RESULTS

The present study was conducted on 45 asthmatic children with mild to moderate persistent bronchial asthma aged from 5 to 15 years under low dose I.C.S who were not controlled.

The study patients were divided into 3 groups :

Group I : Patients received moderate dose (200 ug / day) ICS.

Group II: Patients received sustained release theophylline (10 – 12 mg/kg/d) + low dose ICS (100 µg/d).

Group III : Patients received montelukast (5 mg/once daily) + low dose ICS (100 µg/d).

Comparison between the 3 groups in demographiuc data are illustrated in tables from (1- 4).

Patients received the treatment for 3 months comparing the post treatment data illustrated in tables from (5 – 14) & Figures from (1 - 10).

According to level of asthma control they were divided into three groups ***(According to Gina, 2009)***:

1) Controlled patients
2) Partially controlled
3) Un controlled patients.

Table (1): Comparison between the studied groups as regard to age of patients.

Age in years / Study group	X ± SD	T	P
Group I	7.6 ± 3.1	$t_1 = 0.068$	>0.05
Group II	7.5 ± 2.3	$t_2 = 0.29$	> 0.05
Group III	7.3 ± 3.2	$t_3 = 0.26$	> 0.05

F = 0.056 P > 0.05

This table shows that in group I the mean age ± SD was 7.6 ± 3.1, in group II it was 7.5 ± 2.3 and in group III was 7.3 ± 3.2 with P > 0.05.

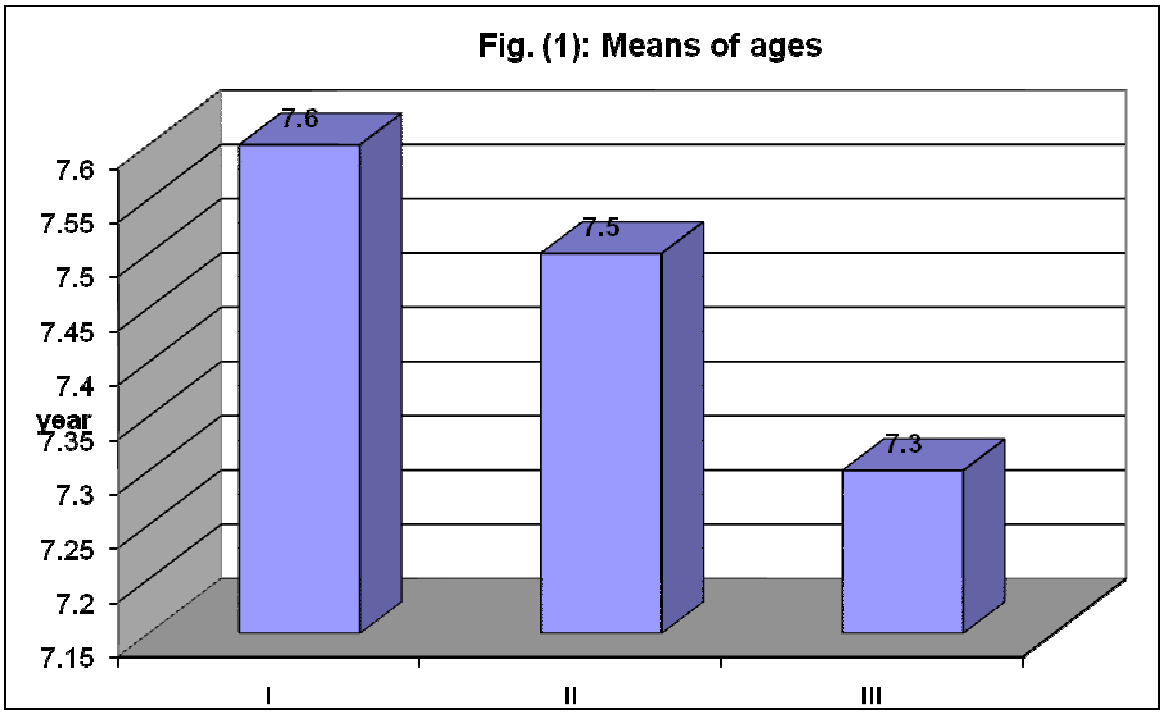


Table (2) : Sex distribution

Study group / Sex	Group I		Group II		Group III		Total	
	No.	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**
Males	9	60.0	9	60.0	10	66.7	28	62.2
Females	6	40.0	6	40.0	5	33.3	17	37.8
Total	15	100.0	15	1000	15	100.0	45	100.0

X^2=0.189 p = 0.909 > 0.05

This table shows that there is no statistically significant difference in sex distribution of the studied three groups P > 0.05. in stead the male number were 28 patients and the number of females were 17.

