests are performed with a finger stick blood sample and produce results within 20 to 40 minutes [10]. In an immunocompetent patient, negative HCV antibody test, usually rules out chronic HCV infection. However, a false-negative antibody test result may occur in patients who have acute HCV infection or who are immunocompromised due to advanced HIV infection, use of immunosuppressive therapy, long-term hemodialysis, or other conditions [11,12] and thus merit confirmatory HCV RNA testing. Successful treatment of chronic HCV infection results in absence of detectable HCV RNA, but antibodies to HCV are typically retained for a very long period, may be lifelong. It is important for making understand the patient by treating heath care provider, that they will continue to have antibodies but not active HCV infection. Although antibodies to HCV will continue to be present after treatment, HCV antibodies do not offer protection from HCV reinfection. All individuals with no detectable HCV RNA are considered susceptible to reinfection if re-exposed to HCV. The journey of antiviral treatment for hepatitis C has seen a paradigm shift from simple Interferon to Pegylated Interferon to orally available Directly Acting Antiviral drugs (DAA). The Interferons had many side effects which has been reported in many studies [13]. The Pegylated Interferons had lesser side effects then simple Interferon. The availability of DAA has revolutionized the field of antiviral therapy for patients chronically infected with HCV. Antiviral therapy usually consists of at least two antiviral substances from different drug classes with different modes of action. All different recommended regimens achieve SVR rates of more than 95% if administered correctly [3].

The great success associated with oral antiviral after attainment of SVR is being unintentionally being decreased by wrong interpretation of anti HCV antibody positivity by many General Physicians, health care providers from different fields and patient's themselves. Many time SVR achieved patients when later on, as expected found to be anti HCV antibody positive during Pre anesthetic checkup before surgery, during pregnancy, blood donation or dialysis, then they are wrongly told that they are still having HCV infection, thus suggesting them to get repeat HCV RNA Quantitative test and repeat treatment. Many times treating surgeons and Gynecologist wrongly and unethically refuse to operate or to do delivery, just due to fear of getting nosocomial HCV infection from patient. Many times such patients are referred back to treating Gastroenterologist or Hepatologist to get treatment till anti HCV antibody test becomes negative. Hence, once our patient achieves SVR, then we issue a printed certificate, that he has cleared HCV virus from body and treatment has been completed successfully. Moreover, we always advice our SVR achieved patients for neither getting anti HCV antibody test in future, nor to go for blood donation, as in India before blood donation anti HCV antibody test is done as part of HCV screening whereas in developed countries they do Nucleic acid testing. Thus this patient will falsely be referred for retreatment and his donated blood will also be discarded. The same thing happens during dialysis when they are pressurized to get HCV RNA test repeatedly.

Our study is in agreement with available literature, that these anti HCV antibody can remain positive even lifelong after achieving SVR. In our study pool, in 98.8% patients they remained positive after 3-7 years' interval and only 1.2% patients became anti HCV antibody negative.

8. Results

Out of total 2500 patients in our study group who have already attained SVR after successful completion of treatment, majority i.e. 2470 patients (99.8%) had anti HCV antibody positivity, atleast three to seven years after attainment of SVR. Only 30 patients (1.2%) has become anti HCV antibody negative after three to seven years of SVR.

9. Conclusion

The treating team, General Physicians, health care providers from different streams, Patient and their relatives have to clearly understand the scientifically proven fact that anti HCV antibody test will remain positive for long duration, may be life long, in majority of HCV patients, even after attainment of SVR and does not mean failure, relapse or need of repeat confirmatory HCV RNA test or treatment. These patients cannot be denied surgery, PAC fitness or sexual restrictions on basis of same.

10. Statement of Ethics

The authors have no ethical conflicts to disclose.

11. Funding Source

To conduct this research no funding was received.

12. Author Contributions

Parveen Malhotra- Conceived, Designed and Formulated this Prospective analysis

Usha Gupta-Reviewed draft of paper

Yogesh Sanwariya - Data Analysis

Sugam and Shobhit Singh- Data Collection

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