

## Evaluation of Biofield Modality on Viral Load of Hepatitis B and C Viruses

Mahendra Kumar Trivedi<sup>1</sup>, Shrikant Patil<sup>1</sup>, Harish Shettigar<sup>1</sup>, Sambhu Charan Mondal<sup>2</sup> and Snehasis Jana<sup>2\*</sup>

<sup>1</sup>Trivedi Global Inc., 10624 S Eastern Avenue Suite A-969, Henderson, NV 89052, USA

<sup>2</sup>Trivedi Science Research Laboratory Pvt. Ltd., Hall-A, Chinar Mega Mall, Chinar Fortune City, Hoshangabad Rd., Bhopal- 462026, Madhya Pradesh, India

\*Corresponding author: Snehasis Jana, Trivedi Science Research Laboratory Pvt. Ltd., Hall-A, Chinar Mega Mall, Chinar Fortune City, Hoshangabad Rd., Bhopal-462026, Madhya Pradesh, India, Tel: +91-755-6660006; E-mail: [publication@trivedisrl.com](mailto:publication@trivedisrl.com)

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### Abstract

**Study background:** Nowadays, hepatitis is a major challenge for clinical research, regulatory bodies, and clinicians who are trying to assess the more effectiveness of antiviral therapy against patients. Viral load count is the amount of particular viral DNA or RNA in a blood samples. It is one of the surrogate biomarker of hepatitis. High viral load indicates that the immune system is failed to fight against viruses. The aim of this study was to evaluate the impact of biofield modality on hepatitis B virus (HBV) and hepatitis C virus (HCV) in terms of viral load as surrogate marker.

**Method:** The viral load assay was performed on stock human plasma samples of HBV and HCV before and after 7 days of biofield treatment using Roche COBAS® AMPLICOR analyzer according to manufacturer's instructions. Viremia (viral DNA for HBV, RNA for HCV) was considered as surrogate marker for assessment of the impact of Mr. Trivedi's biofield treatment.

**Result:** The viral load of HBV DNA in infected plasma samples showed a significant alteration in the biofield treated group as compared to control. Additionally, viral load count of HCV RNA in infected plasma samples was significantly reduced by 67% in the biofield treated group as compared to control. As the biofield treatment has significantly reduced HCV RNA, it could be beneficial for particularly HCV infected populations.

**Conclusion:** Altogether, data suggest that biofield treatment has significantly alteration in HBV and reduced the viral load count in HCV infected plasma samples and could be a suitable alternative treatment strategy for hepatitis patients in near future.

**Keywords:** Hepatitis B virus; Hepatitis C virus; Biofield treatment; Viral load; HBV DNA; HCV RNA

### Abbreviations

HBV: Hepatitis B Virus; HCV: Hepatitis C Virus; HBsAg: Serum Hepatitis B Surface Antigen; HBeAg: Hepatitis B Early Antigen; IFN: Interferon; EMG: Electromyography; ECG: Electrocardiography; EEG: Electroencephalogram; ALT: Alanine Aminotransferase; NCCAM: National Center for Complementary and Alternative Medicine; NIDDK: National Institute of Diabetes and Digestive and Kidney Diseases

### Introduction

Hepatitis B is a double-stranded DNA virus and prototype member of the hepadnaviridae family. The viral particle, spherical in shape with a diameter of 42 nm consists of an inner core (protein shell) with an outer surface coat. The outer surface coat (or envelope) composed of several proteins collectively known as surface proteins and surrounds an inner protein shell. This inner shell is also known as core particle or capsid. Finally the core particle surrounds the viral DNA and the enzyme DNA polymerase [1]. The HBV traditionally classified into eight genotypes (A to H) based on the complete nucleotide sequence. Apart from these another two genotypes I and J are also subsequently

reported [2]. Serum hepatitis B surface antigen (HBsAg) and HBV DNA are considered reliable indicators of active HBV infection. HBV has a unique life cycle lead to the massive production of viral loads during replication without affecting the infected cell [3]. Hepatitis B virus (HBV) infection is a global public health problem. It is estimated that the prevalence of death is about 6 lakh per annum out of 240 million of HBV carriers in the world, related liver disease [4,5]. HBV is transmitted from person to person, via sex, blood and through needles and it directly attacks to liver hepatocytes cells. Persistent infection by HBV causes chronic liver disease that lead to the development of hepatic cirrhosis and hepatocellular carcinoma [6].

