

## Clinical Trial of Tibetan Medicine in the Treatment of Chronic Hepatitis B

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### Abstract

**Objectives** To assess the effectiveness of Tibetan medicine in the treatment of chronic hepatitis B in terms of improvement in abnormal liver function test, HBV related symptoms and to compare the Specific and Traditional Tibetan medicine for HBV.

**Design** Randomised controlled trial

**Setting** Men-Tsee-Khang branch clinic at Bylakuppe Tibetan settlement, Mysore.

**Participant** 50 confirmed chronic hepatitis B patients who have been diagnosed during a mass screening and survey done in 2003-04 in the settlement.

**Intervention** patients were allocated into two arms - one arm received a Specific Tibetan Medicine (STM) for chronic hepatitis B and the other arm were treated with Traditional Tibetan Medicine (TTM) in order to monitor any pathological changes and relieve in symptoms.

**Results** The Specific Tibetan Medicine and the Traditional Tibetan Medicine were comparable for LFT and hepatitis B related symptoms (Table 1,2,3&4). However, in spite of randomization, the Specific Tibetan Medicine group i.e., group-I have significantly higher LFT value and worse symptoms, indicating poorer LFT control in the study that received the Specific Tibetan Medicine. Both the group of Specific and Traditional Tibetan medicine showed significant improvement in improving Liver Function Test and HBV related symptoms. However, there is no any case of conversion from 49 patients who completed the six months course of study.

**Conclusion** Statistic comparisons between the two groups and within the group over the time period and their respective (Specific and Traditional) Tibetan Medicine shows that both are effective on their own merits. However, there is no any case of conversion from 49 patients who completed the six months course of study.

### Introduction

Hepatitis B is one of the major diseases of mankind and is a serious public health problem. Of more than 2 billion people who have been infected with the hepatitis B virus (HBV),

more than 350 million have chronic (lifelong) infections. These chronically infected persons are at high risk of death from cirrhosis of the liver and liver cancer, disease that kills about one million persons each year. The risk factor in developed countries has fallen sharply due to change in lifestyle and stringent strategy. Developing countries like India has become one of the leading breeding places of HBV. It is calculated that one in every twenty persons in India is infected with HBV.

The number of people infected with HBV in Tibetan community has overgrown since it was first screened in late 1999 in most of the Tibetan settlements. Its prevalence rate stands at 11.66 % in Bylakuppe settlement by the end of August 2001. The pace at which this virus is spreading has not shown any signs of slowing down. The recent screening of HBV in most of the Tibetan settlements has only confirmed its penetration. Modern Health Care system does not claim to have any specific treatment other than heavy antiviral drugs for chronic HBV aiming at support and maintaining comfort. In such situation, many people have started looking for alternative treatment.

Traditional Tibetan Medicine has shown great potential in being effective to most of the chronic ailments. There is no any study exploring the effectiveness of Tibetan medicine in the treatment of chronic hepatitis B. The objective was to provide better treatment option for chronic hepatitis B patient, and we hypothesised that Tibetan medicine is effective in treating chronic hepatitis B.

## **Materials and Methods**

The participants recruited were the patients who were confirmed chronic hepatitis B. The inclusion criteria demands the confirmation of HBV positive through Elisa test after the six months period of diagnosed HBsAg positive, aged between 15-55 years and who is willing to signed a informed written consent form.

We designed the study as open randomised controlled trial. There are 50 patients randomly allocated in two groups where group-I (n=25) receives Specific Tibetan Medicine (STM) and group-II is treated according to Traditional Tibetan Medication (TTM). 1 patient withdrew at the end of 8 weeks due to inevitable condition that deviates the inclusion criteria. Each group has three turns of visit as 1st visit at the baseline or 0 month, 2nd visit or follow-up after 3 months, 3rd visit or follow-up after 6 months to analyse the condition of liver function through Liver Function Test and its mean value. Besides, HBsAg test and LFT, we also analysed the urine and pulse characteristics of each patients along with the treatment for 3 months in the first phase. During the second phase of study, the mean changes in the LFT, Elisa of HBsAg as well as that of hepatitis B related symptoms and pulse alteration are specified. After the third phase of study or during 3rd visit, all the tests are repeated and changes in variables are recorded. Diet and behaviour patterns were advised and maintained simultaneously. Patients in both the groups were interviewed by the attending Tibetan Physician of Men-Tsee-Khang and a case report form of each group were completed.

Hepatitis B (HbsAg+ve) research process that we undertook was primarily initiated with an Elisa test for chronic HBsAg, which was based on the fact sheet on hepatitis B by WHO, October 2000. Serum Bilirubin -Total and Bilirubin- Direct were investigated by using

Diazo Method, AST( SGOT) and ALT(SGPT) by Karmen's method, Gamma GT by Szasz and Persijin method, Alkaline Phosphatase (ALP) by PNP method, total protein by Biuret method, Albumin by BCG method at the beginning which was common to all i.e., 3 visits that we have made in this round of research. Materials & methods we used were latest and were accredited by National Accreditation Board for testing & Calibration Research, Laboratories, Department of science & Technology, India. All the patients were sent to the above mentioned laboratory for all serological tests, which was approximately 60 kms from the Bylakuppe clinic. Weight, BP, urine and pulse characteristics were analysed once in every 20 days.

### **Assessments**

For the liver function test, comparison between two groups was done by using t- test and Chi-square test.  $P < 0.05$  was considered significant. Comparison within the group over the time period was done by using repeated measure ANOVA and Post-hoc analysis was done using bonferroni test. For the symptoms, comparison within the group was done by using Friedman test and multiple comparison was done using Newman killis. The data was managed in Epi Info 2002.

