Results

Table 2 *(Percentage of male and female in studied cases)*

	N	%
male	680	63
female	400	37
Total	1080	100.0

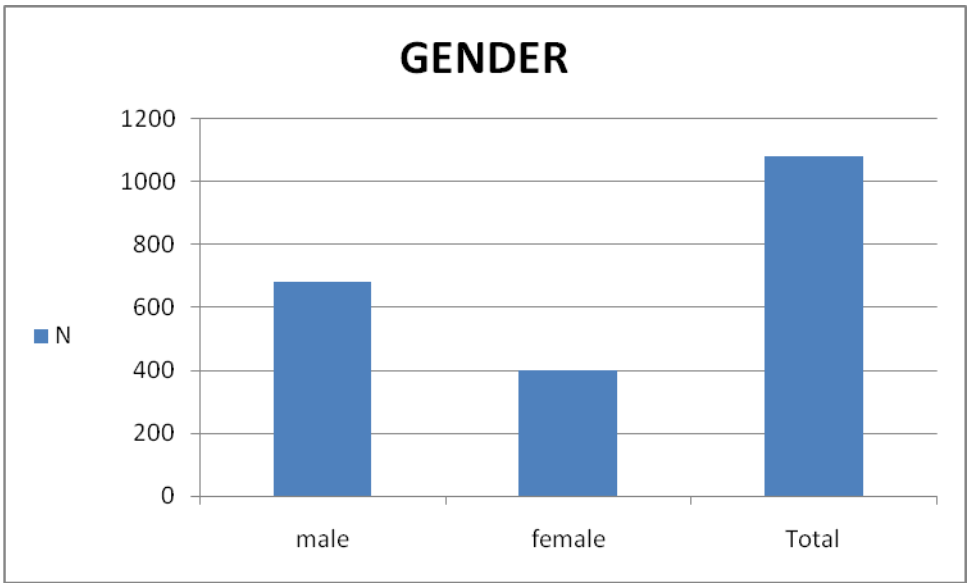


Figure 3*(Percentage of male and female in studied case)*

The study was conducted on 1080 patients, 680 males (63%) and 400 females (37% of patient population) as shown in table 2 and figure 3

Table 3*(Percentage of diabetics and non diabetics in studied case)*

	N	%
diabetic	113	10.5
non	967	89.5
Total	1080	100.0

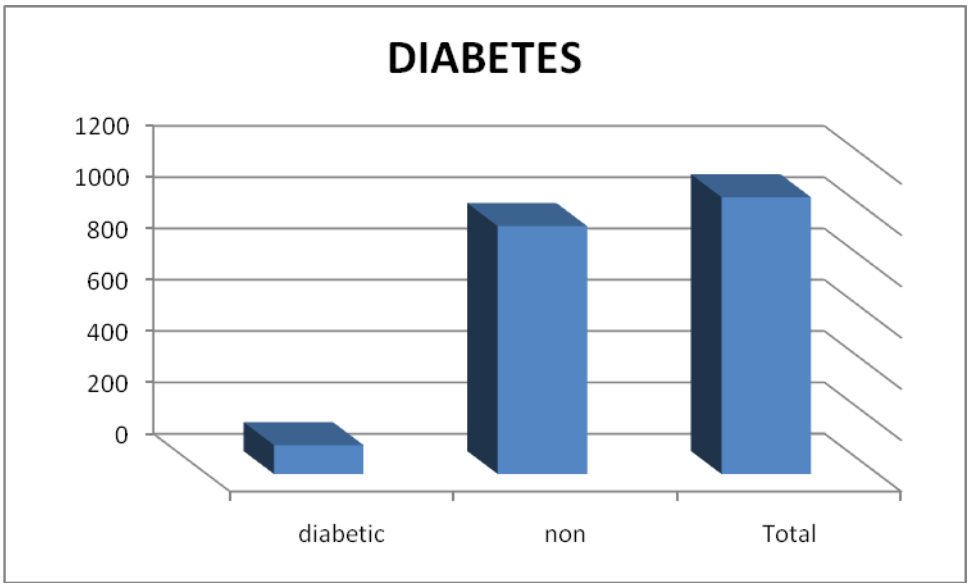


Figure 4*(Percentage of diabetics and non diabetics in studied case)*

113 patients were diabetics (10.5 %) and 967 were (89.5%) non diabetics as shown in table 3 and figure 4

Table 4*(characteristics in studied case)*

	Minimum	Maximum	Mean	Std. Deviation
Wt.	50	125	86.66	16.188
Age	19	60	40.47	8.911
Glucose	70.70	213	103.53	49.50
Creat	.70	1.7	1.14	7.726
Alb	3.50	5.1	4.66	2.737
AlkPh	20.60	413.95	178.07	88.11
AST	5.00	262	49.93	32.792
ALT	7.00	324	62.58	46.349
T.Bil	.50	4.0	.99	2.819
Hb	12	18.30	14.40	1.283
WBC	2800	11430	6444.74	1773.440
ANC	1757.2	7096.6	2693.70	1193.604
Plt*1000	151	380	208.38	62.967
PT/seconds	12.0	17.4	13.79	8.607
PCR	1040	6300.000	477.992	125.885
BMI	18.3	35	26.4	4.433

The mean age of patients was 40.47± 8.911 years.

The mean body mass index was 26.4 ± 4.433Kg/m^2.

The mean PCR was 477.992 copies/IU ±125.885.

The other laboratory findings are shown in table 4

Table 5 *(Percentage of fibrosis stage in studied case)*

STAGE	F1	F2	F3	F4	TOTAL
NO	146	527	272	135	1080
%	13.50601	48.75116	25.16189	12.58094	100

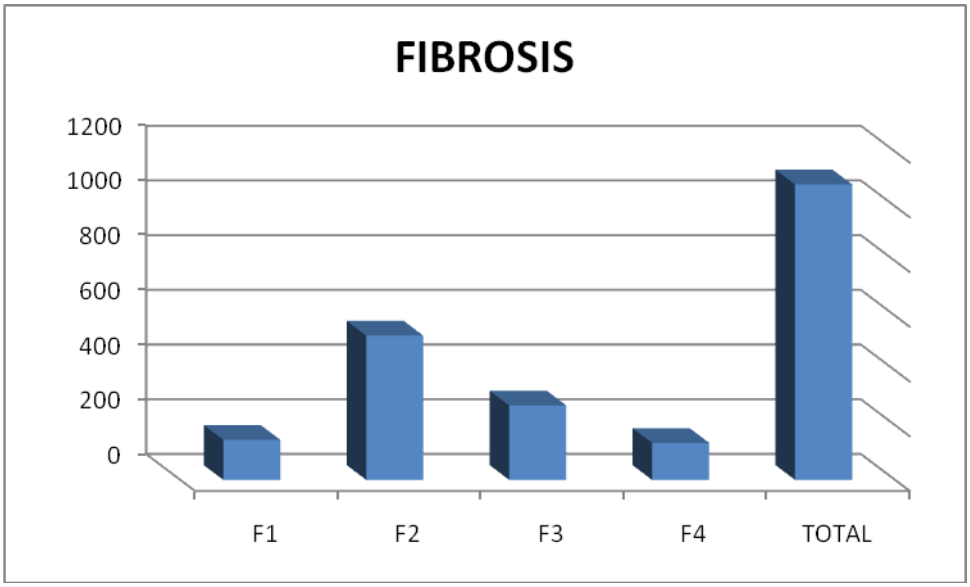


Figure 5 *(Percentage of fibrosis stage in studied case)*

Table 6 *(Percentage of activity stage in studied case)*

STAGE	A1	A2	A3	TOTAL
NO	479	455	146	1080
%	44.31082	42.09066	13.59852	100

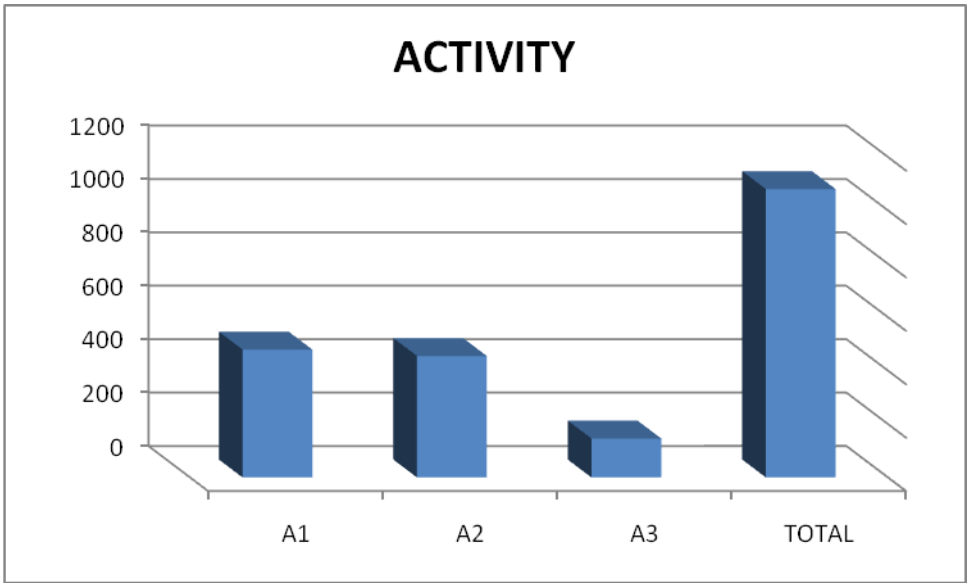


Figure 6 *(Percentage of activity stage in studied case)*

Histopathological evaluation was done for histological activity index, grade of fibrosis and the results are shown in table 5and 6 and figure 5 and 6.

Response over weeks:

Table 7 (Response of group 1 all over weeks)

GROUP 1	536								
WEEK	12			24		48		72	
RESULT	NEG	2 LOG	POS	NEG	POS	NEG	POS	NEG	POS
	368(68.6%)	77(14.4%)							
NO(%)	445(83%)		91(17%)	371(69%)	74(13%)	338(63%)	33(6%)	310(58%)	28(5%)

patients of group 1 had the following results shown in table 7:

Out of 536 patients 368 cases (68.6%) had cleared HCV from their blood and had negative PCR by 12th week (early virological response) and 77 cases (14.4%) had decreased virus level more than 2 logs and 91 cases (17%) couldn't clear virus from their blood (non responder).

Out of 445 patients who completed course to 24th week 371 cases (69% of total cases) had cleared HCV from their blood (late virological response) and 74 cases (13% of total cases) couldn't clear virus from their blood (non responder).

Out of 371 of patients who completed course to 48th week 338 cases (63% of total cases) had cleared HCV from their blood (end

treatment response) and 33 cases (6% of total cases) couldn't clear virus from their blood (non responder).