Table (3): Residence distribution

Study group / Residence	Group I		Group II		Group III		Total	
	No.	%	No.	%	No.	%	No.	%
Rural	7	96.7	8	53.3	7	46.7	22	48.9
Urban	8	53.3	7	46.7	8	53.3	23	51.1
Total	15	100.0	15	1000	15	100.0	45	100.0

Chi square (x^2) = 0.178 p = 0.915 > 0.05

This table shows that there was no statistically significant difference between the three groups P > 0.05 as regard residence.

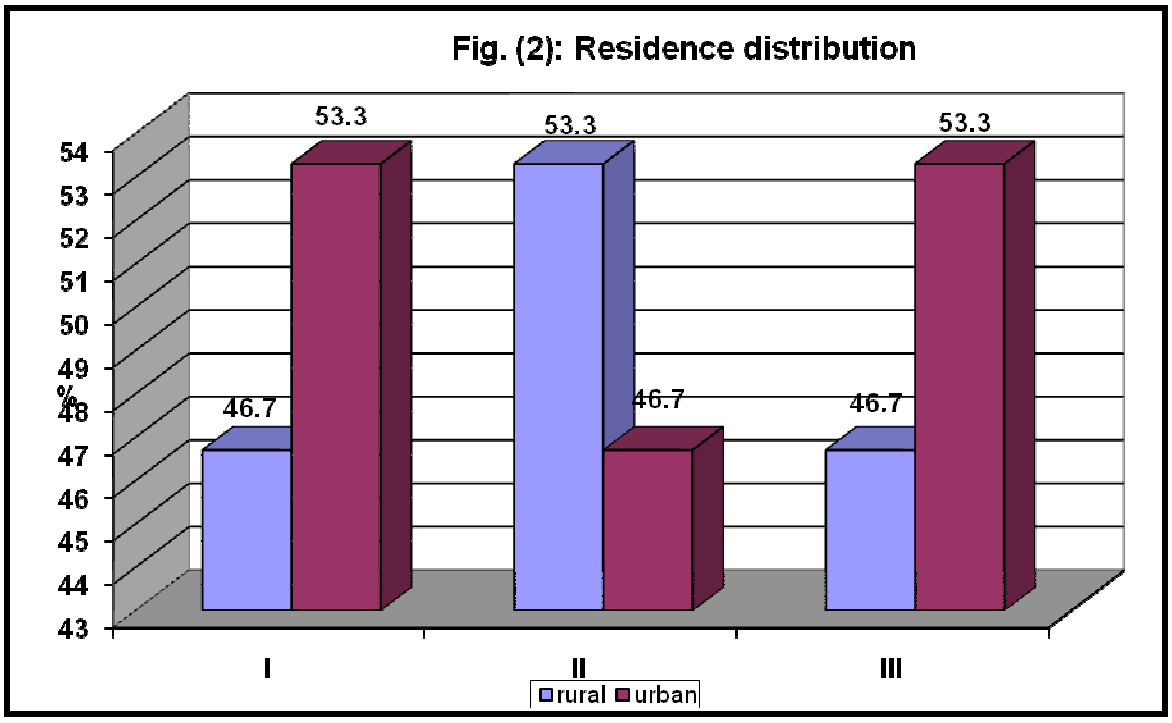


Table (4): Family history of atopy in the studied group.

Study group / Atopy	Group I		Group II		Group III		Total	
	No.	%	No.	%	No.	%	No.	%
+ve	8	53.3	8	53.3	9	60.0	25	55.6
-ve	7	46.7	7	46.7	6	40.0	20	44.4
Total	15	100.0	15	1000	15	100.0	45	100.0

$X^2 = 0.18$ $P = 0.194$ > 0.05

The table shows there was the family history of atopy in 55.6% of all asthmatic children under study and 44.4% have no history of atopy with $P > 0.05$ with no statistical significance difference.