### **Statistical Analysis**

Data were recorded on a pre-designed Performa and managed on Epi-info software (developed by WHO). All the entries were checked before data analysis. Qualitative variables were summarized by frequency in the two groups. Mean, standard deviation was computed for quantitative variables for both the groups, separately. Two-sample student 't' test and repeated measures analysis were performed to compare mean values of laboratory parameters in the two groups. STATA 9.0 (intercooled version) statistical software was used for data analysis.

### **Result**

The Specific Tibetan Medicine and the Traditional Tibetan Medicine were comparable for LFT and hepatitis B related symptoms (Table 1,2,3&4). However, in spite of randomization, the Specific Tibetan Medicine group i.e., group-I have significantly higher LFT value and worse symptoms, indicating poorer LFT control in the study that received the Specific Tibetan Medicine.

Between the comparisons of two groups the mean value of Total Bilirubin and Indirect Bilirubin were showing significant difference at baseline, so mean % increment of LFT was calculated and did not show significant difference. Only Globulin was showing significant difference between the two groups during 3rd visit (follow-up after six months) with the mean value 2.47 in the group-I and 2.26 in the group-II (table-1 & graph-1). Over the time period within the group, the mean value of protein and Globulin were showing significant changes in group-I (Specific Tibetan Medicine). Protein was showing significant difference

from baseline to visit-3 and visit-2 to visit -3. The mean value of Indirect-Bilirubin, GGT and Globulin were showing the significant difference in group-II (Traditional Tibetan Medicine). Indirect bilirubin was showing the significant difference from Baseline to visit-3. The mean value  $0.69 \pm 0.22$  at baseline,  $1.63 \pm 5.04$  at visit 2 and  $0.58 \pm 0.16$  at visit 3. Serum GGT was showing significant difference from baseline to visit-2 & visit-2 to visit-3 with the mean value of  $33.52 \pm 21.55$  at baseline,  $31.28 \pm 16.18$  at visit-2 and  $43.79 \pm 23.35$  at visit-3.

Globulin was showing significant difference from baseline to visit-3 with the mean value of  $0.45 \pm 0.68$  at baseline,  $2.47 \pm 0.32$  at visit-2 and  $2.26 \pm 0.41$  at visit-3 (table-1 & graph-2).

There is no significant difference in Total Bilirubin, Direct Bilirubin, SGOT, SGPT, ALP between the groups and did not change during the course of study. Normal and abnormal subjects and percent were also calculated (table-2). Normal percent increased over the period of time within the both group though few of the LFT variables were not showing significant differences. Clinically, normal percent increment is important, as it was sign of LFT improvement.

As far as hepatitis B related symptoms, between the comparisons of the two groups only the headache and abdominal bloating were showing significant differences at visit-3 only. Headache was showing significant difference.

Over the period of time, headache and abdominal bloating were showing significant difference in group-II only. So, it is clear that group II is better than group I in case of disappearance of symptoms (table - 3 & 4).

Over the period of time, fatigue, loss of appetite, and weak digestion were showing significant difference in group-I. Jaundice, fatigue, nausea/vomiting, weak digestion, and abdominal bloating were showing significant difference in group-II (table -4).

Weight, blood pressure, age, sex and marital status were not showing significant difference between the groups. Weight and blood pressure also did not show any changes during the course of study (table - 10 & 11).

## Discussion

Statistic comparisons between the two groups and within the group over the time period and their respective (Specific and Traditional) Tibetan Medicine shows that both are effective on their own merits. It is evident from the effectiveness of Tibetan medicine over the remarkable significance shown in above paragraph that both Specific Tibetan Medicine and Traditional Tibetan Medicine were beneficial for hepatitis B patient. In group-I (Specific Tibetan Medicine) has proved statistically significant difference in the mean value of two L.F.T variables. In the same way, Traditional Tibetan Medicine has proved statistically significant progress in the mean value of three L.F.T variables. Besides that, mean value of Total Protein has appreciatively got 100% normal in 2nd and 3rd visit. Plus mean value of Total Protein, Albumin and Globulin increased even though it was within the ranges, which shows the positive sign. Even though we could not phrase out single hepatitis B negative out

of 49 patients, we can claim it universally that Tibetan medicine can prove effective in livening up the strength of liver and to strengthen the immune system to fight against the negative feed back of virus.

The other side to look at this study for not having any case of conversion could be the time phase of six months. Since there are cases of chronic hepatitis B patient being completely cured by Tibetan medicine we could look into the possibility of treating patient on longer course of treatment to assess its real potential.

## Conclusion

There has not been any report published in English medical literature regarding the effectiveness of Tibetan Medicine in the treatment of chronic hepatitis B. In this study, we report significant improvement in liver function test and hepatitis B related symptoms with Tibetan medicine in treating chronic hepatitis B patient. However, there is no any conversion case of HBV positive to negative.

We thank Bylakuppe branch clinic staff, our pharmacy department, Dr. R.M Pandey for statistical support, Dr. Tseten D. Sadutshang for technical advise, Mrs. S. Yangdon for data feeding and most of all, Men-Tsee-Khang administration for enthusiastically supporting the study.

Funding: The study was funded by Men-Tsee-Khang administration.

Ethical approval: The study was approved by the local ethics committee of Men-Tsee-Khang (according to the Declaration of Helsinki).

Baseline =( 0 month, initial test).