Out of 338 of patients who completed course to 48th week 310 cases (58% of total cases) had cleared HCV from their blood (sustained virological response) and 28 cases (5% of total cases) had regained the HCV again (relapse).

Table 8(Response of group 2all over weeks)

GROUP 2	544								
WEEK	12			24		48		72	
RESULT	NEG	2 LOG	POS	NEG	POS	NEG	POS	NEG	POS
	367(67.4%)	45(8.2%)							
NO(%)	412(75%)		132(25%)	316(58%)	96(17.6%)	268(49%)	48(8.8%)	250(46%)	18(3.3%)

patients of group 2 had the following results shown in table 8:

Out of 544 patients 367 cases (67.4%) had cleared HCV from their blood and had negative PCR by 12th week (early virological response) and 45 cases (8.2%) had decreased virus level more than 2 logs and 132 cases (25%) couldn't clear virus from their blood (non responder).

Out of 412 patients who completed course to 24th week 316 cases (58% of total cases) had cleared HCV from their blood (late virological response) and 96 cases (17.6% of total cases) couldn't clear virus from their blood (non responder).

Out of 316 patients who completed course to 48th week 268 cases (49% of total cases) had cleared HCV from their blood (end treatment response) and 48 cases (8.8% of total cases) couldn't clear virus from their blood (non responder).

Out of 268 patients who completed course to 48th week 250 cases (46% of total cases) had cleared HCV from their blood (sustained virological response) and 18 cases (3.3% of total cases) had regained the HCV again (relapse).

Table 9(response of both groups all over the weeks of therapy)

group 1	WEEK	12			24		48		72	
	RESULT	NEG	2 LOG	POS	NEG	POS	NEG	POS	NEG	POS
		368	77							
	%	83		17	69	13	63	6	58	5
group 2	RESULT	NEG	2 LOG	POS	NEG	POS	NEG	POS	NEG	POS
		367	45							
	%	75		25	58	17.6	49	8.8	46	3.3
p value		0.001*			0.002*		0.001*		0.001*	

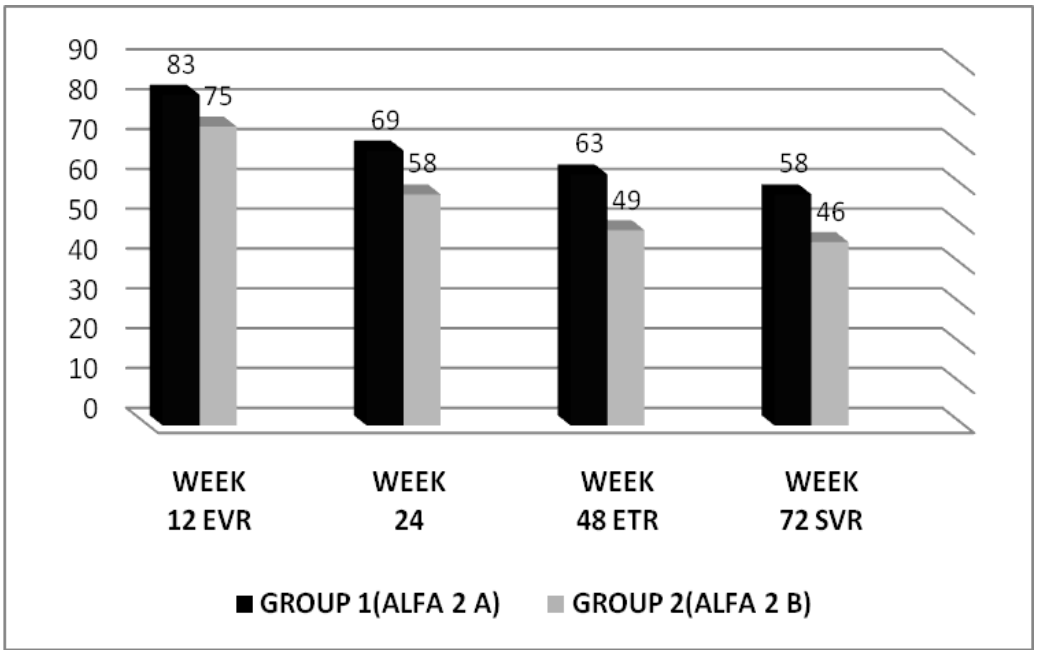


Figure 7*(*response of both groups all over the weeks of therapy*)*

As shown in table 9 and figure 7, Peg interferon alfa-2a (group 1) was more effective than Peg interferon alfa-2b (group 2) and there is a significant difference in response between two groups in week 12,24,48 and 72.

Hematological side effects

1-Anemia

A: Group 1

Table 10 (Mean hemoglobin changes during 48 weeks of therapy in group 1)

HB	MINIUM	MAXIMUM	MEAN	ST DEVIATION
W0	**12**	**18.30**	**14.40**	**1.283**
W1	**11.8**	**17.30**	**13.70**	**1.675**
W2	7.50	17.10	12.30	1.57
W4	8.10	16.20	11.28	1.44
W8	7.20	15.00	11.18	1.35
W12	6.30	15.80	10.80	1.48
W16	6.40	15.80	10.94	1.57
W20	5.40	17.60	10.53	1.84
W24	5.30	15.40	10.52	1.98
W28	5.60	12.30	11.26	11.57
W32	5.50	12.10	11.03	11.43
W36	5.40	12.00	9.62	5.89
W40	7.60	11.95	10.96	5.80
W44	7.10	11.85	10.69	5.747
W48	8.00	11.84	11.33	5.779

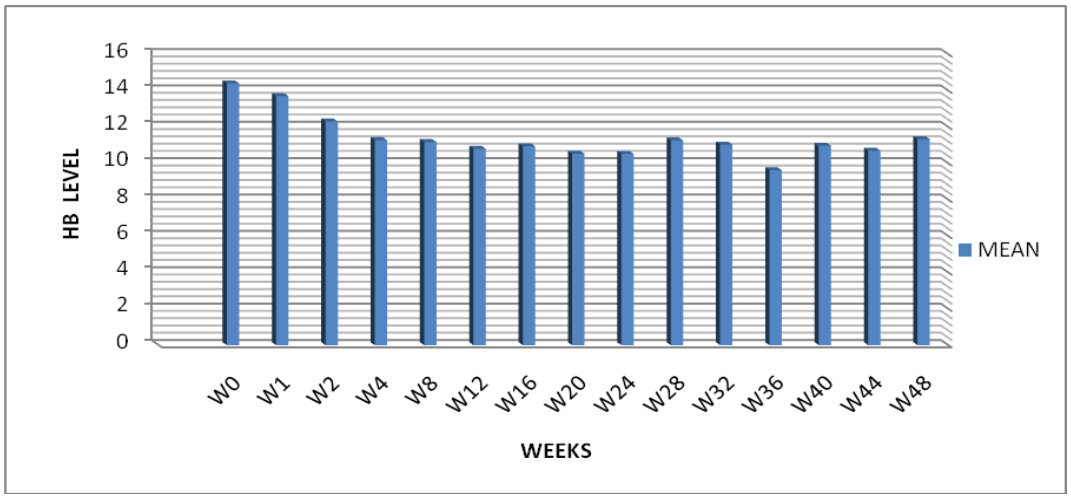


Figure 8(Mean hemoglobin changes during 48 weeks of therapy in group 1)

As shown in table 10 and figure 8 the mean hemoglobin level is decreased about 3.16 mg/dl in the first 4 weeks and then stabilize around a low level (about 10.5 ± 0.8) allover the period of therapy.

Table 11 (Incidence of developing mild ,moderate and severe anemia in group 1)

GROUP 1						
HB	RESPONDER 311		NON RESPONDER 225		TOTAL 536		
	NO	%	NO	%	NO	%	
NORMAL >12 mg/dl	171(55%)		85(37.8%)		256(47.8%)		p value
							0.006*
MILD 10-12 mg/dl	80(25.7%)		67(29.8%)		147(27.4%)		p value
							0.356
MODERATE 10-8.5 mg/dl	40(12.9%)		44(19.6%)		84(15.7%)		p value
							0.132*
SEVERE <8.5 mg/dl	20(6.4%)		29(12.9%)		49(9.1%)		p value
							0.009*

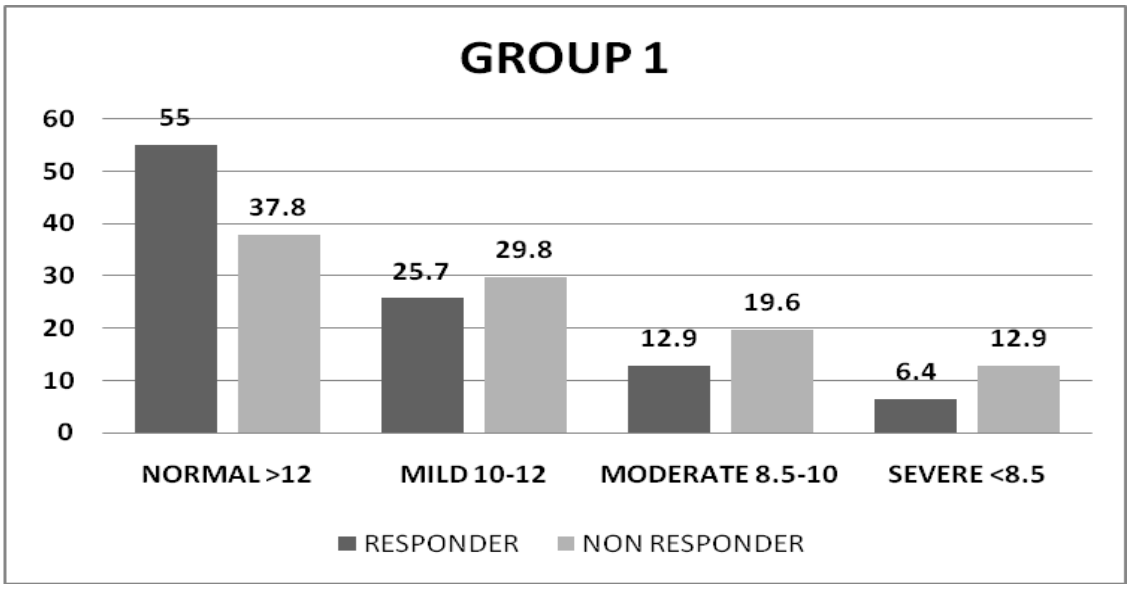


Figure 9(Incidence of developing mild ,moderate and severe anemia in group 1)

As shown in table 11 and figure 9,

256 of all 536 patients (47.8%) did not had anemia (hemoglobin level above 12 mg/dl) during course of treatment 171 responder patients (55%) and non responder patients (37.8%) .

