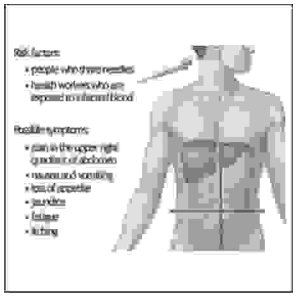
ORIGINAL PROF-1219

HEPATITIS C PATIENTS;

TREATMENT COMPLIANCE OF HAVING POOR SOCIO-ECONOMIC BACK GROUND.



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ABSTRACT... Objectives: To determine the impact of antiviral treatment of Hepatitis C patients with poor socio-economic resources. **Design:** Prospective cohort study. **Place and Duration:** Department of Medicine, Sheikh Zayed Medical College / Hospital, Rahim Yar Khan, from August 2006 to February 2007. **Subjects and Method:** One hundred known cases of hepatitis C were selected. PCR and biochemical tests were performed before the start of therapy. Interferon and Ribavirin therapy was given according to standard therapeutic protocol. Patients were continuously motivated and educated for regular treatment. The observations were collected regularly. **Results:** Out of hundred cases 95 improved symptomatically. One got worse while 4 remained symptomatic. At the end of therapy PCR was performed only in 4 cases. **Conclusion:** In non affording patients although exact status of viral clearance is not known but some thing is better than nothing rule was applied for treatment of patients.

Key words: Hepatitis C, PCR, Interferon, Ribavirin.

INTRODUCTION

Hepatitis C virus infection is a global health problem affecting an estimated 170 million individuals world wide[1,2]. It has been associated with a lot of morbidity and mortality[3-5]. It can lead to chronic liver diseases i.e. cirrhosis of liver and hepato cellular carcinoma. Now a days one of the commonest cause of hospital admissions in Pakistan is due to viral liver diseases[6,7]. The common hepatotrophic viruses encountered are A, B, C, D, E and non A-E. Following the introduction of HBV and HAV vaccines it is hoped that the magnitude of these infections will eventually decline. However other Hepatitis viruses continue to pose a problem. Many patients suffering from hepatitis C are found in the district Rahim Yar Khan and adjoing areas of Sindh and Baluchistan[6-7]. Poverty prevails and lack of proper medical facilities in the far flung areas make the situation more miserable and gloomy. Non availability of proper management of such cases is very harmful for the patients as the disease progresses[9]. These cases cause a lot of socio-economic burden to the family and they are the potential reservoirs for the spread of the disease. So all the resources should be utilized for prevention and management of hepatitis C cases.

AIMS AND OBJECTIVES

Prime Minister's Programme for control of Hepatitis had been started. This is the study of those patients receiving antiviral treatment under this programme. Objective is to assess whether provision of free medicines and laboratory assistance can help the patients or not. To identify the factors which can improve the utility of this programme and to point out any short comings.

PATIENTS AND METHODS

It is a prospective, open label, single centered interventional study. Initially 100 patients were enrolled for the treatment. 4 patients were lost in follow up after 3-4 injections so another 4 patients were registered. The study was carried out with 100 patients. Following criteria was adopted in order of priority in the light of guidelines provided by 'Standard Operating Procedure by Ministry of Health Punjab' to register the patients for therapy.

1. Patients registered with the related Zakat committees as eligible for Zakat.
2. All government servants from BPS 1- 16.
3. Cases of financial hard ships as indicated by the applicant and assessed by the Zakat committee.

Both male and female patients above the age of 15 years with compensated chronic HCV infection not previously treated with interferon or ribavirin were eligible for enrollment on first come first serve basis. A complete proforma was filled mentioning - name, age, sex, occupation, address, symptoms before treatment, during treatment and after treatment, since when they were known to have HCV infection and why they were checked for the viral markers? The patients were asked about-I.V. drug injection, sex history, shaving habits, ear piercing, dental surgery, G.I. Endoscopy, blood transfusion, renal dialysis, alcohol intake and any history of surgical procedure. Viral serology of family members was also enquired and recorded.

STUDY PROTOCOL

Inclusion Criteria: Hb > 11 g/dl for females and > 12 g/dl for males. TLC > 3000/cmm. Neutrophil count > 1500/cmm. Platelet count>100,000/cmm S. Bilirubin < 3mg and normal albumin, creatinine, PT and APTT. Liver biopsy was not done in any case.

Exclusion Criteria

Previously interferon treated patients with relapse were not included.

Presence of drug abuse, chronic systemic disease, malignancy, bleeding disorder, clinically significant cardiac or neurological illness, psychiatric disorders, auto immune disease, pregnancy and lactating mothers were not including in the study.

Abdominal ultrasonography for liver size, echo texture, any focal mass, portal vein diameter, splenic size and ascites was done in the beginning. At entry neutrophil, platelet, leukocyte counts were done. PT, APTT, S. Albumin, ALT, AST, S. Bilirubin and Hb % were done for every patient on their first visit and then repeated at 2, 4, 8, 12, 20 and 24 weeks. The patients were evaluated in OPD for safety, tolerance and efficacy of treatment regularly at fortnightly basis and were motivated and told about disease prevention and control.

The patients were provided one week's therapy. They were advised to maintain the cold chain and bring back the empty vials. In case of public holidays they were provided two weeks treatment so that no dosage is missed.

Clinical examination and assessment regarding any un-towards effects and progress or regression of disease were done in OPD fortnightly. Thyroid function tests, genotyping and quantitative PCR for HCV were not available in the hospital laboratory and all patients refused to get it done from outside laboratories due to high cost of the tests.

Qualitative PCR was done also from outside laboratories and all the patients got it done as it was compulsory prior to therapy according to guidelines provided.

