Ways to manage hepatitis C without cirrhosis: Treatment by comparison of coded eastern medicine hepcinal with interferon alpha 2b and ribavirin

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Abstract: Hepatitis C virus (HCV) infection is a serious and significant global health problem in the Pakistan and elsewhere. In majority of cases HCV infection remains asymptomatic but in advance cases it may progress to fibrosis of liver, shrinkage of liver cells or failure of liver. The hepatitis C may progress to cause liver cirrhosis that mostly develop in 20% of the affected patients in 20 years with an increased risk in male, alcoholic drink, immune-compromised and who acquire HCV infection after the age of 40 years. This was an open-label prospective study conducted on 66 clinically and immunologically diagnosed cases of HCV infection. In Hepcinal treated group, there were significant improvement in HCV associated symptoms compared to control group ($p<0.05$). While Interferon therapy resulted in significant improvement in serological response (55.88%) compared to Hepcinal treated patients (46.88%). It was concluded that Hepcinal has shown better clinical response but no significant serological response ($p=0.3244$) and it might be an alternative therapy to treat hepatitis C infection and to prevent its progression into chronic ailment.

Keywords: Hepatitis C, chronic active hepatitis C, interferon.

INTRODUCTION

The infection or inflammation of the liver that is specifically caused by hepatitis C virus (HCV) is termed as Hepatitis C. In majority of cases this type of infection remains asymptomatic but in advance cases it may progress to fibrosis of liver, shrinkage of liver cells or failure of liver (Ryan KJ, 2004). First six months of HCV infection is termed as acute hepatitis C infection. Mostly this acute type of infection may remain asymptomatic; It shows symptoms within a day only if intravenous injections or blood route is major cause. If infection can last for more than six months, then it is termed as chronic hepatitis C. It remains asymptomatic and discovered accidentally by usual routine checkup. The patient suffering from hepatitis C are usually asymptomatic being discovered only following a routine biochemical test when elevations in aminotransferases, usually Alanine transaminase (*ALT*) also known as S*erum Glutamic Pyruvate Transaminase* (*SGPT*) are noticed. The elevation of ALT may be minimal or fluctuating where as 20% of cases have normal ALT. These patients are diagnosed when anti-HCV are detected on blood donation. However severe chronic hepatitis C and even liver cirrhosis can be present with only minimal elevation of aminotransferases. The hepatitis C may progress to cause liver cirrhosis that mostly develop in 20% of the affected patients in 20 years with an increased risk in male, alcoholic drink, immune-compromised and who acquire HCV infection after the age of 40 years (Danish I, 2007). As hepatitis C is inflicting population and chemical compounds treatment option, therefore it is better to identify new treatment approaches that will result in intensive study of specific causative and its early treatment completely with no chances of relapse. Although HCV is being diagnosed 22 years ago, even though it continues to be a major health concern challenge and huge burden on whole community throughout the whole world. According to WHO estimates nearly 3 % of the world's population in affected with HCV (Report of WHO, 1999; Alter MJ, 2007). In this study we aimed to investigate the efficacy of herbal coded Hepcinal for the treatment of hepatitis C without cirrhosis.

Epidemiology

All over the world one of the 10th leading cause of death are chronic liver disease and cirrhosis. This disease equally contract both male and female disproportionately in 35-64 years of age and it is 5th leading cause of mortality in age 45 to 64 years (NCHS, 1996, Singh GK *et al*., 1996). Mostly main causes of chronic liver disease are alcoholic abuse and chronic hepatitis B and C (Singh GK, 2000). An estimated 70% of chronically infected patient with hepatitis C virus will develop the chronic progressive liver disease, and in general 40% of all the patients suffering from chronic liver disease already have HCV infection (Stuart C *et al*., 1998, Bradley H, 2005). Overall prevalence of the hepatitis C in Pakistan is calculated as 4.9% (Alter MJ *et al*., 1999; Atlanta GA, 2000). Genotype three is the predominant type of genome