147 of all 536 patients (27.4%) had mild anemia (hemoglobin level below 12 and above 10 mg/dl) during course of treatment 80 responder patients (25.7%) and 67 non responder patients (29.8%) .

84 of all 536 patients (15.7%) had moderate anemia (hemoglobin level below 10 and above 8.5 mg/dl) during course of treatment 40 responder patients (12.9%) and 44 non responder patients (19.6%) .
This moderate anemia had led to modification of the dose (decrease recommended Ribavirin dose by 200 mg)

49 of all 536 patients (9.1%) had severe anemia (hemoglobin level below 8.5 mg/dl) during course of treatment 20 responder patients (6.4%) and 29 non responder patients (12.9%) .
This severe anemia had led to stoppage of the dose .

B:Group 2

Table 12 (Mean hemoglobin changes during 48 weeks of therapy in group 2)

HB	MINIUM	MAXIMUM	MEAN	ST DEVIATION
W0	**12.34**	**17.97**	**14.07**	**0.953**
W1	**11.47**	**16.97**	**13.37**	**1.345**
W2	7.17	16.77	11.97	1.24
W4	7.77	15.87	10.95	1.11
W8	6.87	14.67	10.85	1.02
W12	5.97	15.47	10.47	1.15
W16	6.07	15.47	10.61	1.24
W20	5.07	17.27	10.2	1.51
W24	4.97	15.07	10.19	1.65
W28	5.27	12.27	10.93	11.24
W32	5.17	12.07	10.7	11.1
W36	5.07	11.97	9.29	5.56
W40	7.27	11.92	10.63	5.47
W44	6.77	11.82	10.36	5.417
W48	7.67	11.81	11	5.449

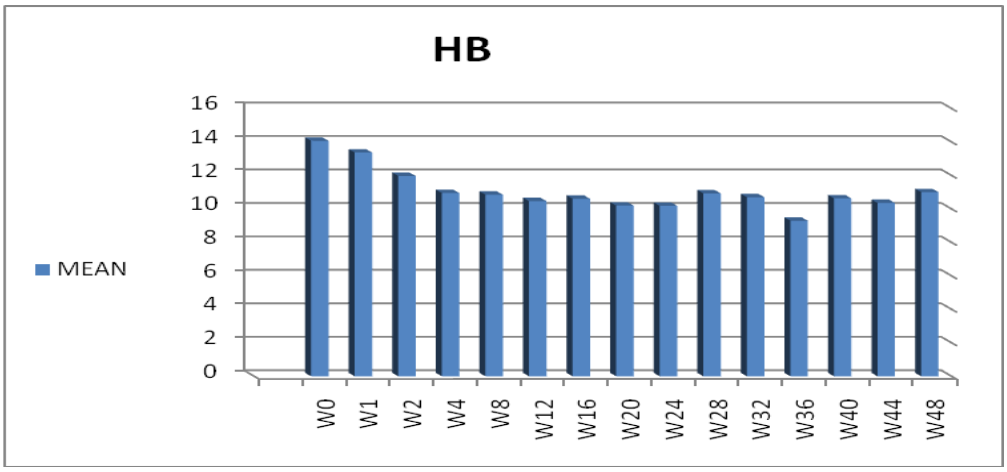


Figure 10 (Mean hemoglobin changes during 48 weeks of therapy in group 2)

As shown in table 12 and figure 10 the mean hemoglobin level is decreased about 3.12mg/dl in the first 4 weeks and then stabilize around a low level (about 10.5 ± 0.4) allover the period of therapy.

Table 13(Incidence of developing mild ,moderate and severe anemia in group 2)

GROUP 2						
HB	RESPONDER 252		NON RESPONDER 292		TOTAL 544	
	NO	%	NO	%	NO	%	
NORMAL >12 mg/dl	143(56.7%)		114(39%)		257(47.2%)	p value 0.003*
MILD 10-12 mg/dl	68(27%)		96(32.9%)		164(30.1%)	p value 0.262
MODERATE 10-8.5 mg/dl	31(12.3%)		53(18.2%)		84(15.4%)	p value 0.343
SEVERE <8.5 mg/dl	10(4%)		29(9.9%)		39(7.2%)	p value 0.004*

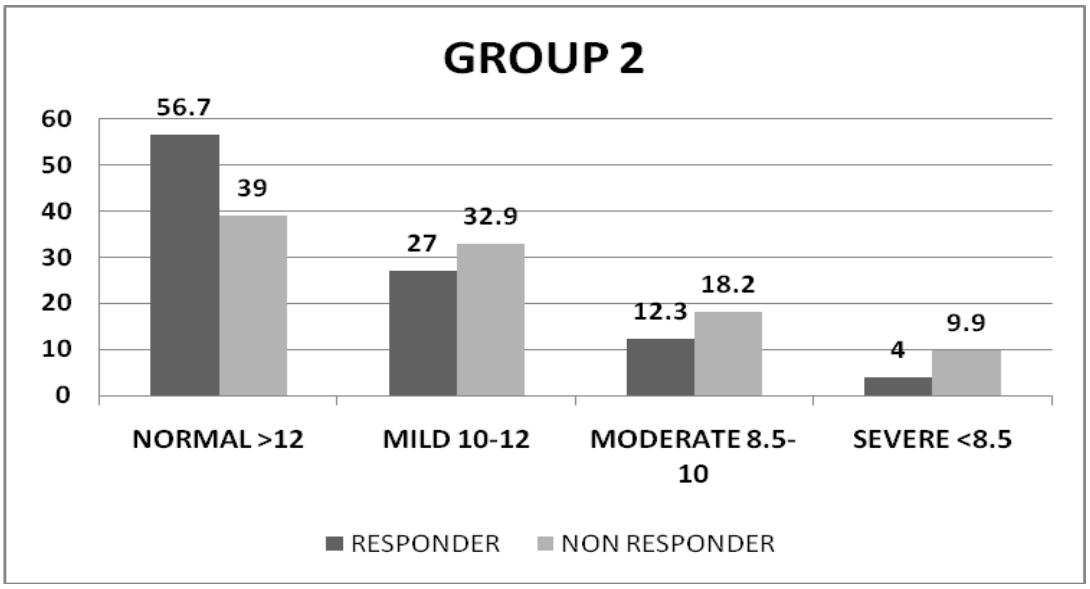


Figure 11(Incidence of developing mild ,moderate and severe anemia in group 2)

As shown in table13 and figure 11,

257 of all 544 patients (47.2%) did not had anemia (hemoglobin level above 12 mg/dl) during course of treatment 143 responder patients (56.7 %) and 114 non responder patients (39%) .

164 of all 544 patients (30.1%) had mild anemia (hemoglobin level below 12 and above 10 mg/dl) during course of treatment 68 responder patients (27 %) and 96 non responder patients (32.9%) .

84 of all 544 patients (15.4%) had moderate anemia (hemoglobin level below 10 and above 8.5 mg/dl) during course of treatment 31 responder patients (12.3%) and 53 non responder patients (18.2%) .
This moderate anemia had led to modification of the dose (decrease recommended Ribavirin dose by 200 mg)

39 of all 544 patients (7.2%) had severe anemia (hemoglobin level below 8.5 mg/dl) during course of treatment 10 responder patients (4 %) and 29 non responder patients (9.9%) .
This severe anemia had led to stoppage of the dose .

2-Neutropenia

A: Group 1

Table 14 (Mean neutrophilic count changes during 48 weeks of therapy in group 1)

ANC	MINIMUM	MAXIMUM	MEAN	ST DEVIATION
W0	1753.90	8485	3608.07	915.02
W1	436	6580	3011	814.52
W2	600.00	7544.00	2546.47	772.167
W4	382.50	4413.00	1920.16	595.963
W8	339.40	5878.50	1887.46	647.866
W12	260.90	5045.80	1760.13	633.702
W16	187.20	4380.00	1329.56	650.332
W20	325.80	3957.40	1403.72	774.053
W24	137.20	6020.00	1510.89	856.324
W28	315.00	5820.00	1496.61	824.758
W32	270.00	5620.00	1528.12	838.613
W36	170.00	5000.00	1444.71	799.407
W40	270.00	8200.00	1454.12	985.045
W44	300.00	9046.00	1411.27	1041.714
W48	310.00	8876.00	1535.70	1156.017

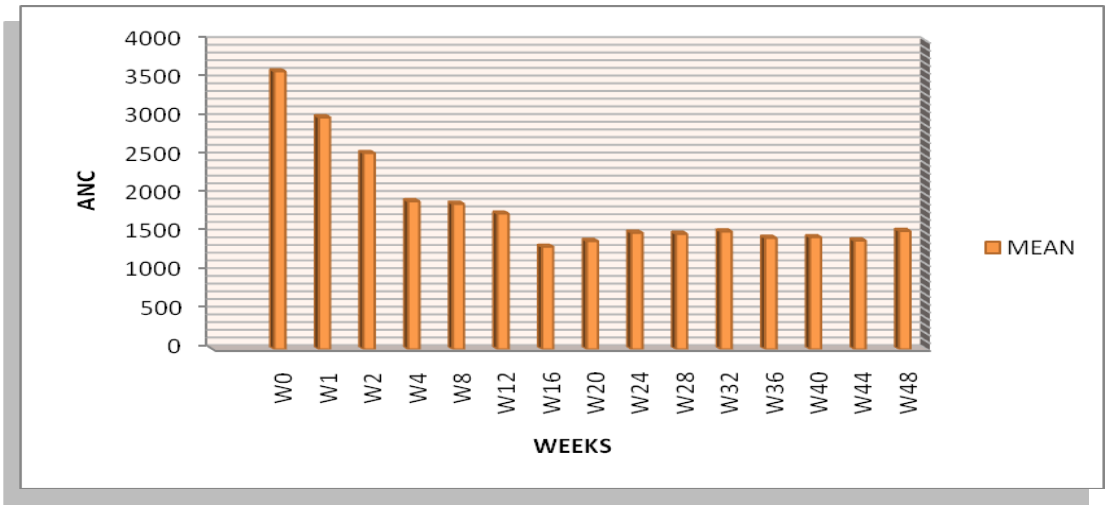


Figure 12 (Mean neutrophilic count changes during 48 weeks of therapy in group 1)

As shown in table 14 and figure 12 the mean absolute neutrophilic count is dropped about 30% of the basal value in the first 4 weeks and then stabilize around a low level (about 1900.5 ± 600) all over the period of therapy.