Hepatitis C is single-stranded RNA virus belongs to Flaviviridae family. It causes acute hepatitis with a high propensity for chronic infection. Chronic HCV infection can progress to severe liver disease including cirrhosis and hepatocellular carcinoma [7]. The Centers for Disease Control and Prevention estimates that about 16,500 people were newly infected with hepatitis C virus in the year 2011. In recent years new infections per year is markedly reduce as compare to past decade (1980's) [8,9]. Hepatitis B virus (HBV) and hepatitis C virus (HCV) are classified as biosafety level II and blood borne viruses endemic worldwide which represent a major global public health problem. HCV infections are the most frequent viral infections in humans that causes hepatic cirrhosis and hepatocellular carcinoma that leads to high rate of morbidity and mortality [10]. Chances of coexisting diseases like HCV infection and psoriasis are very high in

hepatitis viral endemic area. [11]. Viral load test is a blood test that indicates the presence and measure the amount of HCV RNA and HBV DNA in the blood. HCV contains RNA, which is the genetic material that helps to replicate, and produce more copies of viral RNA [12].

Since, HCV is a blood borne pathogen; the experiment was carried out with extra precautions during handling of materials potentially containing HCV. Presently, a combination of pegylated interferon (IFN) alpha and ribavirin is the standard of care to prevent long term sequelae of HCV associated liver diseases [13]. However, the combination treatment regimen is very expensive and not uniformly effective due to wide variation of genotypic surrogates. However, feedback from various studies has suggested that 62%-90% of patients with confirmed HCV infection are not receiving antiviral treatment [14].

Although several treatment strategy are available against hepatitis patients infected by HBV or HCV such as IFN-based therapy, polymerase inhibitors and second generation protease inhibitors but some difficulties are present. First, most of hepatitis infected patients do not respond or relapse after therapy. Second, the current treatment has significant side effects and is poorly tolerated [15].

Therefore, new, more effective and better tolerated anti-HCV/HBV drugs or some alternative treatment strategy are needed. Based on above lacunas an alternative way which may be useful to improve the viral loads by either enhancing the application of existing agents or by means of some alternative strategy or introducing new drugs. Biofield treatment is an alternative approach which may be useful to improve these unfilled space associated with hepatitis infected patients. The human biofields is the energetic matrix that surrounds the human [16]. It directly links with the cellular activity that allows the DNA to communicate faster than light and maintain intelligence in the organisms [17]. According to universal principles of Maxwell's equations and principle of reciprocity defines electromagnetic connections related to human biofield [18]. The biofield can be monitored by using electromyography (EMG), electrocardiography (ECG) and electroencephalogram (EEG) [19]. Thus, a human has ability to harness the energy from environment/Universe and can transmit into any object (living or non-living) around the Globe. The object(s) always receive the energy and responded into useful way that is called biofield energy. This process is known as biofield treatment. Mr. Mahendra Trivedi's biofield treatment has been well known to altered characteristics features of microbes [20-22], improve the overall productivity of crops [23,24], and also transform the structural, physical and chemical properties of materials [25-27]. Viral load count in HBV and HCV infected hepatitis patients is very important parameter to know about the disease condition. Therefore, authors interested, to evaluate the impact of biofield treatment on viral load in HBV and HCV infected plasma samples.

## Materials and Methods

The viral samples (HBV and HCV) of infected stored stock plasma samples were procured from department of microbiology laboratory, P.D. Hinduja National Hospital and Medical Research Centre, Mumbai. Both HBV and HCV viral load assay were performed on infected plasma samples before and after biofield treatment using Roche COBAS AMPLICOR<sup>™</sup> analyzer according to manufacturer's instructions.

## Biofield treatment strategy and experimental design

Two sets of each viral samples (HBV; 31 samples and HCV; 30 samples) were used in this experiment for determination of viral load count. The first sets of both viral samples were considered as control. No treatment was given to these sets. The second sets of both viral loads (plasma) were handed over to Mr. Trivedi for biofield treatment under laboratory condition with sealed parafilm eppendorf vials in ice packs. Mr. Trivedi provided the treatment through his energy transmission process to second sets of samples without touching the samples. After treatment, all treated samples were handed over in the same condition and stored at -70°C for analysis. Both the control and treated samples were analyzed after 7 days for viral load count in infected plasma as per the standard protocols. An optimum precautionary measure was taken to maintain the cold chain throughout the experiment. The differences of viral load count before and after the treatment were noted.