Visit-II= (follow-up after 3 months).

Visit-III=(follow-up after 6 months).

History of HepB.	Male			Female		
	Yes	No	dont know	Yes	No	dont know
	6	15	17	5	3	4

Alcohol consumer	Male	Female
Habitual	0	0
Occasional	0	0
Never	29	13
Ex-alcohol	8	0

**TABLE 1: MEAN  $\pm$  S.D TABLE OF LIVER FUNCTION TEST B/W THE GROUPS AND WITHIN THE GROUP OVER THE TIME PERIOD.**

Variables	Group	Baseline	Visit-II	Visit-III	Chi-square	P- value
		(Mean $\pm$ S.D.)	(Mean $\pm$ S.D.)	(Mean $\pm$ S.D.)		
TOTAL-BILRUBIN	GP-I n=24	93 $\pm$ 0.50	0.87 $\pm$ 0.27	0.90 $\pm$ 0.39	0.11	0.75
	GP-II n=25	1.25 $\pm$ 0.56	0.97 $\pm$ 0.35	1.01 $\pm$ 0.74	2.16	0.15
	<i>T Value</i>	2.14	-1.16	-0.67		
	<i>P Value</i>	<b>0.03 *</b>	0.25	0.50		
DIRECT-BILRUBIN	GP-I n=24	0.38 $\pm$ 0.42	0.24 $\pm$ 0.18	.31 $\pm$ 0.29	1.33	0.26
	GP-II n=25	0.56 $\pm$ 0.51	0.36 $\pm$ 0.35	.45 $\pm$ 0.68	0.56	0.46
	<i>T Value</i>	1.40	1.59	-.95		
	<i>P Value</i>	0.16	0.11	0.34		
INDIRECT - BILIRUBIN	GP-I n=24	0.55 $\pm$ 0.17	.63 $\pm$ .13	0.58 $\pm$ 0.13	1.03	0.32
	GP-II n=25	0.69 $\pm$ 0.22	1.63 $\pm$ 5.04	0.58 $\pm$ 0.16	5.21	<b>0.03* B*</b>
	<i>T Value</i>	-2.39	-0.97	0.04		
	<i>P Value</i>	<b>0.02*</b>	0.34	0.96		
AST (SGOT)	GP-I n=24	79.18 $\pm$ 66.06	60.66 $\pm$ 64.25	57.12 $\pm$ 48.28	2.54	0.125
	GP-II n=25	50.72 $\pm$ 38.44	34.84 $\pm$ 19.97	38.35 $\pm$ 19.27	2.46	0.13
	<i>T Value</i>	1.86	1.92	1.80		
	<i>P Value</i>	0.07	0.06	0.07		
ALT (SGPT)	GP-I n=24	84.05 $\pm$ 92.17	58.46 $\pm$ 50.93	57.23 $\pm$ 48.99	2.97	0.10
	GP-II n=25	72.77 $\pm$ 73.12	39.77 $\pm$ 34.76	55.89 $\pm$ 50.68	1.16	0.29
	<i>T Value</i>	0.48	1.5	0.09		
	<i>P Value</i>	0.63	0.13	0.92		
ALP	GP-I n=24	158.79 $\pm$ 85.93	161.46 $\pm$ 71.89	162.54 $\pm$ 68.06	1.27	0.27
	GP-II n=25	115.65 $\pm$ 36.78	123.77 $\pm$ 74.45	131.2 $\pm$ 055	2.78	0.11
	<i>T Value</i>	1.77	1.80	1.78		
	<i>P Value</i>	0.08	0.07	0.08		
GGT	GP-I n=24	52.46 $\pm$ 73.05	44.46 $\pm$ 44.38	58.38 $\pm$ 68.17	1.15	0.30
	GP-II n=25	33.52 $\pm$ 21.55	31.28 $\pm$ 16.18	43.79 $\pm$ 23.35	4.86	<b>0.04* A* C*</b>
	<i>T Value</i>	1.24	1.39	1.01		
	<i>P Value.</i>	0.22	0.17	0.31		
TOTAL-PROTEIN	GP-I n=24	6.35 $\pm$ 0.31	6.55 $\pm$ 0.38	6.53 $\pm$ 0.25	4.97	<b>0.04* B*</b>
	GP-II n=25	6.36 $\pm$ 0.38	6.43 $\pm$ 0.27	6.44 $\pm$ 0.18	1.22	0.28
	<i>T Value</i>	-0.14	1.32	1.41		
	<i>P Value.</i>	0.88	0.19	0.16		
ALBUMIN	GP-I n=24	3.90 $\pm$ .32	3.86 $\pm$ 0.39	4.04 $\pm$ .028	2.87	0.10
	GP-II n=25	2.32 $\pm$ 0.42	3.96 $\pm$ 0.32	4.19 $\pm$ 0.40	2.30	0.14
	<i>T Value</i>	-1.27	-0.99	-1.51		
	<i>P Value.</i>	0.21	0.32	0.14		
GLOBULIN	GP-I n=24	2.44 $\pm$ 0.32	2.59 $\pm$ 0.53	2.47 $\pm$ 0.30	248.79	<b>0.00* B* C*</b>
	GP-II n=25	0.45 $\pm$ 0.68	2.47 $\pm$ 0.32	2.26 $\pm$ 0.41	235.04	<b>0.00* C*</b>
	<i>T Value</i>	1.18	0.93	2.06		
	<i>P Value.</i>	0.24	0.35	<b>0.04*</b>		

Baseline vs Visit-II= A\*  
 Baseline vs Visit-III=B\*  
 Visit-II vs Visit-III=C\*  
 Baseline=0 Month(initial test) .  
 Visit-II=(follow-up after 3 Months).  
 Visit-III(follow-up after 6 Months).