Table 15 (Incidence of developing mild ,moderate and severe neutropenia in group 1)

GROUP 1						
ANC	**RESPONDER 311**		**NON RESPONDER 225**		**TOTAL 536**	
	NO	**%**	**NO**	**%**	**NO**	**%**	
NORMAL >1500/mm3.	**150(48.2%)**		**88(39.1%)**		**238(44.4%)**		**p value**
							0.011*
MILD 1500-750/mm3.	**93(29.9%)**		**74(32.9%)**		**167(31.2%)**		**p value**
							0.402
MODERATE 750-500/mm3.	**56(12.3%)**		**50(22.2%)**		**106(19.8%)**		**p value**
							0.067
SEVERE <500/mm3.	**12(3.9%)**		**13(5.8%)**		**25(4.7%)**		**p value**
							0.239

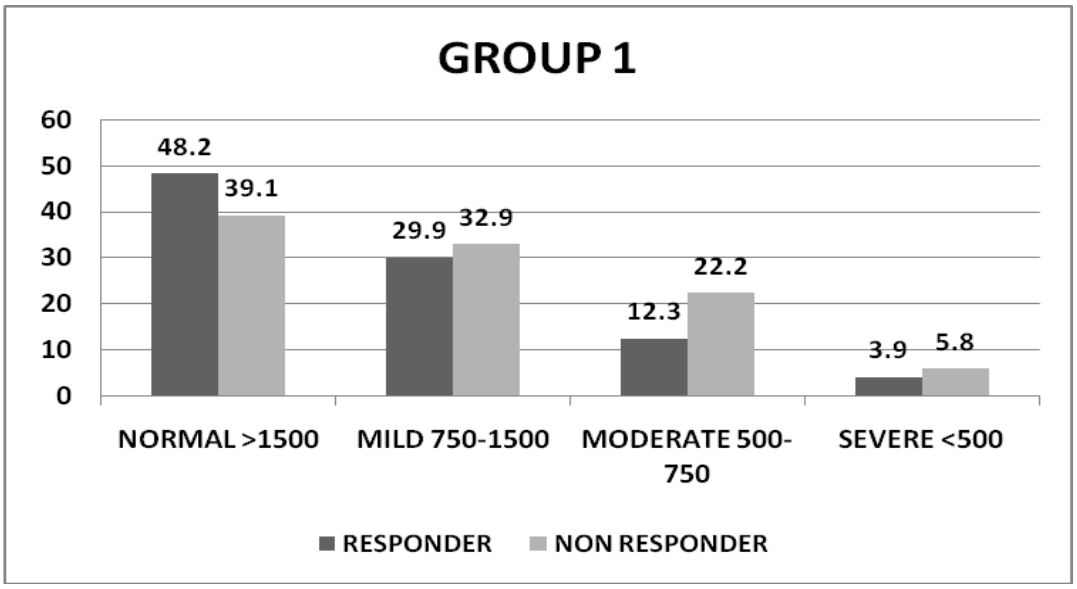


Figure 13(Incidence of developing mild ,moderate and severe neutropenia in group 1)

As shown in table 15 and Figure 13,

238 of all 536 patients (44.4%) did not had neutropenia (ANC above 1500 /mm^3) during course of treatment 150 of the 311 responder patients (48.2%) and 88 non responder patients (39.9%) .

167 of all 536 patients (31.2%) had mild neutropenia (ANC above 7500 /mm^3 and below 1500 /mm^3) during course of treatment 93 responder patients (29.9%) and 74 non responder patients (32.9%) .

106 of all 536 patients (19.8%) had moderate neutropenia (ANC above 500 /mm^3 and below 750 /mm^3) during course of treatment 56 responder patients (12.3%) and 50 non responder patients (22.2%) .
This moderate neutropenia had led to modification of the dose (decrease recommended interferon dose by the half)

25 of all 536 patients (4.7%) had severe neutropenia (ANC below 500 /mm^3) during course of treatment 12 responder patients (3.9%) and 13 non responder patients (5.8%) .
This severe neutropenia had led to stoppage of the interferon dose .

B:Group 2

Table 16 (Mean neutrophilic count changes during 48 weeks of therapy in group 2)

ANC	MINIMUM	MAXIMUM	MEAN	ST DEVIATION
W0	1777	8508	3631	938
W1	459	6603	3034	837.5
W2	623	7567	2569.47	795.167
W4	405.5	4436	1943.16	618.963
W8	362.4	5901.5	1910.46	670.866
W12	283.9	5068.8	1783.13	656.702
W16	210.2	4403	1352.56	673.332
W20	348.8	3980.4	1426.72	797.053
W24	160.2	6043	1533.89	879.324
W28	338	5843	1519.61	847.758
W32	293	5643	1551.12	861.613
W36	193	5023	1467.71	822.407
W40	293	8223	1477.12	1008.045
W44	323	9069	1434.27	1064.714
W48	333	8899	1558.7	1179.017

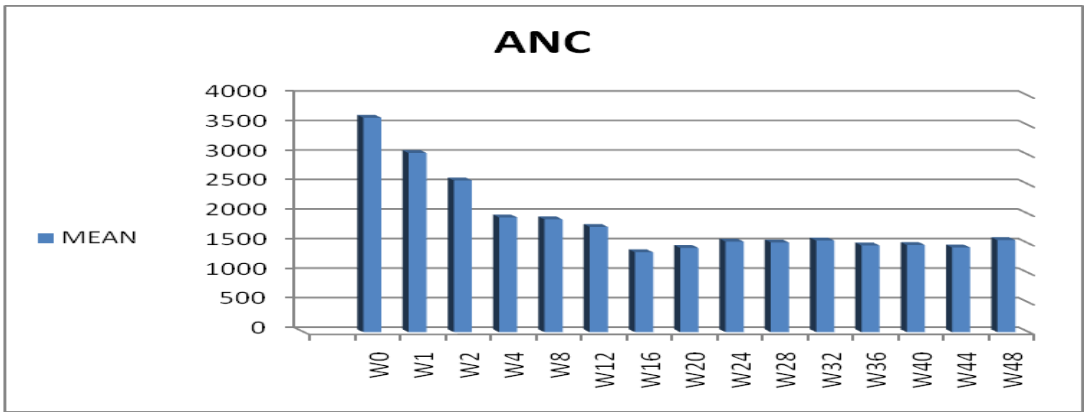


Figure 14 (Mean neutrophilic count changes during 48 weeks of therapy in group 2)

As shown in table 16 and figure 14 the mean absolute neutrophilic count is dropped about 35% of the basal value in the first 4 weeks and then stabilize around a low level (about 1800.5 ± 700) all over the period of therapy.

Table 17 (Incidence of developing mild ,moderate and severe neutropenia in group 2)

GROUP 2						
ANC	**RESPONDER 252**		**NON RESPONDER 292**		**TOTAL 544**	
	NO	**%**	**NO**	**%**	**NO**	**%**	
NORMAL >1500/mm3.	**116(46%)**		**114(39%)**		**230(42.3%)**		**p value**
							0.173
MILD 1500-750/mm3.	**78(31%)**		**108(27%)**		**186(34.2%)**		**p value**
							0.333
MODERATE 750-500/mm3.	**48(19%)**		**50(17.1%)**		**98(18%)**		**p value**
							0.492
SEVERE <500/mm3.	**10(4%)**		**20(6.8%)**		**30(5.5%)**		**p value**
							0.302

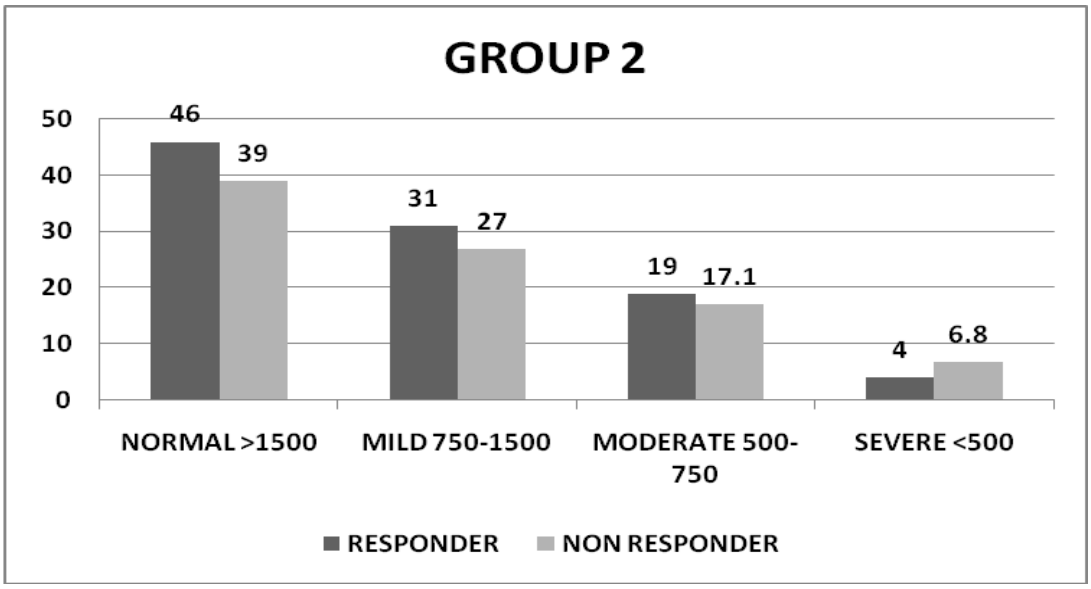


Figure 15(Incidence of developing mild ,moderate and severe neutropenia in group 2)

As shown in table 17 and Figure 15,

230 of all 544 patients (42.3%) did not had neutropenia (ANC above 1500 /mm^3)during course of treatment 116 responder patients (46 %) and 114 non responder patients (39%) .

186of all 544 patients (34.2%) had mild neutropenia (ANC above 7500 /mm^3 and below 1500 /mm^3) during course of treatment 78 responder patients (31 %) and 108 non responder patients (27%) .

98 of all 544 patients (18%) had moderate neutropenia (ANC above 500 /mm^3 and below 750 /mm^3) during course of treatment 48 responder patients (19%) and 50 non responder patients (17.%) .
This moderate neutropenia had led to modification of the dose (decrease recommended interferon dose by the half)

30 of all 544 patients (5.5%) had severe neutropenia (ANC below 500 /mm^3) during course of treatment 10 responder patients (4 %) and 20 non responder patients (6.8%) .
This severe neutropenia had led to stoppage of the interferon dose .