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occurring in Pakistan (Thomas *et al*, 2004), which requires six months therapy for complete removal from the body (PMRC, 2009). The treatment strategy for chronic hepatitis C is rapidly evolving, to achieve satisfactory response and long-term viral eradication. Interferon alpha 2b was first introduced in 1986 to cure hepatitis (Ahmed W *et al*, 2010). The sustained virologic response rate with Interferon monotherapy was only 10-20 % (Rehman *et al*., Hoofnagle *et al*., 2011). Later it was found that Ribavirin, which is an orally active synthetic guano sine analogue with antiviral and immunomodulatory property, could improve the outcome when it is added with Interferon therapy (Tong MJ *et al*., 1986; Ferrell GC *et al*., 1998). It was a major burst through in the treatment of HCV infection. Initial pilot studies showed that Interferon and Ribavirin was more effective than Interferon alone (McHutchison *et al*., 1998). It is estimated by World Health Organization (WHO) that approximately 200 million people are infected with HCV worldwide annually, with 3.5-4.0 million newly infected each year. In Pakistan genotype 3 is more common and prevalence of hepatitis C in Pakistan especially in Karachi (Devis *et al*., 1998), while in United States genotype 1a and 1b are more common among 70 % of patients (Lau *et al*., 1998). In North and South America the genotypes and sub genotypes of 1, 2, and 3 accounts for more than 90% of hepatitis C infection. These genotypes are also present in Europe, Japan, Australia, Russia, China, and New Zealand. In South Africa about 50 % infections are genotype 5a. The genotypes four and five are found mostly outside the Africa. In Southeast Asia the genotype six is found (Bodenheimer *et al*., 2004). In different part of the world it was studied that in blood donors the prevalence of HCV is 0.5-8%. Also 9% anti-HCV positive cases show blood donors in Pakistan and for healthy family and volunteer blood donor's accounts for 4% and 8% respectively (Rehman *et al*., 2004).

In Pakistan: anti HCV prevalence 13.5% in chronic liver disease. Karachi: 43.06% shows seropositivity in chronic liver diseases and cirrhosis combined, with 45.7% cases of chronic liver disease and 37.7% cases in cirrhosis (Devis *et al*., 1998).

Diagnosis of hepatitis C

Hepatitis C as a first step is diagnosed by medical history. Therefore general physical examination and non-invasive techniques are taken into consideration and assessment such as blood test, liver enzymes, antibodies hepatitis C virus and viral load by PCR method. In liver functions test (LFTs) serum glutamate pyruvate transaminase (SGPT) or alanine aminotransferases (ALT), serum glutamic-oxaloacetic transaminase (SGOT) and alkaline phosphatase may rise above than normal range. These are not always raised in chronic hepatitis C infection, then there must be necessary to repeat the test also confirm the HCV infection by serological and molecular tests for viral particles.

Gold standard investigation

All the patients with positive anti- HCV must be further diagnosed by molecular test for viral particles (HCV RNA by PCR called as gold standard for HCV diagnosis) that either infection is present or not. There are two types of PCR techniques available i.e. qualitative and quantitative HCV RNA based on PCR techniques. Quantitative HCV RNA can detect even lower limit of less than 100 copies of HCV RNA per milliliter of serum (59 IU/ml). Enzyme Linked Immuno Sorbent Assay (ELISA) is the primary serologic screening assay to detect HCV infection it uses 2ndand 3rd generation enzyme linked immune- sorbent assay. ELISA has the advantage that it may detect the antibodies four to ten weeks of post infection. There is a chance this test may show false results in the population of decreased risk that is approximately 0.5-1.0% of patients (Thierry *et al*., 2003a).

Treatment

Allopathic treatment

The current allopathic approaches in vague to treat hepatitis C is Interferon alpha 2b and Ribavirin. It can decrease the viral load and diminish HCV at early stage but there is relapse of therapy after 5-6 months later HCV RNA by PCR may become positive when diagnosed after discontinuation of treatment in round about 60-70% of patients. The biochemical response i. e. ALT, SGPT level to be in normal and decreased viral load detected by PCR method, consequently it shows the success of the therapy.

Herbal treatment

The eastern/herbal coded medicine Hepcinal is designed in such manner that it should cover treatment of hepatitis C from symptomatic and pathogenic point of view. Hepcinal tablets should have the potential to eradicate HCV and provide strength to the liver to function better and play its role for detoxification. Hepcinal components should exert to decrease the viral load gradually and after 3 month continuous use of Hepcinal, the viral load is decreased to the negligible level and patient gets complete relief from disease. As such the HCV in the low frequency of occurrence colonize the liver and remains for all the time, but the toxicity manifestation is held in allegiance.