GP-I= The Specific Tibetan Medicine.  
 GP-II=The Traditional Tibetan Medicine.  
 AST(SGOT)=Asparate Transaminase.  
 ALT(SGPT)= Alanine Transaminase.  
 ALP=Alkaline Phosphatase.  
 GGT=Gamma Glutamyl Transpeptidase.

TABLE 2 : NORMALAND ABNORMAL SUBJECTS , % AND P-VALUE BETWEEN THE TWO GROUPS.

**VISIT-1**

VARIABLES	Normal /Abnormal	GROUP-I	GROUP-II	Chi-Square	P-VALUE
TOTAL-BILIRUBIN	<i>Normal</i>	16(66.67)	12(48)	1.74	0.19
	<i>Abnormal</i>	8(33.33)	13(15)		
DIRECT-BILIRUBIN	<i>Normal</i>	16(66.7)	11(44)	2.5	0.11
	<i>Abnormal</i>	8(33)	14(56)		
SGOT	<i>Normal</i>	7(29)	15(60)	4.7	<b>0.03*</b>
	<i>Abnormal</i>	17(70.8)	10(40)		
SGPT	<i>Normal</i>	5(20.8)	11(44)	2.99	0.08
	<i>Abnormal</i>	19(79)	14(56)		
GGT	<i>Normal</i>	14(58)	16(64)	0.17	0.68
	<i>Abnormal</i>	10(41.7)	9(36)		
ALP	<i>Normal</i>	13(54)	22(88)	6.27	<b>0.00*</b>
	<i>Abnormal</i>	11(45.8)	3(12)		
PROTEIN	<i>Normal</i>	22(91.7)	22(88)	0.18	0.67
	<i>Abnormal</i>	2(8)	3(12)		
ALBUMIN	<i>Normal</i>	24(100)	24(96)	0.98	0.32
	<i>Abnormal</i>	0(0)	1(4)		
GLOBULIN	<i>Normal</i>	16(66.67)	15(60)	0.23	0.63
	<i>Abnormal</i>	8(33)	10(40)		

**VISIT-2**

VARIABLES	NORMAL /ABNORMAL	GROUP-I	GROUP-II	CHI-SQUARE	P-VALUE
TOTALBILIRUBIN	<i>Normal</i>	20(83)	19(76)	0.41	0.52
	<i>Abnormal</i>	4(16.7)	6(24)		
DIRECTBILIRUBIN	<i>Normal</i>	18(75)	14(56)	1.95	0.16
	<i>Abnormal</i>	6(25)	11(14)		
SGOT	<i>Normal</i>	10(41.7)	17(68)	3.43	0.06
	<i>Abnormal</i>				
SGPT	<i>Normal</i>	13(54)	19(76)	2.58	0.11
	<i>Abnormal</i>	11(45.8)	6(24)		
GGT	<i>Normal</i>	17(70.8)	22(88)	2.22	0.14
	<i>Abnormal</i>				
ALP	<i>Normal</i>	15(62.5)	22(88)	4.31	<b>0.03*</b>
	<i>Abnormal</i>	9(37.5)	3(12)		

<b>PROTEIN</b>	<i>Normal</i>	24(100)	25(100)	-	-
	<i>Abnormal</i>	0(00)	0(00)		
<b>TOTALPROTEIN</b>	<i>Normal</i>	24(100)	25(100)	-	-
	<i>Abnormal</i>	0(00)	0(00)		
<b>ALBUMIN</b>	<i>Normal</i>	22(91.7)	25(100)	2.17	0.14
	<i>Abnormal</i>				
<b>GLOBULIN</b>	<i>Normal</i>	18(75)	20(80)	0.18	0.68
	<i>Abnormal</i>	6(250)	5(20)		

## VISIT-3

VARIABLES	NORMAL /ABNORMAL	GROUP-1	GROUP-2	X <sup>2</sup>	P-VALUE
<b>TOTALBILIRUBIN</b>	<i>Normal</i>	18(75 )	20(80 )	.16	0.68
	<i>Abnormal</i>	6(25 )	5( 20 )		
<b>DIRECTBILIRUBIN</b>	<i>Normal</i>	18(75 )	20(80 )	.16	0.68
	<i>Abnormal</i>	6(26 )	5(20 )		
<b>SGOT</b>	<i>Normal</i>	13(54 )	14(56 )	.02	0.90
	<i>Abnormal</i>	11(45.8 )	11(44 )		
<b>SGPT</b>	<i>Normal</i>	15(62.5 )	15(60 )	.03	0.86
	<i>Abnormal</i>	9(73.5 )	10(40 )		
<b>GGT</b>	<i>Normal</i>	16(66.7 )	18(72 )	.16	0.69
	<i>Abnormal</i>	8(33 )	7(28 )		
<b>ALP</b>	<i>Normal</i>	13(54 )	18(72 )	1.68	0.20
	<i>Abnormal</i>	11(45.8 )	7(28 )		
<b>PROTEIN</b>	<i>Normal</i>	24(100 )	25(100 )	-	-
	<i>Abnormal</i>	0(00 )	0(00 )		
<b>TOTALPROTEIN</b>	<i>Normal</i>	24(100 )	25( 100 )	-	-
	<i>Abnormal</i>	0( 00 )	0(00 )		
<b>ALBUMIN</b>	<i>Normal</i>	24(100 )	25(100 )	-	-
	<i>Abnormal</i>	0(00 )	0( 00 )		
<b>GLOBULIN</b>	<i>Normal</i>	18(75)	12(48)	3.76	0.05
	<i>Abnormal</i>	6(25)	13(5 2)		