3-Thrombocytopenia

A: Group 1

Table 18(Mean platelets count changes during 48 weeks of therapy in group 1)

PLATELETS	MINIMUM	MAXIMUM	MEAN	ST DEVIATION
W0	151	380	288.38	62.967
W1	75.00	300.0	243	135
W2	57.00	316.00	217.64	72.915
W4	44.00	312.00	199.51	65.245
W8	34.00	392.50	163.90	55.179
W12	33.50	474.30	161.98	55.829
W16	22.40	493.00	146.96	57.928
W20	19.00	260.00	135.48	129.604
W24	33.00	306.00	121.8	53.424
W28	30.00	290.00	119.81	47.784
W32	18.00	221.00	126.48	162.322
W36	26.00	216.00	118.07	161.568
W40	36.00	389.00	121.88	63.048
W44	46.00	415.00	136.22	63.809
W48	55.00	383.00	142.66	66.628

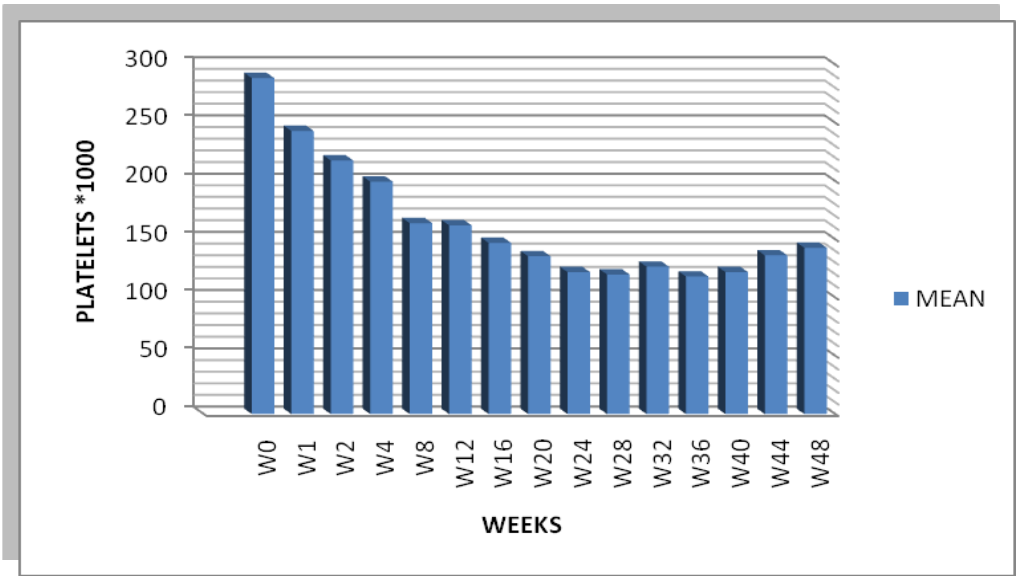


Figure 16 (Mean platelets count changes during 48 weeks of therapy in group 1)

As shown in table 18 and figure 16 the mean platelets count is dropped about 27% of the basal value in the first 4 weeks and then stabilize around a low level (about 120.000 ± 30.000) all over the period of therapy.

Table 19 (Incidence of developing mild ,moderate and severe thrombocytopenia in group 1)

GROUP 1						
platelets	**RESPONDER 311**		**NON RESPONDER 225**		**TOTAL 536**	
	NO	**%**	**NO**	**%**	**NO**	**%**	
NORMAL >150.000/mm3.	**198(64%)**		**120(53%)**		**318(59.3%)**		**p value 0.048***
MILD 150.000-50.000/mm3.	**103(32.7%)**		**89(40%)**		**192(35.8%)**		**p value 0.156**
moderate <50.000/mm3.	**7(2.3%)**		**12(5.3%)**		**19(3.6%)**		**p value 0.074**
Severe <25.000/mm3.	**3(1%)**		**4(1.7%)**		**7(1.3%)**		**p value 0.427**

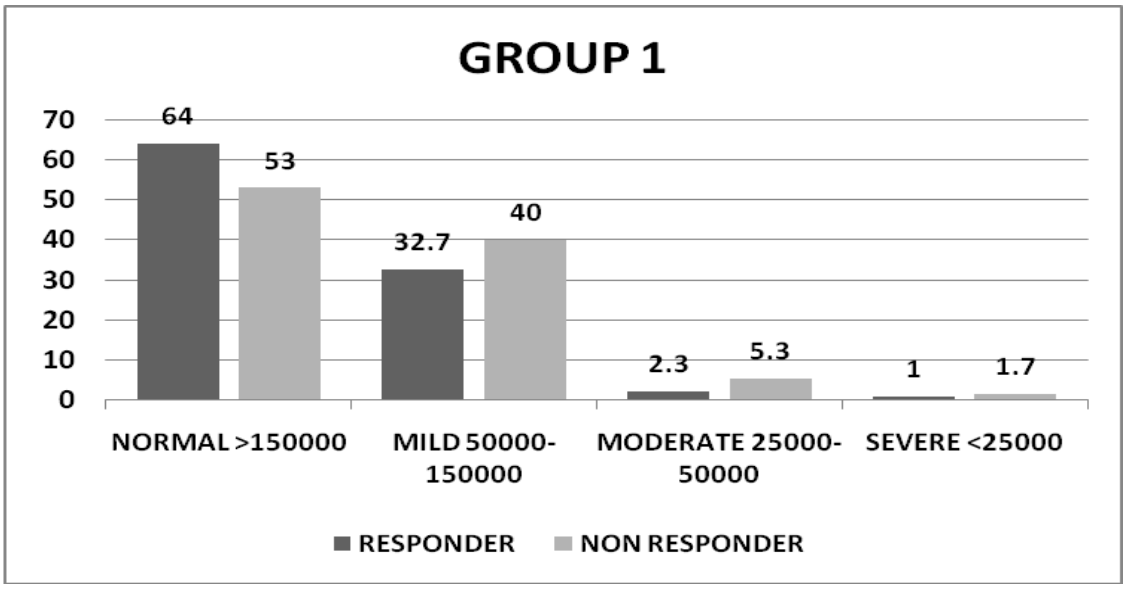


Figure 17 (Incidence of developing mild ,moderate and severe thrombocytopenia in group 1)

As shown in table 19 and Figure 17,

318 of all 536 patients (64%) did not had thrombocytopenia (platelets above 150.000 /mm^3) during course of treatment 198 of the 311 responder patients (64%) and 120 non responder patients (53%) .

192 of all 536 patients (35.8%) had mild thrombocytopenia (platelets above 50000 /mm^3 and below 150.000 /mm^3) during course of treatment 103 responder patients (32.7%) and 192 non responder patients (35.8%).

19of all 536 patients (3.6%) had moderate thrombocytopenia (platelets above 25000 /mm^3 and below 50000 /mm^3) during course of treatment 7 responder patients (2.3%) and 12 non responder patients (5.3%) .
This moderate thrombocytopenia had led to modification of interferon dose (decrease recommended interferon dose by the half)

7of all 536 patients (1.3%) had severe thrombocytopenia (platelets below 25000 /mm^3) during course of treatment 3 responder patients (1%) and 4 non responder patients (1.3%) .
This severe thrombocytopenia had led to stoppage of the interferon therapy.

B: Group 2

Table 20 (Mean platelets count changes during 48 weeks of therapy in group 2)

PLATELETS	MINIMUM	MAXIMUM	MEAN	ST DEVIATION
W0	158	387	295.4	69.97
W1	82	300.7	250	142
W2	64	317.3	224.64	79.915
W4	51	313.6	206.51	72.245
W8	41	399.5	170.9	62.179
W12	40.5	481.3	168.98	62.829
W16	29.4	500	153.96	64.928
W20	26	260.7	142.48	136.604
W24	40	313	128.8	60.424
W28	37	297	126.81	54.784
W32	25	221.8	133.48	169.322
W36	33	216.8	125.07	168.568
W40	43	396	128.88	70.048
W44	53	422	143.22	70.809
W48	62	390	149.66	73.628

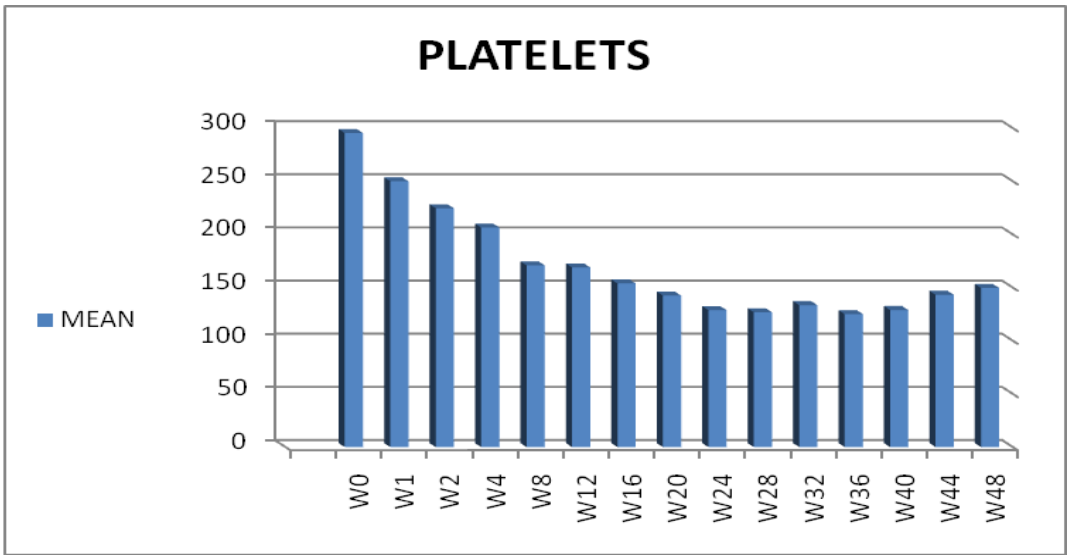


Figure 18 (Mean platelets count changes during 48 weeks of therapy in group 2)

As shown in table 20 and figure 18 the mean platelets count is dropped about 25% of the basal value in the first 4 weeks and then stabilize around a low level (about 130.000 ± 20.000) all over the period of therapy.