Objectives

- It relates to the use of coded eastern/herbal medicine Hepcinal with specific adjusted dose and time duration of treatment. The major treatment prospect will be compared with the efficacy and response results between control and test group and also to know the adverse effects of control drug with test drug if any.
- To evaluate the efficacy, safety, clinical and biochemical response of test and control drug for the management of hepatitis C without cirrhosis.

Methodology

Patients and method

This study is carried out on patients of age above 20-70 years after written consent taken from them for research clinical trial purpose. The clinical trial was conducted on 66 patients in which 34 are control and 32 are test by taking written consent from them. These including all socioeconomic status patients at different health care centers i.e. at Shifaul Mulk Memorial Hospital and Sohail Memorial Hospital. In this study project the patients were selected according to inclusion criteria. The patients are categorized into two different groups i.e. test group and control group on whom eastern/herbal coded formulation and allopathic formulation are applied respectively. The detailed history of the patients and questionnaire was documented on clinical trial proforma at every follow up visit under the supervision of monitor physician and supervisor. This research based study was case controlled trial in which one group is selected as control group and one was selected as test group, for both groups all the conditions were similar. For the treatment of hepatitis C, designed strategy is given in table 1 and test drug formulation is given in table 2.

STATISTICAL ANALYSIS

All the data collected at Shifaul Mulk Memorial Hamdard University Karachi and Sohail Memorial Hospital was subjected to statistical analysis to determine the level of significance of case control study. Applied for statistical analysis of data to be checked and verified for range and consistency with the customized data entry and processing programs (Microsoft Access XP2007). Each case control study report including the entered data would be recorded electronically. Data was analyzed with the Statistical Analysis Software SPSS, version 17.0. All the material and data had processed and maintained on Microsoft Access XP2007. Table and Flow charts developed using Excel Software.

Inclusion criteria

- The patients of above 20 years age were included.
- The patient suffering from hepatitis C without cirrhosis.
- Patient living in Gaddap Town and peripheral areas of Karachi.
- All the socio-economical classes including lower, middle and upper.
- Patients both males and females and willing to comply with study requirements.

Exclusion criteria

- Patient with any concurrent physical illness e.g. uncontrolled hypertension and diabetes or chronic ailments not related to liver.
- Renal impairment and any other CNS disorders.
- Immunocompromized patients.
- Infant or newborn babies and patients having hyperpyrexia (103°F or more).

Test drug

Contents and dosage form design of test drug (Hepcinal)

The eastern/herbal coded Hepcinal has the following contents *Silybum marianum*, *Picrorrhiza kurroa*, *Glycyrrhiza glabra*, *Tamarix gallica*, *Emblica officinalis* and *Rosa damascena.* All the plants were authenticated and identified by botanist at Hamdard University and Heribion Pakistan (Pvt.) Limited. This test drug was manufactured at FEM Herbal Pharma, Faculty of Eastern Medicine, Hamdard University, Karachi after approval from Ethical Research Committee of Faculty of Eastern Medicine, Hamdard University. This drug was manufactured in the form of tablets (one tablet 500 mg) after approval from Ethical Research Committee, Faculty of Easter Medicine, Hamdard University.

Control drug (Interferon alpha 2b and Rivavirin)

The Interferon is a copy of protein that naturally found in low levels in the human body. It was approved by United States FDA in 1991 to treat the hepatitis C. The Interferon has been approved standard therapy for chronic hepatitis C. The patients selected on basis of persistently abnormal liver function tests rather than in presence or absence of symptoms. About half of the patients treated with Interferon respond with improved liver function tests and the viral load. Half of the patients, who cannot respond, relapse once the Interferon is stopped. In one study, half of chronic hepatitis C patients who showed response to alpha Interferon had a relapse within six months after stoppage of treatment. Most prevalent genotypes in Pakistan are 2 and 3 have shown better response to treatment. The usual dose of Interferon alpha 2b monotherapy is 3 MIU thrice per week for about 12 months and gives approximately 12% the sustained virological response (SVR). Now a day the standard therapy for treating this disease is combination of pegylated Interferon and Ribavirin. This therapy has achieved SVR approximately of 80% for genotypes 2 and 3. Ribavirin is an antiviral chemotherapeutic agent with broad spectrum of activity and less toxicity. It is active against at least 20 different RNA and DNA viruses. It has structure similar to nucleoside guanosine, one of the 4 basic components of RNA. It works by blocking mRNA that prevent the viral replication and also stops the infection without affecting normal functions of the body (Bradley H *et al*., 2005).