## COBAS<sup>®</sup> amplicor HBV monitor test for estimation of viral load

HBV viral load was performed on samples before and after the treatment using COBAS AMPLICOR<sup>™</sup> analyzer. The COBAS<sup>®</sup> amplicor HBV monitor test is an *in vitro* nucleic acid amplification test for the quantification of HBV DNA in human plasma on the COBAS AMPLICOR<sup>™</sup> analyzer. This technique is a gold standard automated solution for testing of HBV viral load in major pharmaceutical trials [28].

## COBAS<sup>®</sup> amplicor HCV monitor test for estimation of viral load

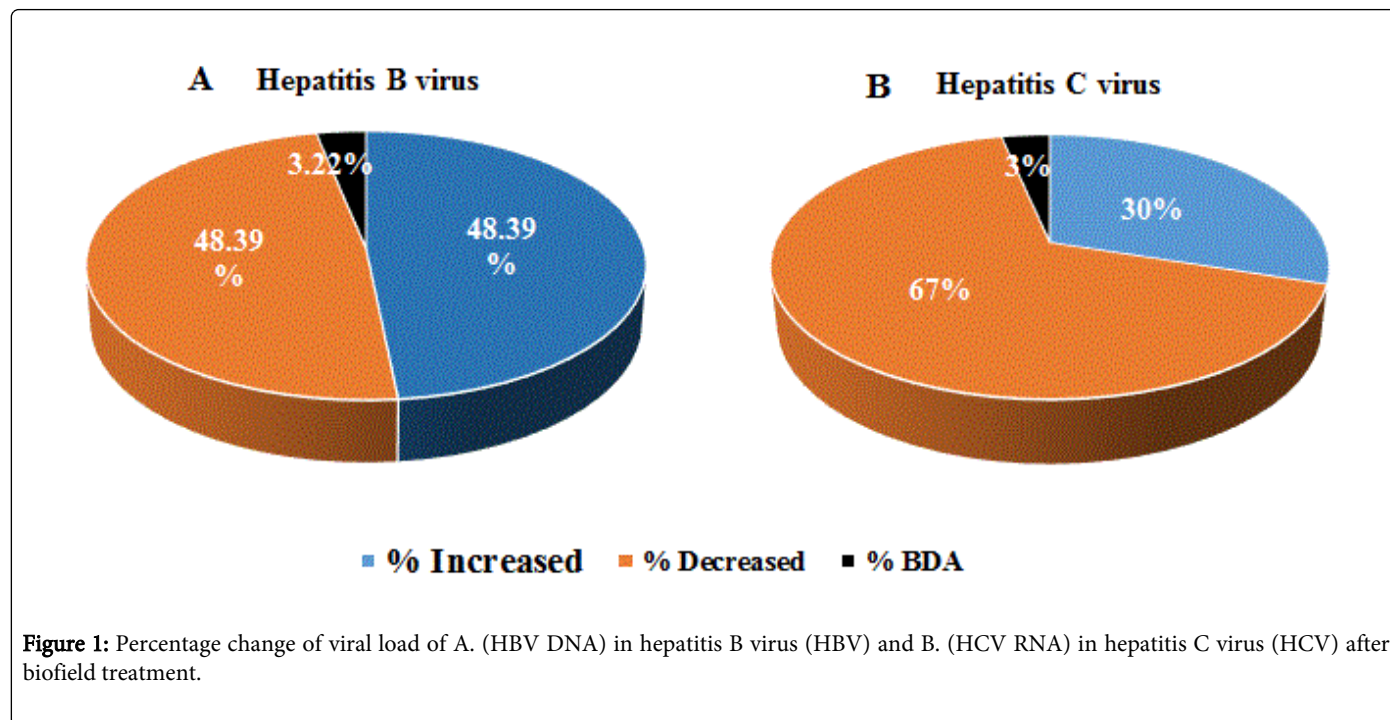
HCV viral load was performed on samples before and after the treatment using COBAS AMPLICOR<sup>™</sup> analyzer. The COBAS<sup>®</sup> amplicor HCV monitor test (v2.0) is an *in vitro* nucleic acid amplification of HCV RNA in human plasma on the COBAS AMPLICOR<sup>™</sup> analyzer. This is an automated, sensitive, reliable, and specific method for quantification of hepatitis C viral load in HCV infected patients [29].