**Table3: P-VALUE OF SYMPTOMS WITHIN THE GROUPS.**

VARIABLES		CHI-SQUARE	P-VALUE
<b>JAUNDICE</b>	GROUP-1 n=24	5.54	
	GROUP-2 n=25	10.29	<b>0.00*</b>
<b>FATIGUE</b>	GROUP-1 n=24	9.96	<b>0.01*</b>
	GROUP-2 n=25	20.67	<b>0.00*</b>
<b>ABDOMINAL PAIN</b>	GROUP-1 n=24	0.47	0.79
	GROUP-2 n=25	0.04	0.98
<b>LOSS OF APPETITE</b>	GROUP-1 n=24	6.0	<b>0.04*</b>
	GROUP-2 n=25	0.38	0.82
<b>NAUSEA/VOMITING</b>	GROUP-1 n=24	4.68	0.09
	GROUP-2 n=25	5.82	<b>0.05*</b>
<b>JOINT PAIN</b>	GROUP-1 n=24	0.67	0.71
	GROUP-2 n=25	0.28	0.66
<b>LIGHTENING OF STOOLS</b>	GROUP-1 n=24	5.64	0.06
	GROUP-2 n=25	0.200	9.80
<b>HEADACHE</b>	GROUP-1 n=24	5.38	0.06
	GROUP-2 n=25	9.81	<b>0.00*</b>
<b>PAIN BY THE SIDE OF LIVER</b>	GROUP-1 n=24	4.17	0.12
	GROUP-2 n=25	8.86	<b>0.02*</b>
<b>DARK URINE</b>	GROUP-1 n=24	1.31	0.50
	GROUP-2 n=25	8.77	<b>0.01*</b>
<b>MILD FEVER</b>	GROUP-1 n=24	0.40	0.81
	GROUP-2 n=25	0.80	0.67
<b>MALAISE</b>	GROUP-1 n=24	0.17	0.91
	GROUP-2 n=25	19.44	<b>0.00*</b>
<b>WEAK DIGESTION</b>	GROUP-1 n=24	6.26	<b>0.04*</b>
	GROUP-2 n=25	7.88	<b>0.01*</b>
<b>WEIGHT LOSS</b>	GROUP-1 n=24	2.28	0.32
	GROUP-2 n=25	1.44	0.48
<b>ABDOMINAL BLOATING</b>	GROUP-1 n=24	2.00	0.37
	GROUP-2 n=25	11.42	<b>0.00*</b>
<b>YELLOWISH-SKIN</b> (soles,palms)	GROUP-1 n=24	4.71	0.09
	GROUP-2 n=25	4.63	0.09
<b>YELLOW-SKIN</b> (temples,behind ears)	GROUP-1 n=24	1.52	0.46
	GROUP-2 n=25	2.00	0.36

TABLE 4: Baseline characteristics of patients in the GP-I and GP-II in regard of symptoms

BASELINE					
VARIABLES		GROUP-1	GROUP-2	CHI-SAQARE	P-VALUE
JAUNDICE	Yes	6(25 )	14(56 )	6.05	0.05
	No	16( 66.7)	8( 32)		
	Sometimes	2(8 )	3(2 )		
FATIGUE	Yes	1(45.8 )	16(64 )	1.64	0.44
	No	10( 41.7)	7( 28)		
	Sometimes	3(12.5 )	2(8 )		
ABDOMINA PAIN	Yes	5( 20.8)	4( 16)	.20	0.90
	No	13(54 )	14(56 )		
	Sometimes	6( 25)	7( 28)		
LOSS OF APPETITE	Yes	3(12.5 )	7(28 )	3.78	0.15
	No	18(75 )	12( 48)		
	Sometimes	3(12.5 )	6(24 )		
NAUSEA/VOMITTING	Yes	6(25 )	12(48 )	3.73	0.15
	No	14( 58)	8( 32)		
	Sometimes	4(16.7 )	5(20 )		
JOINT PAIN	Yes	( 16.7)	4( 16)	.01	0.99
	No	15(62.5 )	16(64 )		
	Sometimes	5( 20.8)	5( 20)		
LIGHTENING	Yes	2(8 )	4(16 )	2.10	0.35
	No	13( 54)	16( 64)		
	Sometimes	3(37.5 )	5(20 )		
HEADACHE	Yes	7(2 9 )	13( 52)	1.68	0.43
	No	11( 45.8)	3(12 )		
	Sometimes	6(25 )	9( 36)		
PAIN BY THE SIDE - OF LIVER	Yes	7(29 )	11(44 )	1.68	0.43
	No	14(58)	10(40 )		
	Sometimes	3(12.5)	4(16 )		
DARK URINE	Yes	2(8 )	2(8 )	3.36	0.19
	No	18( 75)	13( 52)		
	Sometimes	4(16.7 )	10(40 )		
MILD FEVER	Yes	2(8.33 )	3(12.5 )	2.56	0.28
	No	19( 79)	14( 58)		
	Sometimes	3(12.5 )	7(29 )		
MALAISE	Yes	6(25 )	15(60 )	7.09	0.03*
	No	9( 37.5)	7( 28)		
	Sometimes	9(37.5 )	3(12 )		
WEAK DIGESTION	Yes	6(25 )	8(32 )	4.87	0.09
	No	16( 66.7)	12( 48)		
	Sometimes	2(8 )	5(20 )		
WEIGHTLOSS	Yes	6(25)	8(32)	2.12	0.35
	No	16(66.7)	12(48)		
	Sometimes	2(8)	5(20)		
ABDOMINAL PAIN	Yes	5(20.8)	6(24)	.30	0.86
	No	16(66.7)	17(68)		
	Sometimes	3(12.5)	2(8)		
YELLOWISH-SKIN	Yes	6(25)	5(20)	8.62	0.01*
	No	12(50)	4(16)		