Table 21 (Incidence of developing mild ,moderate and severe thrombocytopenia in group 2)

GROUP 2						
platelets	**RESPONDER 252**		**NON RESPONDER 292**		**TOTAL 544**	
	NO	**%**	**NO**	**%**	**NO**	**%**	
NORMAL >150.000/mm3.	**166(65.8%)**		**163(55.8%)**		**329(60.4%)**		**p value 0.062**
MILD 150.000-50.000/mm3.	**76(30.2%)**		**107(36.7%)**		**183(33.7%)**		**p value 0.482**
moderate <50.000/mm3.	**7(2.8%)**		**17(5.8%)**		**24(4.4%)**		**p value 0.078**
Severe <25.000/mm3.	**3(1.2%)**		**5(1.7%)**		**8(1.5%)**		**p value 0.415**

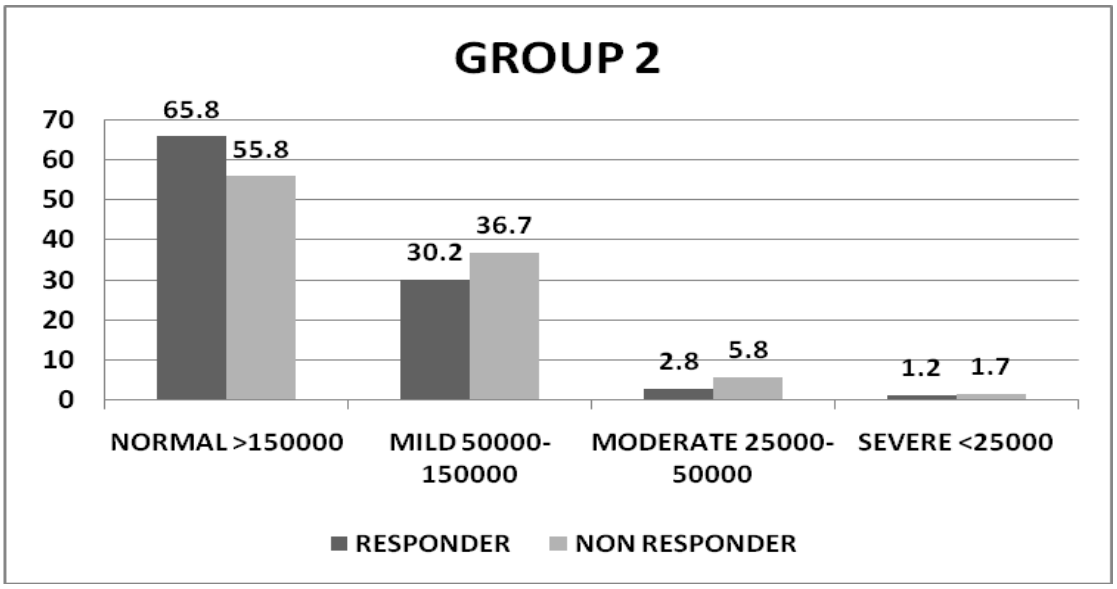


Figure 19 (Incidence of developing mild ,moderate and severe thrombocytopenia in group 2)

As shown in table 21 and Figure 19,

329 of all 544 patients (60.4%) did not had thrombocytopenia (platelets above 150.000 /mm^3) during course of treatment 166 responder patients (65.8%) and163 non responder patients (55.8%) .

183 of all 544patients (36.7%) had mild thrombocytopenia (platelets above 50000 /mm^3 and below 150.000 /mm^3) during course of treatment 76 responder patients (30.2%) and 107 non responder patients (36.7%) .

24 of all 544 patients (4.4%) had moderate thrombocytopenia (platelets above 25000 /mm^3 and below 50000 /mm^3) during course of treatment 7 responder patients (2.8%) and 17 non responder patients (5.8%) .
This moderate thrombocytopenia had led to modification of the dose (decrease recommended interferon dose by the half)

8 of all 544 patients (1.5%) had severe thrombocytopenia (platelets below 25000 /mm^3) during course of treatment 3 responder patients (1.2%) and 5 non responder patients (1.7%) .
This severe thrombocytopenia had led to stoppage of the interferon therapy.

Effect of cumulative ribavirin dose exposure as an impact of anemia on different type of response.

1-Early virological response:

A: Group 1

Table 22 (EVR according to different Ribavirin dose in group 1)

GROUP 1	WEEK 12					
	>90% Of RBV dose		70-90% Of RBV dose		<70% Of RBV dose	
	n	%	n	%	n	%
Total	493.0		32.0		11.0	
RESPONDER	418.0(84.5%)		22.0(68.8%)		5.0(45.5%)	
NON RESPONDER	75.0(15.5%)		10.0(31.3%)		6.0(54.5%)	
X2	47.52					
P. value	0.001					

As shown in table 22,

Out of 536 patients in group 1 445 patients (83%) had cleared the virus either totally 368 (68.6%) or more than 2 log decrease 77 (14.4%)
Out of these 536 patients 493 received to more than 90% of their recommended dose , 418 of them(84.5%) were responder and 32 patients were exposed to 70-90%of their recommended dose , 22 of them (68.8%) were responder and 11 patients were exposed to a less than 70 % of their recommended dose , only 5 patients (45.5%)were responder.
There was a highly significant positive correlation (p value <0.001) between RBV dose and response.

B: Group 2

Table 23 (EVR according to different Ribavirin dose in group 2)

GROUP 2	WEEK12					
	>90% Of RBV dose		70-90% Of RBV dose		<70% Of RBV dose	
	n	%	n	%	n	%
Total	467.0		54.0		23.0	
RESPONDER	365.0(76.0%)		35.0(64.8%)		12.0(52.2%)	
NON RESPONDER	102.0(24.0%)		19.0(35.2%)		11.0(47.8%)	
X2	20.50					
P. value	0.001					

As shown in table 23,

Out of 544 patients in group 2 412 patients (75%) had cleared the virus either totally 367(67.9%) or more than 2 log decrease 45(8.2%).

Out of these 544 patients 467 received to more than 90% of their recommended dose , 365 of them(76%) were responder and 54 patients were exposed to 70-90%of their recommended dose , 35 of them (64.8%) were responder and 23 patients were exposed to a less than 70 % of their recommended dose , only 12 patients (52.2%)were responder.

There was a highly significant positive correlation (p value <0.001) between RBV dose and response.

2-Late virological response:

A: Group 1

Table 24 (Late virological response according to different Ribavirin dose in group 1)

GROUP 1	WEEK 24					
	>90% Of RBV dose		70-90% Of RBV dose		<70% Of RBV dose	
	n	%	n	%	n	%
total	304.0		108.0		33.0	
RESPONDER	282.0(92.8%)		69.0(63.9%)		20.0(60.6%)	
NON RESPONDER	22.0(7.2%)		39.0(36.1%)		13.0(39.4%)	
X2	25.74					
P. value	0.001					

As shown in table 24,

Out of 445 patients allowed to completed course to week 24, 371 patients (69%) had cleared the virus .

Out of these 445 patients 304 received to more than 90% of their recommended dose , 282 of them(92.8%) were responder and 108 patients were exposed to 70-90%of their recommended dose , 69 of them (63.9%) were responder and 33 patients were exposed to a less than 70 % of their recommended dose , 20 patients (60.6%)were responder.

There was a highly significant positive correlation (p value <0.001) between RBV dose and response.

B: Group 2

Table 25 (Late virological response according to different Ribavirin dose in group 2)

GROUP 2	WEEK 24					
	>90% Of RBV dose		70-90% Of RBV dose		<70% Of RBV dose	
	n	%	n	%	n	%
total	297.0		80.0		35.0	
RESPONDER	262.0(88.6%)		44.0(55.0%)		10.0(28.6%)	
NON RESPONDER	35.0(11.4%)		36.0(45.0%)		25.0(71.4%)	
X2	39.62					
P. value	0.001					

As shown in table 25,

Out of 412 patients allowed to completed course to week 24, 316 patients (58%) had cleared the virus .

Out of these 412 patients 297 received to more than 90% of their recommended dose , 262 of them(88.6%) were responder and 80 patients were exposed to 70-90%of their recommended dose , 44 of them (55%) were responder and 35 patients were exposed to a less than 70 % of their recommended dose , 10 patients (28.6%)were responder.

There was a highly significant positive correlation (p value <0.001) between RBV dose and response.

3-End treatment response:

A: Group 1

Table 26 (ETR according to different Ribavirin dose in group 1)

GROUP 1	WEEK 48					
	>90% Of RBV dose		70-90% Of RBV dose		<70% Of RBV dose	
	n	%	n	%	n	%
total	226.0		124.0		21.0	
RESPONDER	215.0(95.2%)		114.0(91.9%)		9.0(42.9%)	
NON RESPONDER	11.0(4.8%)		10.0(8.1%)		12.0(57.1%)	
X2	45.32					
P. value	0.001					

As shown in table 26,

Out of 371 patients allowed to completed course to week 48, 338 patients (63%) had cleared the virus.

Out of these 371 patients 226 received to more than 90% of their recommended dose , 215 of them(95.2%) were responder and 124 patients were exposed to 70-90%of their recommended dose , 114 of them (91.9%) were responder and 21 patients were exposed to a less than 70 % of their recommended dose , 9 patients (42.9%) were responder.

There was a highly significant positive correlation (p value <0.001) between RBV dose and response.

B: Group 2

Table 27 (ETR according to different Ribavirin dose in group 2)

GROUP 2	WEEK 48					
	>90% Of RBV dose		70-90% Of RBV dose		<70% Of RBV dose	
	n	%	n	%	n	%
total	212.0		87.0		17.0	
RESPONDER	192.0(90.7%)		70.0(80.5%)		6.0(35.3%)	
NON RESPONDER	20.0(9.3%)		17.0(19.5%)		11.0(64.7%)	
X2	35.94					
P. value	0.001					

As shown in table 27,

Out of 316 patients allowed to completed course to week 48, 268 patients (49%) had cleared the virus.

Out of these 316 patients 212 received to more than 90% of their recommended dose , 192 of them(90.7%) were responder and 87 patients were exposed to 70-90%of their recommended dose , 70 of them (80.5%) were responder and 17 patients were exposed to a less than 70 % of their recommended dose , 6 patients (35.3%) were responder.

There was a highly significant positive correlation (p value <0.001) between RBV dose and response.

4-Sustained virological response:

A: Group 1

Table 28 (SVR according to different Ribavirin dose in group 1)

GROUP 1	SVR					
	>90% Of RBV dose		70-90% Of RBV dose		<70% Of RBV dose	
	n	%	n	%	n	%
total	217.0		112.0		9.0	
RESPONDER	208.0(93.8%)		98.0(91.5%)		4.0(44.4%)	
NON RESPONDER	9.0(6.2%)		14.0(12.5%)		5.0(55.6%)	
X2	67.21					
P. value	0.001					

As shown in table 28,

Out of 338 patients who achieved negative PCR in week 48, 310 patients (58%) had maintained clearing the virus 6 months after stoppage of treatment .

Out of these 338 patients 217 received to more than 90% of their recommended dose , 208 of them(93.8%) were responder and 112 patients were exposed to 70-90%of their recommended dose , 98 of them (91.5%) were responder and 9 patients were exposed to a less than 70 % of their recommended dose , 4 patients (44.4%) were responder.

There was a highly significant positive correlation (p value <0.001) between RBV dose and response.

B: Group 2

Table 29 (SVR according to different Ribavirin dose in group 2)

GROUP 2	SVR					
	>90% Of RBV dose		70-90% Of RBV dose		<70% Of RBV dose	
	n	%	n	%	n	%
total	189.0		70.0		9.0	
RESPONDER	184.0(96.8%)		63.0(85.7%)		3.0(33.3%)	
NON RESPONDER	5.0(3.2%)		7.0(14.3%)		6.0(66.7%)	
X2	37.63					
P. value	0.001					

As shown in table 29,

Out of 268 patients who achieved negative PCR in week 48, 250 patients (46 %) had maintained clearing the virus 6 months after stoppage of treatment .