## Results and Discussion

The viral loads expressed as International unit (IU/ml) of HBV and HCV are shown in Tables 1 and 2. Viremia (viral DNA for HBV, RNA for HCV) and alanine aminotransferase (ALT) levels are the two surrogate biomarkers of hepatitis patients [30]. Hepatitis B early antigen (HBeAg) and HBsAg are the serologic markers of HBV that provide information regarding the degree of immune control of viral replication. [31]. In this experiment viral load was considered as surrogate marker for assessment of the impact of Mr. Trivedi's biofield treatment after 7 days. Because, humans are the natural host of the hepatitis virus. Outside its host the virus can remain infectious up to seven days. Study was carried out in total thirty one infected human plasma samples. The result showed that viral load of HBV DNA in infected plasma samples were reduced by 48.39% out of thirty one samples after biofield treatment as compared to control. In addition, viral load were increased by 48.39% in biofield treated group and 3.22% unchanged as compared to control (Figures 1A and 2). Moreover, the study outcomes showed an alteration of viral load of HBV DNA in infected plasma samples in biofield treated group as compared to control. According to Greene et al. National Center for Complementary and Alternative Medicine (NCCAM), 2000 reported

that bioelectromagnetic based therapy i.e. biofield is used as an effective and alternative therapy in viral infected patients [32]. The effectiveness of biofield therapy is further supported by Minga et al. for symptomatic improvement of blood parameter in sickle cell disease like ALT which is one of the surrogate biomarker of hepatitis patients [33]. Based on literature 2012 controlled clinical trial, has conducted jointly by NCCAM and National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and shows that two time higher than usual doses of silymarin (an herbal hepatoprotectant) is no better than placebo in reducing the high blood levels of an enzyme (ALT) that

indicates liver damage [34,35]. This study findings also explored in pros of biofield treatment against HCV infections. Viral load count of HCV RNA were determine in total thirty infected plasma samples. The results showed that viral load of HCV RNA in infected plasma samples were significantly reduced by 67% after biofield treatment as compared to control. Besides, the viral load of HCV RNA were increased by 30% and unable to detect about 3% in biofield treated group as compared to control (Figures 1B and 3). Because, 3% of HCV DNA are inactive not in multiplying state but infectious.



**Figure 1:** Percentage change of viral load of A. (HBV DNA) in hepatitis B virus (HBV) and B. (HCV RNA) in hepatitis C virus (HCV) after biofield treatment.

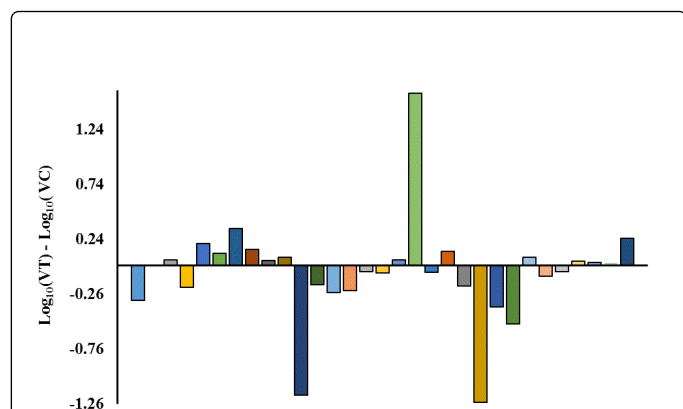
| S. No. | Viral load (Control) | Log <sub>10</sub> (Control) | Viral load (Treatment) | Log <sub>10</sub> (Treatment) | Change in Viral Load Log <sub>10</sub> (Treatment)-Log <sub>10</sub> (Control) |
|--------|----------------------|-----------------------------|------------------------|-------------------------------|--|
| 1.     | 55.13                | 1.74                        | 26.64                  | 1.43                          | -0.32  |
| 2.     | 2257.74              | 3.35                        | 2257.74                | 3.35                          | 0.00   |
| 3.     | 1054840              | 6.02                        | 1191074.40             | 6.08                          | 0.05   |
| 4.     | 23014000             | 7.36                        | 14615000.00            | 7.16                          | -0.20  |
| 5.     | 122221.4             | 5.09                        | 194923.40              | 5.29                          | 0.20   |
| 6.     | 5741.29              | 3.76                        | 7395.56                | 3.87                          | 0.11   |
| 7.     | 4768.19              | 3.68                        | 10451.02               | 4.02                          | 0.34   |
| 8.     | 868005.2             | 5.94                        | 1218321.20             | 6.09                          | 0.15   |
| 9.     | 6305688              | 6.80                        | 7025782.00             | 6.85                          | 0.05   |
| 10.    | 974.95               | 2.99                        | 1167.72                | 3.07                          | 0.08   |
| 11.    | 2783.14              | 3.44                        | 184.63                 | 2.27                          | -1.18  |
| 12.    | 2724.68              | 3.44                        | 1813.74                | 3.26                          | -0.18  |
| 13.    | 18508.51             | 4.27                        | 10489.87               | 4.02                          | -0.25  |