Dose: According to patient body weight:

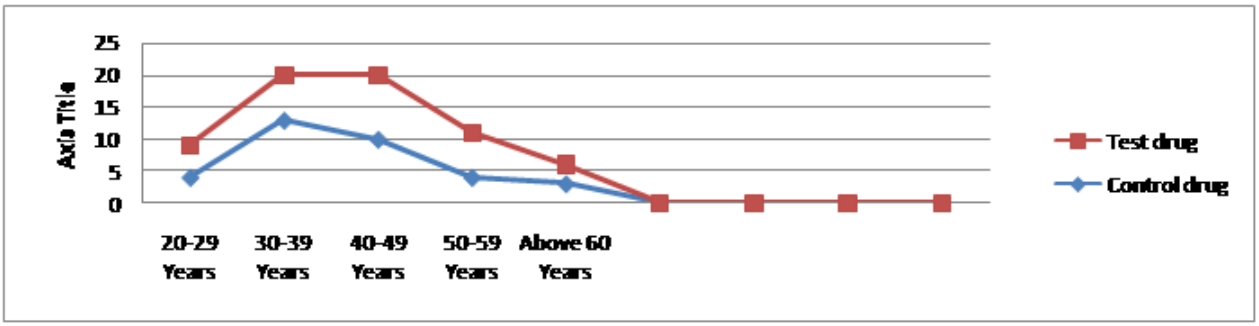
- Greater than 75kg body weight Ribavirin 1200 mg daily in two divided doses
- Between 55 and 75kg body weight Ribavirin 1000mg daily in two divided doses
- Less than 55kg body weight Ribavirin 800mg daily in two divided doses.

Table 1: Design strategy for treatment of Hepatitis C

Number of drugs	1. Test drug 2. Control drug	1. Hepcinal 2. Interferon alpha 2b and Ribavirin
Total Patients	32 test+34 control	
Number of Tests	CBC, LFTs, Anti-HCV, HCV RNA by PCR (viral load) before and after treatment	Follow up 2 weeks after treatment
Duration of treatment	6 months	Post treatment follow up

Table 1: Test and control drug content and dosage form

Diseases	Test Drugs	Test Drugs Formulation	Control Drugs
Hepatitis C	Hepcinal Tab	*Emblica officinalis Gaertn.*(Amla) 75 mg *Glycyrrhiza glabra L.* (Mulathi) 75 mg *Tamarix gallica L.* (Jhao) 50mg *Silybum marianum L.* (Ount Katara) 150mg *Rosa damascena mill L.*(Gul Surkh) 50mg *Picrorrhiza kurroa* Royle ex. (Kutki) 100mg	Interferon alpha 2b Interferon alpha 2b 3MIU injections three times a week for 6-9 months. Ribavirin According to body weight for patients 1. Less than kg body weight Ribavirin 400 mg bid 2. Between 55-75 kg Ribavirin 500 mg bid 3. Greater than 75 kg Ribavirin, 600 mg bid.



Graph 1: Distribution of interval of ages of patients prescribed test and control drug

RESULTS

The mortality rate pertaining to the chronic liver disease in Pakistan is determined to be approximately 120 million. It is quite alarming, and further more in addition those individuals infected with hepatitis C virus are at risk of developing the liver cirrhosis and liver cell carcinoma. Enough epidemiological studies have cited in literature to demonstrate massive threat that is posed by hepatitis C. Hepatitis C also shows momentous genetic variation in all over the world, evidence of its frequent rates of mutation and rapid evolution are encountered in reports. Therefore it appears that majority of the population in Pakistan are treated with the traditional medicine, and that progressively the herbal drug dosage form design are progressively leaving used in hepatitis C treatment and it has shown good promise. Hence one of the objectives of present study was to correlate the effect on viral load with the eastern/herbal treatment and also to validate the claims of earlier preliminary study carried out in our laboratory for the treatment of hepatitis C. In this study, the patients were categorized into two different group *i. e.* Test group and Control group on whom eastern/herbal coded formulation and allopathic formulation were prescribed respectively. The detailed history of the patients and questionnaire was documented on clinical trial proforma at every follow up visit under the supervision of physician monitor and supervisor.