The patients were asked to repeat qualitative PCR for HCV RNA after 6 months treatment. Just 4 patients

turned up,

others were lost in the follow up as soon as their course of therapy completed.

RESULTS

Table-I. Age Distribution (n=100)				
Age in years	**Male**	**Female**	**Total**	**%age**
16-30	30	10	40	40%
31-45	16	17	33	33%
46-60	17	09	26	26%
61 and above	1	-	1	1%
Total	64	36	100	100%

The youngest patient was 16 years male student while oldest patient was a male of 63 years of age. 31 males and 14 females belonged to rural areas while 33 males 22 females belonged to urban areas.

More than one member of the family was having positive viral markers in 12 families.

The usual side effects were fever, flu like symptoms, headache, myalgias and arthralgia, insomnia, fatigue, alopecia and mood changes, Severe depression leading to drug withdrawal was not seen in any case.

Severe laboratory abnormalities leading to modification of the drug dosage was seen in 4 patients they were restarted the treatment when the abnormality was abated. Life threatening side effects leading to with drawl of medicine were not seen in any patients.

Table-II. Occupational status of the patients						
Occupation	**N = 64**		**N=36**		**N=100**	
	Male	**%age**	**Female**	**%age**	**Total**	**%age**
Medical & paramedical	6	9.38	3	8.33	9	9%
Labor	22	34.38	2	5.56	24	24%
Business	21	32.81	-	-	21	21%
Farmers	9	14.06	1	2.78	10	10%
Students	6	9.38	3	8.33	9	9%
House wife	-	-	27	75.00	27	27%
Total	64	100.00	36	100.00	100	100%

Table-III. Indications for anti-HCV assessment							
		N = 64		**N=36**		**N=100**	
		Male	**%age**	**Female**	**%age**	**Total**	**%age**
Symptoms	Suggestive of liver disease	10	15.63	13	36.11	23	23%
	Vague, generalized	38	59.38	20	55.56	58	58%
Routine examination done prior to job or college admission		16	25	3	8.33	19	19%
Total		64	100%	36	100%	100	100%

Table-IV. Viral serology status of other family members enrolled of patients (N=100)						
	N = 64		N=36		N=100	
	Male	%age	Female	%age	Total	%age
Already checked	40	62.50%	28	77.78	68	68%
Not checked	24	37.50%	8	22.22	32	32%
Total	64	100%	36	100%	100	100%

Table-V. Result of screening of family members of enrolled patients				
	Male	Female	Tot.	%age
Positive viral markers	43	25	68	62.96%
Negative viral markers	27	13	40	37.04%

Table-VI. Adverse effects of treatment by Interferon and Ribavirin (N=100)				
	Male	Female	Total	%age
Present	62	35	97	97%
Not present	2	1	3	3%

Table-VII. Laboratory Abnormalities among patients during treatment (N=100)						
	Male	%age	Female	%age	Total	%age
Hb 8.5 – 10.0 g/dl	58	82.86	32	72.73	90	90%
Hb < 8.5 g/dl	6	8.57	4	9.09	10	10%
Platele +< $50x10^9$/L	3	4.29	1	2.27	4	4%
ALT elevation after start of therapy.(ALT flare)	3	4.29%	7	15.91%	10	10%

No new side effect was observed. The adverse effects were usually mild and transient and did not affect the quality of the life of patients much[8,9].

The visits of the patients during treatment remained frequent and regular. Progressive liver damage was not seen in any case.

DISCUSSION

Hepatitis C is well known for its chronicity causing liver cirrhosis and hepato cellular carcinoma. The introduction of assays for the detection of virus has expanded our knowledge regarding prevalence of disease in our own community[11,14]. Different studies done in Pakistan in different setups of people show that a large number of cases are suffering from Hepatitis C infection[15-17]. No proper treatment facilitates, the spread of disease causing a lot of morbidity and mortality[18,19] which can pose both economical and social burden to the nation.

The efficacy, safety and pharmokinetics of interferon and ribavirin for treatment of chronic HCV is well known[20-23]. Interferon and Ribavirin treatment of HCV infection patients can achieve viral clearance and thereby improve histology and prognosis[24-34]. Sustained viral response rate in patients affected by genotype 2 and genotype 3 are generally twice as high as the rates achieved in genotype I patients.

Although the results of this therapy are not excellent but

the treatment options are limited. It should also be noted that treatment of chronic HCV patients should rely on all the factors like viral replication, symptoms, histology and progression of disease and risk of transmission rather than a single parameter. That is why we continued the treatment inspite of economical hurdles. With repeated motivation of patients and attendants the patients showed satisfactory response and got better.

CONCLUSION

Despite the significant advances that have been made in the treatment of chronic HCV infection in recent years, it is still beyond the reach of a poor person. Unfortunately we could not perform many tests and could not treat the patients more scientifically. There is a need to identify modifiable risk factors to prevent further spread of the disease. More resources should be utilized to treat the patients and get a sustained viral response so that progression of the disease is stopped.[35] Screening for new cases should be done more frequently for early treatment and to stop the interfamilial transmission and spread of the disease[36] to community. More time should be spent for the patient's education and counselling so that they stick to standard protocol of treatment. The best compliance was only due to continuous motivational health education i.e., 96% of patients completed their treatment ($p<0.05$) in our study is very significant. Follow up of the patients should continue after treatment to pick any relapses or incomplete response. Continuous education and motivation of patients and their attendants is very important to change their attitude and behaviour in a desired direction and to achieve aims and objectives satisfactorily it helps clear understanding of the problem so that it can be tackled in a better way.

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