(at four centres of soles & palms)	Sometimes	6(25)	16(64)		
<b>YELLOWISH-SKIN</b> (temples & behind ears)	Yes	2(8)	0(0)		0.00*
	No	16(66.7)	25(100)	9.96	
	Sometimes	6(25)	0(0)		

Visit-II (follow-up after 3 Months) characteristics of patients in the GP-I and GP-II in regard of symptoms.

#### VISIT-2

VARIABLES		GROUP-1	GROUP-2	CHI-SQUARE	P-VALUE
<b>JAUNDICE</b>	Yes	1(4)	3(12)	1	0.60
	No	19(79)	18(72)		
	Sometimes	4(16.7)	4(16)		
<b>FATIGUE</b>	Yes	0(0)	1(4)	3.62	0.16
	No	20(83)	15(60)		
	Sometimes	4(16.7)	9(36)		
<b>ABDOMINAL PAIN</b>	Yes	21(80.5)	20(80)	.50	0.48
	No	3(12.5)	5(20)		
	Sometimes				
<b>LOSS OF APPETITE</b>	Yes	0(0)	1(4)	4.40	0.11
	No	17(70.8)	22(88)		
	Sometimes	7(29)	2(8)		
<b>NAUSEA/VOMITING</b>	Yes	1(4)	1(4)	1.24	0.54
	No	16(66.7)	20(80)		
	Sometimes	7(29)	4(16)		
<b>JOINT PAIN</b>	Yes	1(4)	0(0)	1.07	0.59
	No	21(87.5)	23(92)		
	Sometimes	2(8)	2(8)		
<b>LIGHTENING &amp; WHITISH OF STOOL</b>	Yes	0(0)	0(0)	.40	0.22
	No	22(91.7)	24(96)		
	Sometimes	2(8)	1(4)		
<b>HEADACHE</b>	Yes	0(0)	1(4)	3.07	0.22
	No	15(62.5)	10(40)		
	Sometimes	9(37.5)	14(56)		
<b>PAIN BY THE SIDE OF LIVER</b>	Yes	0(0)	0(0)	.50	0.48
	No	21(87.5)	20(80)		
	Sometimes	3(12.5)	5(20)		
<b>DARK URINE</b>	Yes	0(0)	0(0)	.00	0.98
	No	23(95.8)	24(80)		
	Sometimes	1(4)	1(4)		
<b>MILD FEVER</b>	Yes	0(0)	0(0)	2	0.16
	No	24(100)	23(92)		
	Sometimes	0(0)	2(8)		
<b>MALAISE</b>	Yes	1(4)	1(4)	1.11	0.57
	No	15(62.5)	12(48)		
	Sometimes	8(33)	12(48)		
	Yes	0(0)	0(0)		0.29

<b>WEAK DIGESTION</b>	No	16(66.7)	20(80)	1.11	
	Sometimes	8(33)	5(20)		
<b>WEIGHT LOSS</b>	Yes	4(17)	3(12)		0.13
	No	14(60.9)	21(84)	4.13	
	Sometimes	5(21.7)	21(84)		
<b>ABDOMINAL BLOATING</b>	Yes	2(8.7)	0(0)		0.14
	No	17(73.9)	16(64)	3.88	
	Sometimes	4(17)	9(36)		
<b>YELLOWISH -SKIN</b> (at four centres of soles & palm)	Yes	2(8)	2(8)		0.77
	No	10(41.7)	8(32)	.54	
	Sometimes	12(50)	15(60)		
<b>YELLOWISH-SKIN</b> (temples & behind ears)	Yes	0(0)	0(0)		0.07
	No	19(79)	24(96)	3.23	
	Sometimes	5(20.8)	1(4)		

Visit-III (follow-up after 6 Months) characteristics of patients in the GP-I and GP-II in regard of symptoms.

#### VISIT-3

VARIABLES		GROUP-1	GROUP-2	X <sup>2</sup>	P-VALUE
<b>JAUNDICE</b>	Yes	0(0)	1(4)		0.57
	No	19(79)	20(80)	1.12	
	Sometimes	5(20.8)	40(16)		
<b>FATIGUE</b>	Yes	0(0)	0(0)		0.17
	No	23(95.8)	21(84)	1.87	
	Sometimes	1(4)	4(16)		
<b>ABDOMINAL PAIN</b>	Yes	0(0)	0(0)		0.09
	No	23(95.8)	20(80)	2.86	
	Sometimes	1(4)	5(20)		
<b>LOSS OF APPETITE</b>	Yes	0(0)	0(0)		0.67
	No	22(91.7)	22(88)	.18	
	Sometimes	2(8)	3(12)		
<b>NAUSEA/VOMITING</b>	Yes	0(0)	0(0)		0.67
	No	22(91.7)	22(88)	.18	
	Sometimes	2(8)	3(12)		
<b>JOINT PAIN</b>	Yes	2(8)	1(4)		0.65
	No	20(83)	23(92)	.86	
	Sometimes	2(8)	1(4)		
<b>LIGHTENING OR WHITISH OF STOOLS</b>	Yes	0(0)	0(0)		0.30
	No	23(95.8)	25(100)	1.06	
	Sometimes	1(4)	0(0)		
<b>HEADACHE</b>	Yes	0(0)	0(0)		0.00*
	No	22(91.7)	13(52)	9.44	
	Sometimes	2(8)	12(48)		
<b>PAIN BY THE SIDE OF- LIVER</b>	Yes	0(0)	0(0)		0.32
	No	24(100)	24(96)	.98	
	Sometimes	0(0)	1(4)		