Age distribution of the patient

The age distribution of patients classified into the different class intervals ranging the age starting from 20 years to above 60 years. The age distribution of 66 patients that was recorded having 5 class intervals i.e. 20-29, 30-39, 40-49, 50-59 and above 60 shown in graph 1.

Comparative analysis

The comparative clinical study conducted on Hepcinal and Interferon alpha 2b and Ribavirin have been done to

assess the serological, biochemical, hematological and clinical response that shown in fig. 1.

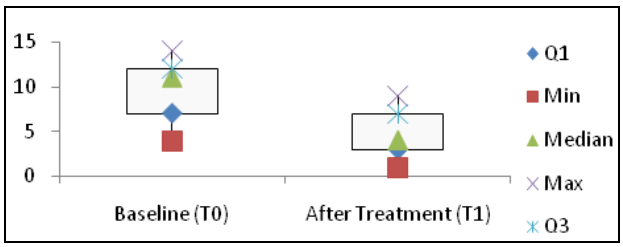
Fig. 1: Parameters for the assessment the efficacy of both drugs.

Intensity of symptoms

Intensity of symptoms is a signal of active infection accessing the inflammatory process. In this study, we recorded the intensity of symptoms as absent: 0, mild: 1, moderate: 2 and sever: 3 at baseline (T0) and after the completion of treatment (T1). Median values, interquartile ranges were determined and p values were calculated by using Wilcox on signed-rank test to record the indirect effects of hepcinal in the reduction of inflammatory process.

Table 2: Overall improvement in severity of symptoms in Test group by Wilcoxon signed rank test

Overall severity of symptoms				
Baseline (T0)		After treatment (T1)		
Median	IQR	Median	IQR	p value
11	7-14	4	3-7	0.006



Graph 2: Overall improvement in intensity of symptoms.

Improvement in symptoms with Hepcinal

There was a statistically significant decrease in the overall symptom score from baseline (T0: median 12, IQR 7-14) to after completion of treatment (T1: median 4, IQR e 3-7) as given in table 3 and graph 2.

The efficacy of herbal formulation is a characteristic of a complex mixture of chemical compounds present in different herbs used as multiple dosage form design. The clinical trial in case of test drug, therefore, has been designed in a manner that reflects the characteristic bioactivity as used in ethno pharmacology.

Improvement profile with control therapy

Interferon does not exhibited a statistically significant decrease in the overall symptom score from baseline (T0: median 11, IQR 8-14) to after treatment (T1: median 8, IQR 5-10) as shown in table 5 and graph 4.

Summary

The summary has been shown in the different tables and the signs and symptoms improvement in patients are enumerated which shows the performance at the baseline and treatment completed as show in table 8.