|     |          |      |             |      |       |
|-----|----------|------|-------------|------|-------|
| 14. | 282199   | 5.45 | 167373.20   | 5.22 | -0.23 |
| 15. | 16367.69 | 4.21 | 14499.19    | 4.16 | -0.05 |
| 16. | 14401.88 | 4.16 | 12299.91    | 4.09 | -0.07 |
| 17. | 297768.6 | 5.47 | 336692.60   | 5.53 | 0.05  |
| 18. | 390883.5 | 5.59 | 14635424.00 | 7.17 | 1.57  |
| 19. | 33280.02 | 4.52 | 28803.76    | 4.46 | -0.06 |
| 20. | 51379.68 | 4.71 | 69090.10    | 4.84 | 0.13  |
| 21. | 1161.8   | 3.07 | 753.32      | 2.88 | -0.19 |
| 22. | 9828310  | 6.99 | 558700.00   | 5.75 | -1.25 |
| 23. | 6072144  | 6.78 | 2567800.00  | 6.41 | -0.37 |
| 24. | 5468822  | 6.74 | 1598400.00  | 6.20 | -0.53 |
| 25. | 974.95   | 2.99 | 1167.72     | 3.07 | 0.08  |
| 26. | 1119065  | 6.05 | 891359.60   | 5.95 | -0.10 |
| 27. | 60.68    | 1.78 | 53.28       | 1.73 | -0.06 |
| 28. | 9380684  | 6.97 | 10295398.00 | 7.01 | 0.04  |
| 29. | 8835748  | 6.95 | 9497456.00  | 6.98 | 0.03  |
| 30. | 78431.86 | 4.89 | 83102.74    | 4.92 | 0.03  |
| 31. | 52.91    | 1.72 | 94.35       | 1.97 | 0.25  |

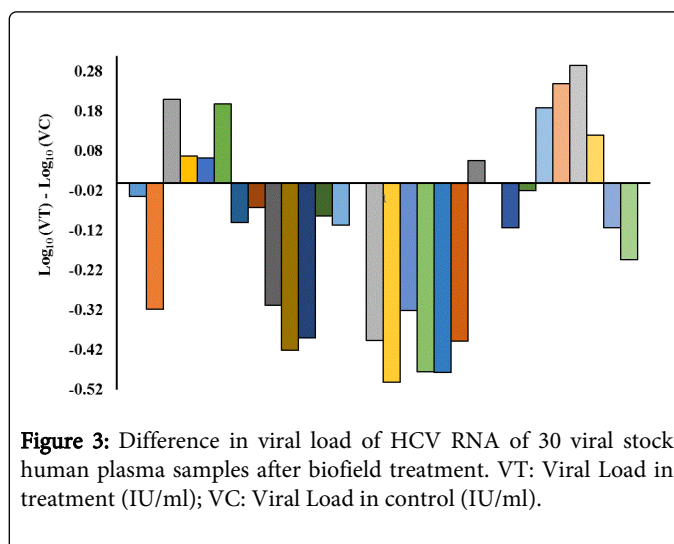
All the values are expressed as (IU/ml); Serial number 1-31 denoted as viral stock human plasma samples

**Table 1:** Viral load of hepatitis B virus (HBV) in infected plasma samples.

The viral particles i.e. HBV DNA and HCV RNA those are in multiplying state, possibly affected by Mr. Trivedi’s biofield treatment. The specific frequencies of electromagnetic radiation which matches with the resonance frequencies of DNA or RNA, probably killed the respective hepatitis viral DNA/RNA and disrupted thus reduced the viable viral titer and vice versa [36,37].



**Figure 2:** Difference in viral load of HBV DNA of 31 viral stock human plasma samples after biofield treatment. VT: Viral Load in treatment (IU/ml); VC: Viral Load in control (IU/ml).



**Figure 3:** Difference in viral load of HCV RNA of 30 viral stock human plasma samples after biofield treatment. VT: Viral Load in treatment (IU/ml); VC: Viral Load in control (IU/ml).