<b>DARK URINE</b>	Yes	0(0)	0(0)		-
	No	24(100)	25(100)	-	
	Sometimes	0(0)	0(0)		
<b>MILD FEVER</b>	Yes	0(0)	0(0)		-
	No	24(100)	23(92)	-	
	Sometimes	0(0)	2(8)		
<b>MALAISE</b>	Yes	0(0)	0(0)		0.66
	No	18(75)	20(80)	0.18	
	Sometimes	6(25)	5(20)		
<b>WEAK DIGESTION</b>	Yes	0(0)	0(0)		0.05
	No	18(75)	12(48)	3.76	
	Sometimes	6(25)	13(52)		
<b>WEIGHT LOSS</b>	Yes	2(8)	1(4)		0.69
	No	19(79)	22(88)	0.73	
	Sometimes	3(12.5)	2(8)		
<b>ABDOMINAL BLOATING</b>	Yes	0(0)	0(0)		<b>0.04*</b>
	No	22(91.7)	17(68)	4.22	
	Sometimes	2(8)	8(32)		
<b>YELLOWISH-SKIN</b> (at four centres of soles & palm)	Yes	1(4)	0(0)		0.58
	No	17(70.8)	19(76)	1.09	
	Sometimes	6(25)	6(24)		
<b>YELLOWISH-SKIN</b> (temples and behind ears)	Yes	0(0)	0(0)		0.14
	No	22(91.7)	25(100)	2.17	
	Sometimes	2(8)	0(0)		

**Table 5: Change in the pulse characteristic following the treatment with Tibetan Medicine .**

Variables	Group	0 Months	3 Months	6 Months
<b>Strong</b>	GP-I n=24	3	2	2
	GP-II n=25	5	1	1
<b>Overflowing</b>	GP-I n=24	5	4	2
	GP-II n=25	4	3	1
<b>Rolling</b>	GP-I n=24	9	6	3
	GP-II n=25	3	2	2
<b>Fast</b>	GP-I n=24	12	10	11
	GP-II n=25	15	9	12
<b>Taut</b>	GP-I n=24	8	2	4
	GP-II n=25	7	4	4
<b>Firm</b>	GP-I n=24	4	1	1
	GP-II n=25	2	0	1
<b>Weak</b>	GP-I n=24	4	8	8
	GP-II n=25	7	7	8
<b>Sunken</b>	GP-I n=24	2	2	2
	GP-II n=25	1	6	1

<b>Declining</b>	GP-I n=24	0	1	1
	GP-II n=25	1	1	0
<b>Slow</b>	GP-I n=24	1	3	0
	GP-II n=25	2	4	1
<b>Loose</b>	GP-I n=24	7	5	1
	GP-II n=25	6	9	3
<b>Empty</b>	GP-I n=24	6	2	1
	GP-II n=25	9	5	4

Note: GP-I = Group-1(The Specific Tibetan Medicine )  
n=24= Number of subjects (patients) in the group -I.  
GP-II= Group-2 (The Traditional Tibetan Medicine)  
n=25= Number of subjects in the group-II.

0 Month= baseline

3 Months= follow-up after 3 Months.

6 Months= follow-up after 6 Months.

**Table 6:Change in the urine colour characteristics following the treatment with Tibetan Medicine.**

<b>Variables</b>	<b>Group</b>	<b>0 Month</b>	<b>3 Months</b>	<b>6 Months</b>
<b>Whitish red</b>	GP-I n=24	2(8.33)	2(8.9)	1(4.17)
	GP-II n=25	1(4)	0(0)	1(4)
<b>Whitish yellow</b>	GP-I n=24	13(54.17)	13(56.52)	12(50)
	GP-II n=25	5(22)	7(28)	12(48)
<b>Yellow</b>	GP-I n=24	4(16.66)	1(4.35)	5(20.84)
	GP-II n=25	9(36)	6(24)	6(24)
<b>Yellowish red</b>	GP-I n=24	5(20.83)	3(13.04)	1(4.17)
	GP-II n=25	6(24)	10(40)	2(8)
<b>White</b>	GP-I n=24	0(0)	2(13.05)	5(20.8)
	GP-II n=25	1(4)	2(8)	4(16)
<b>Dark urine</b>	GP-I n=24	0(0)	1(4.35)	–
	GP-II n=25	3(12)	0(0)	–

**Table 7:change in the characteristics of Urine Bubbles following the treatment with Tibetan Medicine.**

Variables	Group	0 Month	3 Months	6 Months
Large	GP-I n=24	7(29.17)	4(16.66)	4(16.7)
	GP-II n=25	5(20.83)	4(16.67)	2(8)
Saliva-like	GP-I n=24	7(29.170)	5(20.83)	3(12.5)
	GP-II n=25	8(33.33)	8(33.33)	7(28)
Tiny	GP-I n=24	10(41.67)	15(62.5)	18(75)
	GP-II n=25	11(45.83)	12(50)	14(64)