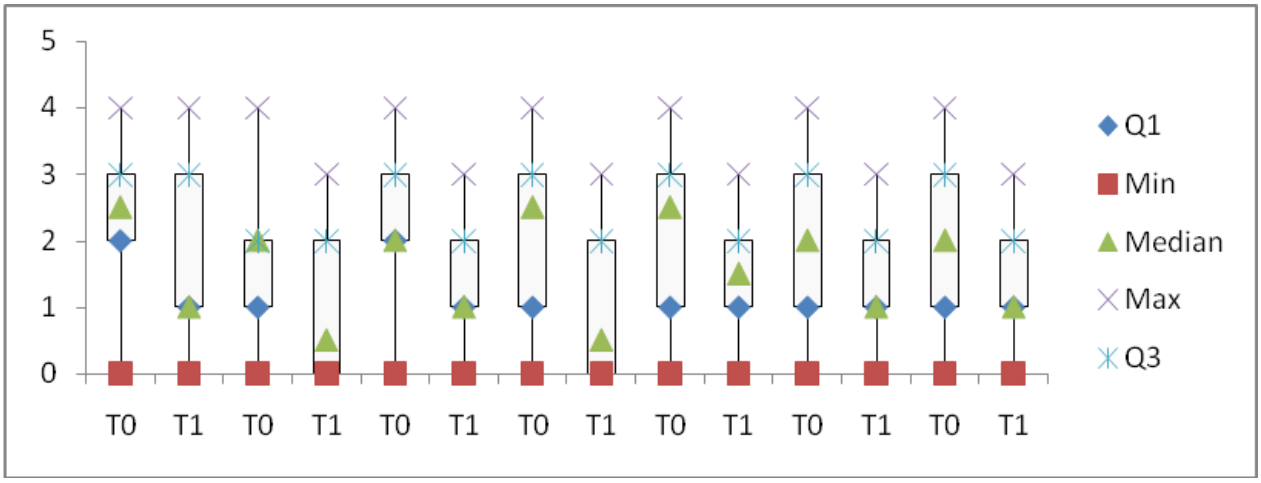
DISCUSSION

According to the statistical analysis clinical response of Hepcinal was 55-94% and control drug was 26-55% clinical response (p value was calculated 0.039), but serological response of test drug is 46.88% and of control drug was 55.88% and p value was calculated 0.3244. It indicated that control drug had shown superior efficacy serologically but clinically it had not shown better results as compared to test drug.. Comparison of data recorded by participants relating to these variables showed no significant differences between test and control groups ($p>0.05$). Chi-Square Test was applied and p-value was calculated as 0.039 indicating that test and control therapy is equally significant in the treatment of Hepatitis C.

A study based on clinical experience with non-standard doses of Interferon alpha 2b and Ribavirin for the treatment of chronic hepatitis C have described that 675 patients exhibited that black patient as compared to white patients treated with peg Interferon the virological response was lower in clinical study than with Interferon and Ribavirin, with significant side effects (Bradley H *et al*., 2005). Complementary and alternative medicine therapy (CAM) might ameliorate the chronic liver disease due to hepatitis C even though it might not inhibit or eradicate the actual viral infection itself. Some CAM therapies appear to exert biological effects that include antioxidant, anti fibrotic or immune modulator activities that may help to ameliorate the disease. Proof of such an effect has been documented (Tina M *et al*., 2008). In a study conducted on six patients when compared with published studies, the larger amount of patients exhibited broader and more intensive approach in the results and findings. Similarly this study conducted on 66 patients both test and control drugs and the results were quite concerning where in the symptomatic efficacy with Hepcinal is better than the Interferon and Ribavirin (Thierry P *et al*., 2003b).

Table 3: Overall improvement in intensity of symptoms in test group by Wilcoxon Signed Rank Test

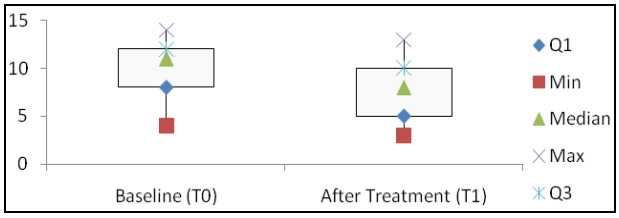
Intensity of symptoms					
Symptoms	Baseline (T0)		After treatment (T1)		
	Median	IQR	Median	IQR	*p* value
Anorexia	2.5	2-3	1	1-2	0.05
Heart burning	2	1-3	0.5	0-1	0.02
Abdominal Pain	2	1-3	1	1-2	0.01
Indigestion/ Flatulence	2.5	2-3	0.5	1-3	0.003
Burning Palm & soles	2.5	2-3	1	0-1	0.03
Fever	2	2-3	1	1-2	0.06
Generalized weakness	2	2-3	1	1-2	0.06



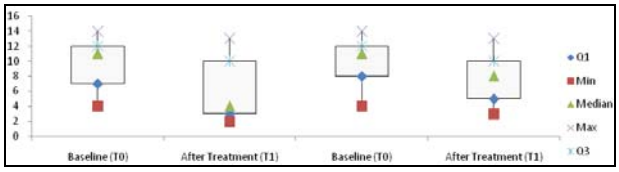
Graph 3: Intensity of anorexia, heart burning, abdominal pain, indigestion/flatulence, nausea/vomiting and fever and generalized weakness respectively, green arrow showing the median values

Table 5: Overall severity of symptoms by Wilcoxon Signed Rank Test

Overall severity of symptoms				
Baseline (T0)		After 1 moth of treatment (T4)		
Median	IQR	Median	IQR	p value
11	8-14	8	5-10	0.31