Out of these 268 patients 189 received to more than 90% of their recommended dose , 184 of them(96.8%) were responder and 70 patients were exposed to 70-90%of their recommended dose , 63 of them (85.7%) were responder and 9 patients were exposed to a less than 70 % of their recommended dose , 3 patients (33.3%) were responder.

There was a highly significant positive correlation (p value <0.001) between RBV dose and response.

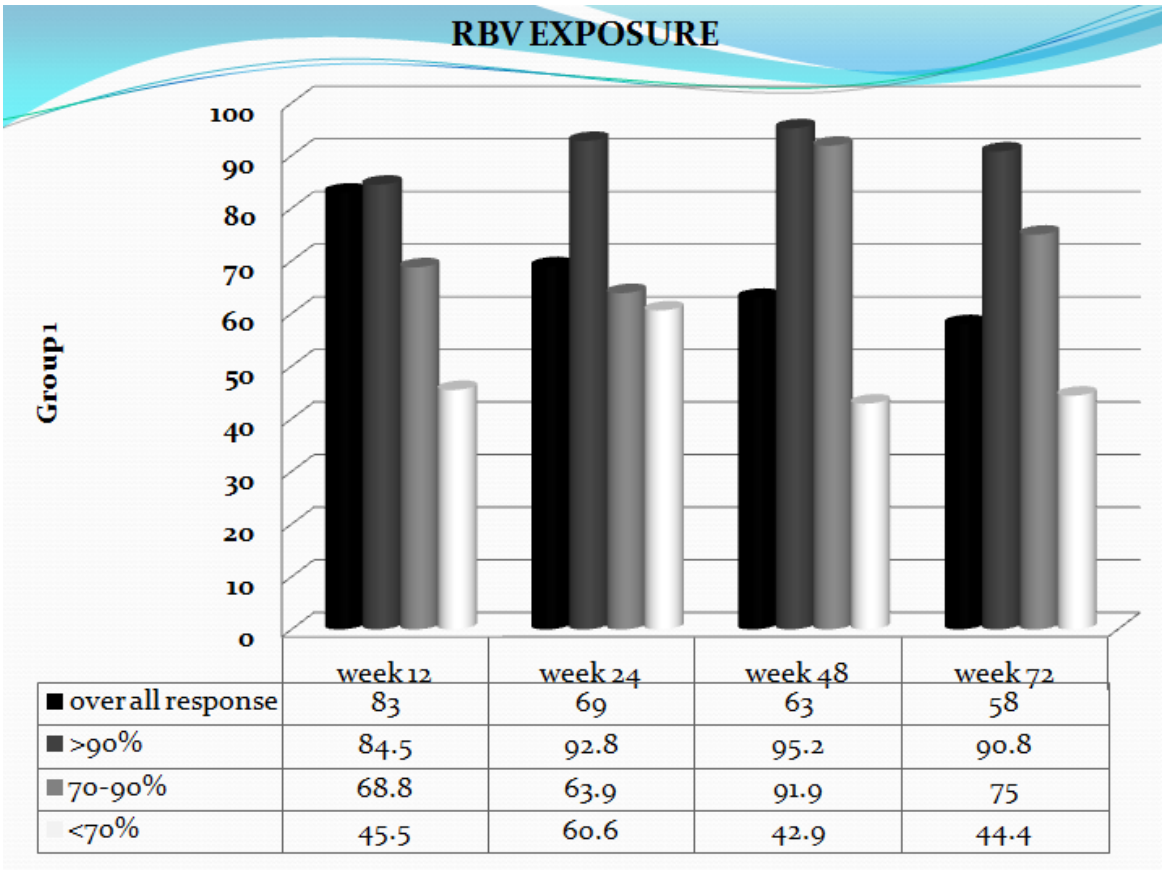
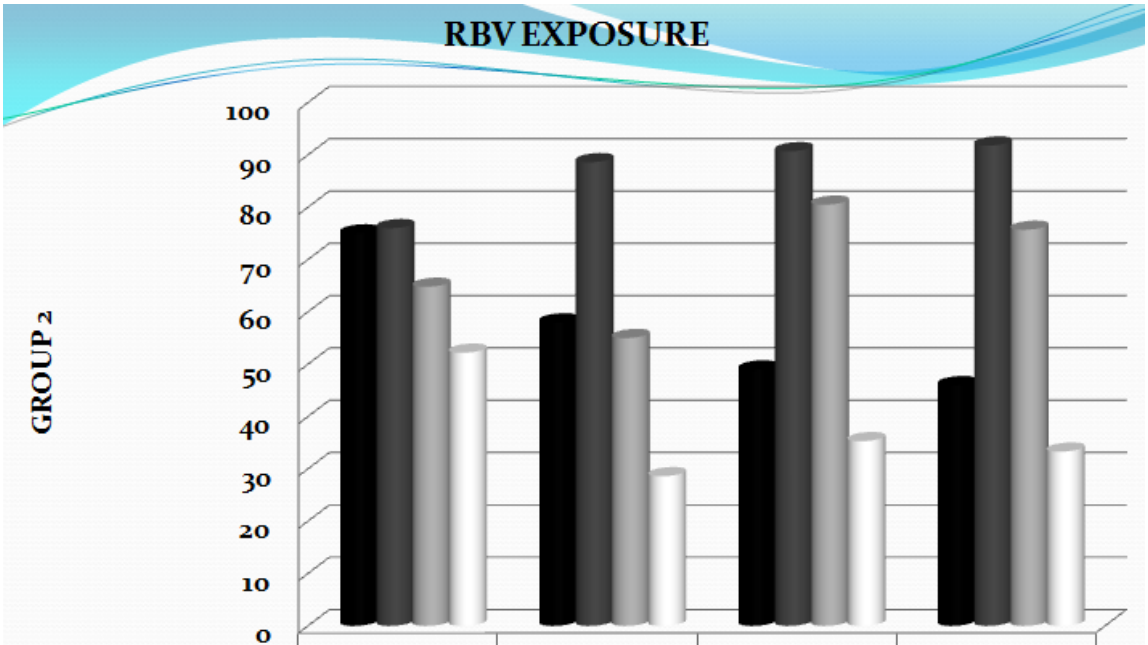


Figure 20(Effect of cumulative ribavirin dose exposure as an impact of anemia on different type of response in group 1)



	week 12	week 24	week 48	week 72
over all response	75	58	49	46
>90%	76	88.6	90.7	91.8
70-90%	64.8	55	80.5	75.7
<70%	52.2	28.6	35.3	33.3

Figure 21(Effect of cumulative ribavirin dose exposure as an impact of anemia on different type of response in group 2)

Effect of cumulative interferon dose exposure as an impact of neutropenia and thrombocytopenia on different type of response.

1-Early virological response:

A: Group 1

Table 30 (EVR according to different PEG –interferon dose in group 1)

GROUP 1	WEEK 12					
	>90% Of INF dose		70-90% Of INF dose		<70% Of INF dose	
	n	%	n	%	n	%
total	519.0		10.0		7.0	
RESPONDER	435.0(83.5%)		7.0(70.0%)		3.0(42.9%)	
NON RESPONDER	84.0(16.5%)		3.0(30.0%)		4.0(57.1%)	
X2	41.36					
P. value	0.001					

As shown in table 30,

Out of 536 patients in group1 445 patients (83%) had cleared the virus either totally 368 (68.6%) or more than 2 log decrease 77 (14.4%).

Out of these 536 patients 519 received to more than 90% of their recommended dose , 435 of them(83.5%) were responder and 10 patients were exposed to 70-90%of their recommended dose , 7 of them (70%) were responder and 7 patients were exposed to a less than 70 % of their recommended dose , only 3 patients (42.9%)were responder.

There was a highly significant positive correlation (p value <0.001) between INF dose and response.

B: Group 2

Table 31 (EVR according to different PEG –interferon dose in group 2)

GROUP 2	WEEK 12					
	>90% Of INF dose		70-90% Of INF dose		<70% Of INF dose	
	n	%	n	%	n	%
total	537.0		6.0		1.0	
RESPONDER	408.0(75.7%)		4.0(66.7%)		0.0(0.0%)	
NON RESPONDER	129.0(24.3%)		2.0(33.3%)		1.0(100.0%)	
X2	54.63					
P. value	0.001					

As shown in table 31,

Out of 544 patients in group2 412 patients (75%) had cleared the virus either totally 367(67.9%) or more than 2 log decrease 45(8.2%).

Out of these 544 patients 537 received to more than 90% of their recommended dose , 408 of them(75.7%) were responder and 6 patients were exposed to 70-90%of their recommended dose , 4 of them (66.7%) were responder and only one patient was exposed to a less than 70 % of his recommended dose , and was non responder (0 %)were responder.

There was a highly significant positive correlation (p value <0.001) between INF dose and response.

2-Late virological response (Week 24) :

A: Group 1

Table 32 (Late virological response according to different PEG –interferon dose in group 1)

GROUP 1	WEEK 24					
	>90% Of INF dose		70-90% Of INF dose		<70% Of INF dose	
	n	%	n	%	n	%
total	363.0		76.0		6.0	
RESPONDER	330.0(90.9%)		41.0(53.9%)		0.0(0.0%)	
NON RESPONDER	33.0(9.1%)		35.0(46.1%)		6.0(100.0%)	
X2	46.25					
P. value	0.001*					

As shown in table 32,

Out of 445 patients allowed to completed course to week 24, 371 patients (69%) had cleared the virus.
Out of these 445 patients 363 received to more than 90% of their recommended dose , 330 of them(90.9%) were responder and 76 patients were exposed to 70-90%of their recommended dose , 41 of them (53.9%) were responder and 6 patients were exposed to a less than 70 % of their recommended dose , no patients (0 %)were responder.
There was a highly significant positive correlation (p value <0.001) between INF dose and response.

B: Group 2

Table 33 (Late virological response according to different PEG –interferon dose in group 2)

GROUP 2	WEEK 24					
	>90% Of INF dose		70-90% Of INF dose		<70% Of INF dose	
	n	%	n	%	n	%
total	383.0		29.0		0.0	
RESPONDER	300.0(78.5%)		17.0(58.6%)		0.0(0%)	
NON RESPONDER	80.0(21.5%)		12.0(41.4%)		0.0(0%)	
X2	49.20					
P. value	0.001					

As shown in table 33,

Out of 412 patients allowed to completed course to week 24, 316 patients (58%) had cleared the virus.

Out of these 412 patients 383 received to more than 90% of their recommended dose , 300 of them(78.5%) were responder and 29 patients were exposed to 70-90%of their recommended dose , 17 of them (58.6%) were responder and no patients were exposed to a less than 70 % of their recommended .

There was a highly significant positive correlation (p value <0.001) between INF dose and response.