**Table 8: Change in the characteristics of Urine Sediments with the treatment of Tibetan Medicine.**

Variables	Group	0 Month	3 Months	6 Months
Like-cotton	GP-I	2 subjects	1subject	0 subject
	GP-II	2 subjects	0 subject	0 subject
Like-hair	GP-I	1 subject	0 subject	0 subject
	GPII	2 subjects	2 subject	0 subject

**Table 9: Change in the scum characteristic following the treatment with Tibetan Medicine.**

Variables	Group	0 Month	3 Months	6 Months
Thick	GP-I	8(53.34)	24(30.77)	1(16.67)
	GP-II	10(45.45)	4(23.53)	1(14.29)
Thin	GP-I	7(60)	9(69.23)	5(83.27)
	GP-II	12(54.55)	13(76.47)	6(85.72)

**Table 10: mean value table of age, weight and blood pressure.**

VARIABLES	Group	0 Month	3 Months	6 Months
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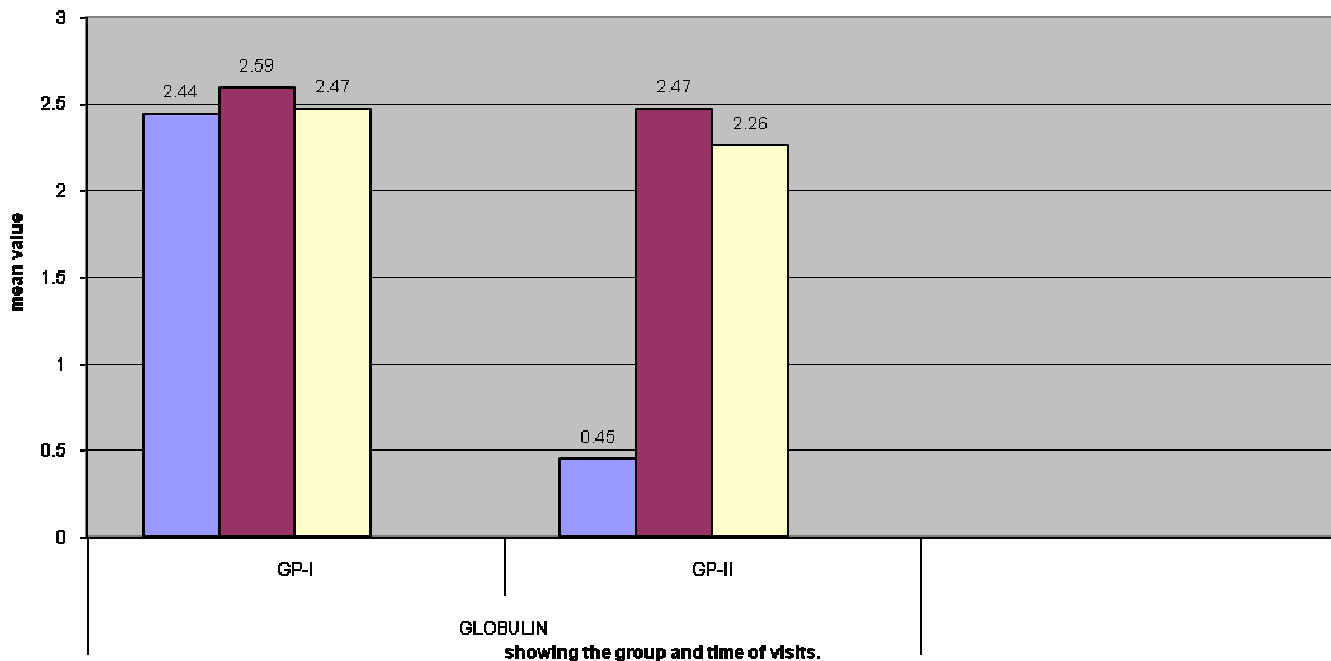
<b>Weight</b>	GROUP-1 N=24	83.2±102.8	60±16.5	57.3±21.2
	GROUP-2 N=25	63.1±12.8	61.6±12.8	62.5±12.6
	t-VALUE=	0.97	-0.35	-0.96
	P-VALUE	0.43	0.73	0.34
<b>B.Psystolic</b>	GROUP-1 N=24	111±10	116.1±14.6	114.6±11.8
	GROUP-2 N=25	108.6±8.96	110±12.7	109.4±10.9
	t-VALUE=	0.85	1.36	1.39
	P-VALUE	0.40	0.18	0.17
<b>B.Pdyasystolic</b>	GROUP-1 N=24	76.5±9.2	81±11	78±9
	GROUP-2 N=25	78±21	78±10.7	78.8±7.7
	t-VALUE=	-0.34	0.73	-0.21
	P-VALUE	0.74	0.47	0.83
<b>Age</b>	GROUP-1 N=24	29.5±17.6	–	–
	GROUP-2 N=25	28±11.8	–	–

**Table11: Number of subjects and % table of sex & marital status.**

VARIABLES		GROUP-I n=24	GROUP-II n=25	CHI-Square	P-Value
<b>Sex</b>	M	18(75)	18(72)	0.05	0.81
	F	6(25)	7(28)		
<b>Marital Status</b>	Married	6(25)	5(20)	0.17	0.67
	Single	18(75)	20(80)		



**graph 1: only Globulin was showing significant difference b/w the two groups in the visit-3.**



**Graph2: following L.F.T variables were showing significant difference within the group over the time period.**