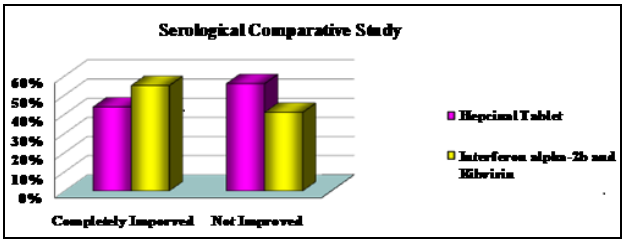


Graph 4: Overall improvement in severity of symptoms



Graph 6: Comparative analysis in intensity of symptoms between two treatment groups

In Egypt a randomized double blind trial with silymarin was conducted on to treat the hepatitis C infection. The silymarin safely given for one year, it gave no promising results, hepatitis C viremia, serum ALT. But as contrary the Hepcinal, which comprises of silymarin also along with other 4 drugs gave better clinical, biochemical and serological response (Tanamlya *et al*., 2004).



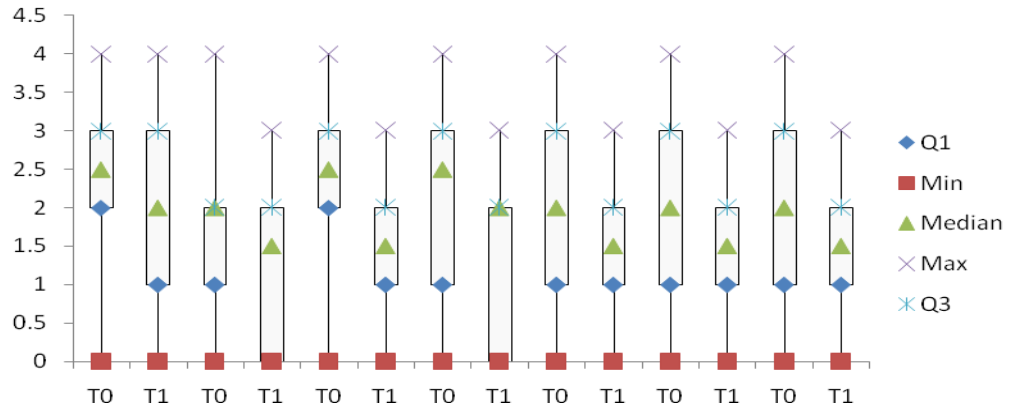
(p*<0.05)

Adverse effects

In case of control most frequently noted adverse effects are nausea, fever, weakness, fatigue, generalized body pain, restlessness and vomiting etc. But on other hand no adverse effects are noticed.

Table 6: Improvement in Intensity of Symptoms with Interferon

Intensity of symptoms					
Symptoms	Baseline (T0)		After treatment (T1)		
	Median	IQR	Median	IQR	*p* value
Anorexia	2.5	2-3	2	1-2	0.14
Heart burning	2	2-3	1.5	1-2	0.01
Abdominal Pain	2.5	1-3	1.5	1-2	0.02
Indigestion/ Flatulence	2.5	2-3	2	1-3	0.04
Burning Palm & Soles	2	1-3	1.5	1-2	0.07
Fever	2	2-3	1.5	1-2	0.06
Generalized Weakness	2	2-3	1.5	1-2	0.06



Graph 5: Intensity of abdominal pain, heart burning, regurgitation, indigestion/flatulence, nausea/vomiting and belching respectively, green arrow showing the median values

Table 7: Comparison in intensity of symptoms between two treatment groups by Wilcoxon Signed Rank Test

Hepcinal					Interferon therapy				
Before treatment		After treatment			Before treatment		After treatment		
Median	IQR	Median	IQR	p value	Median	IQR	Median	IQR	p value
11	7-14	4	3-7	0.006	11	8-14	8	5-10	0.3