According to a recent report regarding biofield treatment which was later approved by the German equivalent of the FDA emphasized that cancer patients have experienced healing with biofield treatment. Nowadays, many scientists and cutting edge practitioners believed that the secrets of regeneration and healing lie not only on costly medical drugs or expensive medical treatments, but also in the body’s own Quantum Energy Biofield (QEB) [38].

| S. No. | Viral load (Control) | Log <sub>10</sub> (Control) | Viral load (Treatment) | Log <sub>10</sub> (Treatment) | Change in Viral Load Log <sub>10</sub> (Treatment)-Log <sub>10</sub> (Control) |
|--------|----------------------|-----------------------------|------------------------|-------------------------------|--|
| 1.     | 4880                 | 3.69                        | 4510                   | 3.65                          | -0.03  |
| 2.     | 2770000              | 6.44                        | 1330000                | 6.12                          | -0.32  |
| 3.     | 870000               | 5.94                        | 1410000                | 6.15                          | 0.21   |
| 4.     | 578000               | 5.76                        | 676000                 | 5.83                          | 0.07   |
| 5.     | 66900                | 4.83                        | 77200                  | 4.89                          | 0.06   |
| 6.     | 4510                 | 3.65                        | 7120                   | 3.85                          | 0.20   |
| 7.     | 1000000              | 6.00                        | 795000                 | 5.90                          | -0.10  |
| 8.     | 4100                 | 3.61                        | 3560                   | 3.55                          | -0.06  |
| 9.     | 2770000              | 6.44                        | 1360000                | 6.13                          | -0.31  |
| 10.    | 1900000              | 6.28                        | 721000                 | 5.86                          | -0.42  |
| 11.    | 4470000              | 6.65                        | 1820000                | 6.26                          | -0.39  |
| 12.    | 611000               | 5.79                        | 504000                 | 5.70                          | -0.08  |
| 13.    | 2630000              | 6.42                        | 2060000                | 6.31                          | -0.11  |
| 14.    | 3090000              | 6.49                        | 3080000                | 6.49                          | 0.00   |
| 15.    | 6370000              | 6.80                        | 2550000                | 6.41                          | -0.40  |
| 16.    | 3170000              | 6.50                        | 1000000                | 6.00                          | -0.50  |
| 17.    | 421500               | 5.62                        | 201000                 | 5.30                          | -0.32  |
| 18.    | 4240000              | 6.63                        | 1420000                | 6.15                          | -0.48  |
| 19.    | 12700                | 4.10                        | 4240                   | 3.63                          | -0.48  |
| 20.    | 5640000              | 6.75                        | 2250000                | 6.35                          | -0.40  |
| 21.    | 448000               | 5.65                        | 510000                 | 5.71                          | 0.06   |
| 22.    | 308000               | 5.49                        | <600                   | <2.78                         | <-2.71   |
| 23.    | 3290000              | 6.52                        | 2540000                | 6.40                          | -0.11  |
| 24.    | 2870000              | 6.46                        | 2750000                | 6.44                          | -0.02  |
| 25.    | 4470000              | 6.65                        | 6910000                | 6.84                          | 0.19   |
| 26.    | 1550000              | 6.19                        | 2760000                | 6.44                          | 0.25   |
| 27.    | 2420000              | 6.38                        | 4790000                | 6.68                          | 0.30   |
| 28.    | 437000               | 5.64                        | 577000                 | 5.76                          | 0.12   |
| 29.    | 1390000              | 6.14                        | 1070000                | 6.03                          | -0.11  |
| 30.    | 127000               | 5.10                        | 81300                  | 4.91                          | -0.19  |

All the values are expressed as (IU/ml); Serial number 1-30 denoted as viral stock human plasma samples

**Table 2:** Viral load of hepatitis C virus (HCV) in infected plasma samples.

So, the current study data explored that biofield treatment significantly reduced the viral load of HCV RNA and simultaneously alter the viral load of HBV DNA in infected plasma samples. Based on the obtained results, it is assumed that the biofield treatment could be

novel, cost effective and an alternative advance as compared to the existing treatment strategy towards hepatitis patients.



## Conclusions

To summarize, the study results showed a significant alteration of HBV DNA from infected plasma samples after biofield treatment. Experimental data also showed significant (67%) reduction of HCV RNA viral load from infected plasma samples in the biofield treated group. It is assumed that Mr. Trivedi's biofield treatment could be beneficial to improve the viral load in HBV/HCV infected hepatitis patients.

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