3-End treatment response:

A: Group 1

Table 34 (ETR according to different PEG –interferon dose in group 1)

GROUP 1	WEEK 48					
	>90% Of INF dose		70-90% Of INF dose		<70% Of INF dose	
	n	%	n	%	n	%
total	242.0		125.0		4.0	
RESPONDER	228.0(95.0%)		110.0(88.0%)		0.0(0.0%)	
NON RESPONDER	14.0(5.0%)		15.0(12.0%)		4.0(100.0%)	
X2	81.24					
P. value	0.001					

As shown in table 34,

Out of 371 patients allowed to completed course to week 48, 338 patients (63%) had cleared the virus.

Out of these 371 patients 242 received to more than 90% of their recommended dose , 228 of them(95%) were responder and 125 patients were exposed to 70-90%of their recommended dose , 110 of them (88%) were responder and 4 patients were exposed to a less than 70 % of their recommended dose , no patients of them were responder (0%).

There was a highly significant positive correlation (p value <0.001) between INF dose and response.

B: Group 2

Table 35 (ETR according to different PEG –interferon dose in group 2)

GROUP 2	WEEK 48					
	>90% Of INF dose		70-90% Of INF dose		<70% Of INF dose	
	n	%	n	%	n	%
total	196.0		114.0		6.0	
RESPONDER	175.0(90.1%)		91.0(80.5%)		2.0(33.0%)	
NON RESPONDER	21.0(9.9%)		23.0(19.5%)		4.0(67.0%)	
X2	65.61					
P. value	0.001					

As shown in table 35,

Out of 316 patients allowed to completed course to week 48, 268 patients (49%) had cleared the virus.

Out of these 316 patients 196 received to more than 90% of their recommended dose , 175 of them (90.1%) were responder and 114 patients were exposed to 70-90%of their recommended dose , 91 of them (80.5%) were responder and 6 patients were exposed to a less than 70 % of their recommended dose , 2 patients (33 %) were responder.

There was a highly significant positive correlation (p value <0.001) between INF dose and response.

4-Sustained virological response:

A: Group 1

Table 36 (SVR according to different PEG –interferon dose in group 1)

GROUP 1	SVR					
	>90% Of INF dose		70-90% Of INF dose		<70% Of INF dose	
	n	%	n	%	n	%
total	227.0		110.0		1.0	
RESPONDER	216.0(95%)		94.0(85.5%)		0.0(0.0%)	
NON RESPONDER	11.0(5%)		16.0(14.5%)		1.0(100.0%)	
X2	66.32					
P. value	0.001					

As shown in table 36,

Out of 338 patients who achieved negative PCR in week 48, 310 patients (58%) had maintained clearing the virus 6 months after stoppage of treatment .

Out of these 338 patients 227 received to more than 90% of their recommended dose , 216 of them(95%) were responder and 110 patients were exposed to 70-90%of their recommended dose , 94 of them (85%) were responder and only one patient were exposed to a less than 70 % of their recommended dose , and was non responder (0%) were responder.

There was a highly significant positive correlation (p value <0.001) between INF dose and response.

B: Group 2

Table 37 (SVR according to different PEG –interferon dose in group 2)

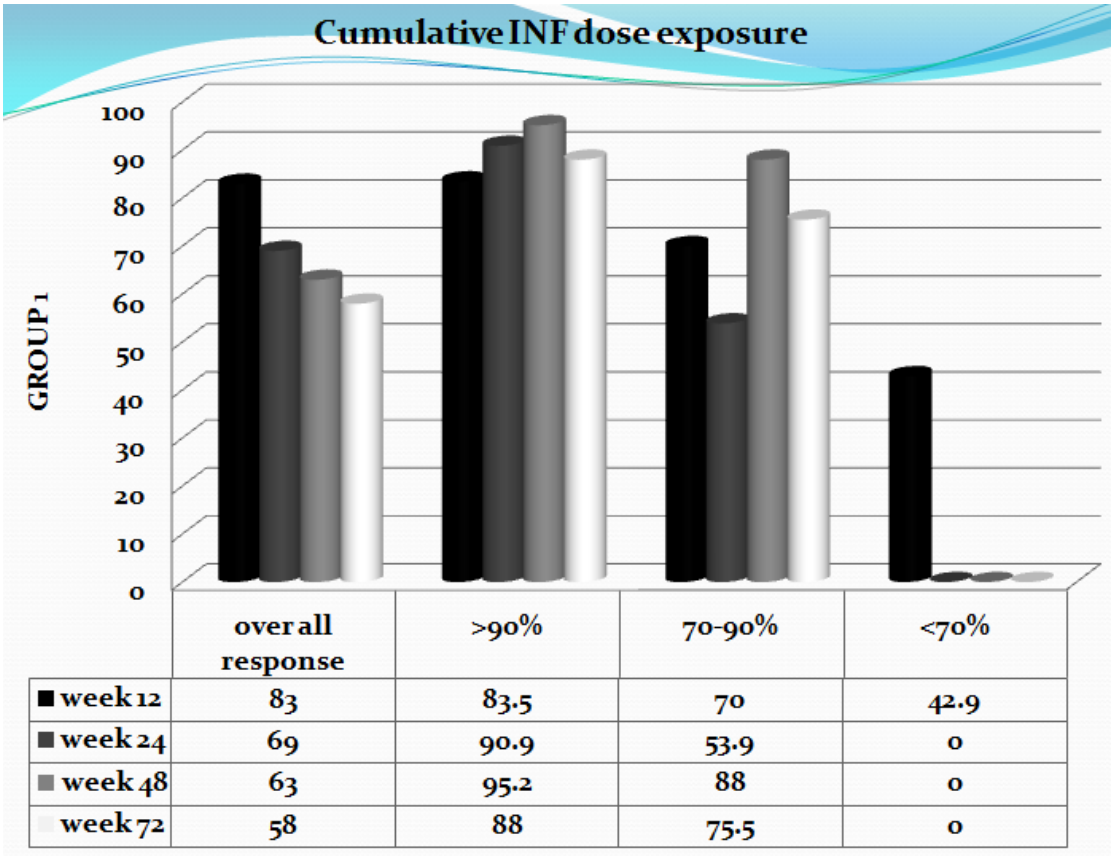
GROUP 2	SVR					
	>90% Of INF dose		70-90% Of INF dose		<70% Of INF dose	
	n	%	n	%	n	%
total	175.0		93.0		0.0	
RESPONDER	166.0(95.0%)		84.0(91.4%)		0.0(0%)	
NON RESPONDER	9.0(5.0%)		9.0(9.6%)		0.0(0%)	
X2	61.82					
P. value	0.001					

As shown in table 37,

Out of 268 patients who achieved negative PCR in week 48, 250 patients (46 %) had maintained clearing the virus 6 months after stoppage of treatment .

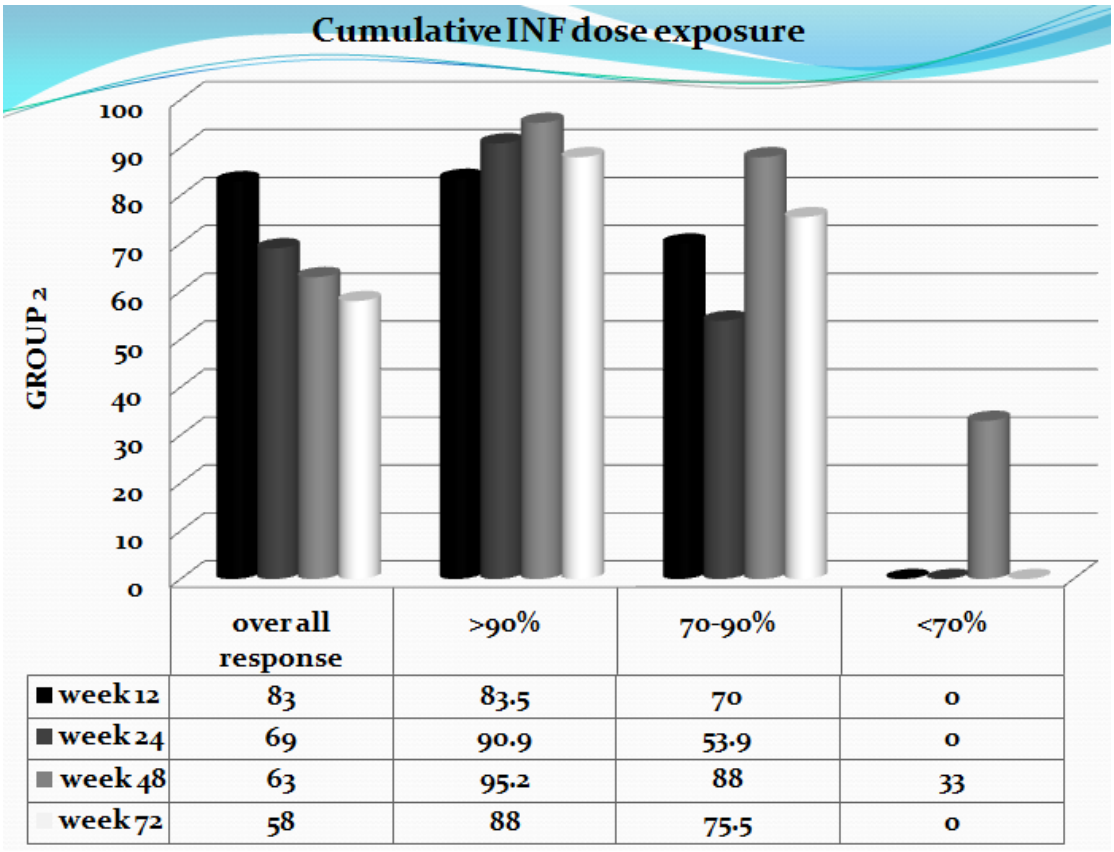
Out of these 268 patients 175 received to more than 90% of their recommended dose , 166 of them (95.0%) were responder and 93 patients were exposed to 70-90%of their recommended dose , 84 of them (91.4%) were responder and no patients were exposed to a less than 70 % of their recommended .

There was a highly significant positive correlation (p value <0.001) between INF dose and response.



	over all response	>90%	70-90%	<70%
week 12	83	83.5	70	42.9
week 24	69	90.9	53.9	0
week 48	63	95.2	88	0
week 72	58	88	75.5	0

Figure 22(Effect of cumulative interferon dose exposure as an impact of neutropenia and thrombocytopenia on different type of response in group 1)



	over all response	>90%	70-90%	<70%
week 12	83	83.5	70	0
week 24	69	90.9	53.9	0
week 48	63	95.2	88	33
week 72	58	88	75.5	0

Figure 23(Effect of cumulative interferon dose exposure as an impact of neutropenia and thrombocytopenia on different type of response in group 2)