Table 8 (A): Clinical assessment

	Hepcinal Tablets		Interferon alpha 2b and Ribavirin		
	Improved	Not Improved	Before treatment	After treatment	p value
	(A)*	(NA)**	(A)*	(NA)**	
Anorexia	25(78.12%)	7 (21.87%)	18(52.94%)	16(47.05%)	0.0407
Heart burn	26(81.25%)	06(18.75%)	19(55.88%)	15(44.11%)	0.0357
Epigastric pain	25(78.12%)	07(21.87%)	18(52.94%)	16(47.05%)	0.0407
Generalized Body pain	23(71.87%)	09(28.12%)	12(35.29%)	22(64.70%)	0.0036
Burning micturation	24 (75%)	8 (25%)	10(29.41%)	24(70.58%)	0.0003
Fever	24 (75%)	8(25%)	11(32.35%)	20(67.64%)	0.0006
Burning palm and sole	27(84.37%)	05(15.62%)	15(44.11%)	19(55.88%)	0.0009
Constipation	25(78.12%)	7 (21.87%)	12(35.29%)	22(64.70%)	0.0006
Joint pain	19(59.37%)	13(40.62)	09(26.47%)	23(67.64%)	0.0226
Abdominal pain	17 (77.27%)	05 (22.73%)	16 (69.56%)	07 (30.44%)	0.023
Fatigue	29 (90.63%)	03 (9.37%)	19 (54.29%)	16 (45.71%)	0.005
Weakness	29 (93.55%)	02 (6.45%)	25 (54.35%)	21 (45.65%)	0.005
Nausea/vomiting	11 (55%)	09 (45%)	07 (36.84%)	12 (63.15%)	0.3406

Table 8 (B): Biochemical assessment for control drug

Biochemical Assessment for Control drug											
		SGPT BT	SGPT AT	Alk Phosphatase BT	Alk Phosphatase AT	Bilirubin BT	Bilirubin AT	S. Urea BT	S. Urea AT	S. Creatinine BT	S. Creatinine AT
N	Valid	34	34	34	34	34	34	34	34	34	34
	Missing	0	0	0	0	0	0	0	0	0	0
Mean		101.06	39.30	395.88	224.38	.7476	.9838	31.412	40.912	0.6653	0.9429
Std. Deviation		48.303	15.377	135.484	115.835	.19327	.47251	8.3198	11.2314	0.19047	0.16284

Table 8 (B): Biochemical assessment for test drug

Biochemical Assessment for Test drug											
		SGPT BT	SGPT AT	Alk Phosphatase BT	Alk Phosphatase AT	Bilirubin BT	Bilirubin AT	S.Urea BT	S.Urea AT	S. Creatinine BT	S. Creatinine AT
N	Valid	32	32	32	32	32	32	32	32	32	32
	Missing	00	00	00	00	00	00	00	00	00	00
Mean		76.25	38.41	401.88	290.28	1.1062	.6484	41.500	28.656	.9344	.6747
Std. Deviation		38.423	13.210	141.116	87.984	.73018	.18976	12.2553	7.0556	.18020	.12879

Table 8 (C): Hematological assessment for test drug

Hematological Assessment for Test drug							
		Platelets Before Treatment	Platelets After Treatment	Hb Before Treatment	Hb After Treatment	TLC Before Treatment	TLC After Treatment
N	Valid	32	32	32	32	32	32
	Missing	0	0	0	0	0	0
Mean		176429.219	161788.44	10.059	12.284	5000.95	6409.13
Std. Deviation		204318.3208	88445.342	1.7625	1.3318	2537.009	2915.868

Table 8 (C): Hematological assessment for control drug

Hematological Assessment for Control drug							
		Anemia Before Treatment	Anemia After Treatment	Platelets Before Treatment	Platelets After Treatment	TLC Before Treatment	TLC After Treatment
N	Valid	34	34	34	34	34	34
	Missing	0	0	0	0	0	0
Mean		12.588	9.312	310297.059	132158.24	6906.76	3933.68
Std. Deviation		1.2424	1.4051	447104.4082	150080.986	2553.684	1625.412

Table 8 (D): Comparative serological assessment

	Before treatment	After treatment	Imp.	Before treatment	After treatment	ImP	p value
HCV RNA by PCR (Viral load)	32	17	46.88%	34	15	55.88%	0.3244
	10386591.31 ±4384710 IU/ml	783436.43 ±4363116IU/ml		1987187.06 ±6136247.793 IU/ml	57526.6265 ±131801.5 IU/ml		

CONCLUSION

It was concluded that Hepcinal possesses a therapeutic value for the improvement in hepatitis-associated symptoms as compared to Interferon therapy, thus preventing the progress of chronic disease as well as improving overall health of the patients. There was no untoward manifestation associated with the use of Hepcinal and this has found good acceptability by all treated patients. This is an exercise of applying modern techniques and clinical design to product that have been in use for centuries. Further research and clinical trial at large scale are needed to prove better efficacy in terms to overcome the burden of hepatitis C.

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