Table (5): Distribution of anaemia among patients of the studied groups.

HB / Studied group	Normal		Abnormal	
	No.	%	No.	%
Group I	6	40	9	60
Group II	7	46.6	8	53.3
Group III	9	60	6	40
Total	22	48.9	23	51.11

$X^2 = 1.85$ $P > 0.05$

This table shows the percent of anaemia in group I was 60 %, in group II was 53.3% and in group III was 40% with $P > 0.05$ and this was according to ***WHO (2004)***, the cut level of Hb to diagnose anaemia in children from 5 – 15 years was < 11.5 gm/dl.

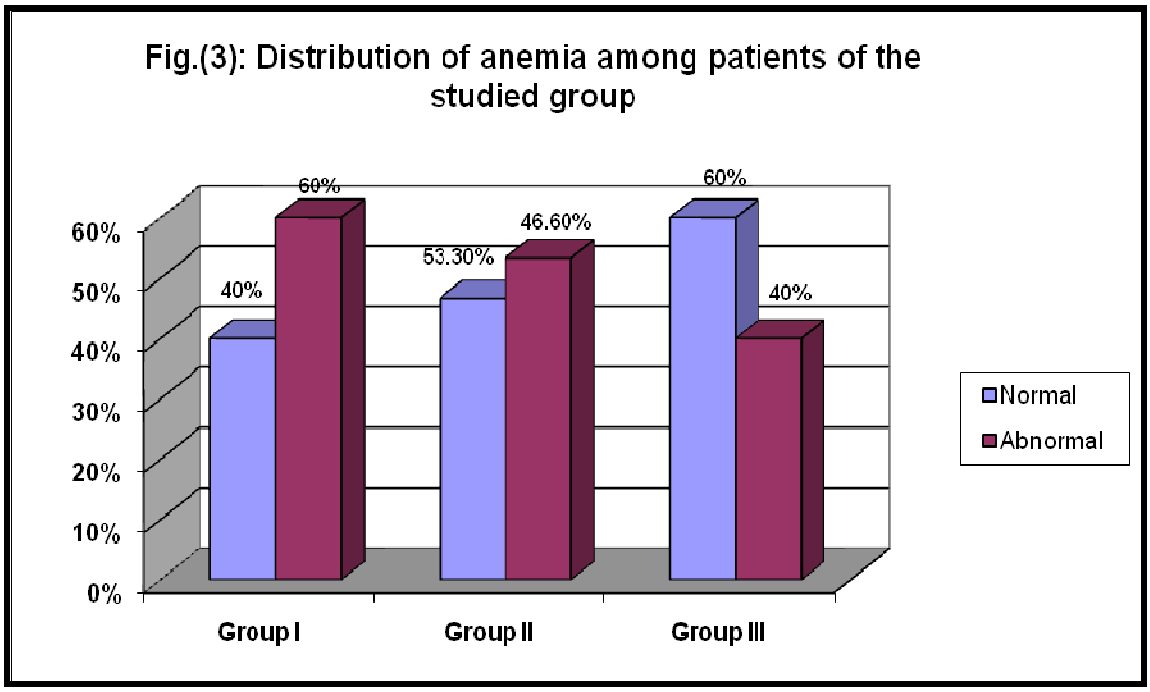


Table (6): Day time symptoms / week in each group after 3 months treatment.

Study group / No. of symptoms /week	Group I		Group II		Group III		Total	
	No.	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**
Day symptoms> 2 time / week	5	33.3	2	13.3	4	26.7	11	24.4
Day symptoms< 2 time / week	10	66.7	13	86.7	11	73.3	34	76.6
Total	15	100	15	100	15	100	45	100
	Z = 1.29 P > 0.05		Z= 2.84 P < 0.001		Z = 1.71 P < 0.05			

This table shows that there were highly statistical significant difference in day time symptoms between controlled, partially and uncontrolled patients in group II ($P < 0.001$) and there was statistical significant difference ($P < 0.05$) in group III and no statistical significant difference ($P > 0.05$) in group I.

Table (7): Comparison between day time symptoms / week in 3 months among the 3 groups.

Study group / No. of symptoms /week	Group I		Group II		Group III		Total	
	No.	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**
Day symptoms> 2 time / week	5	33.3	2	13.3	4	26.7	11	24.4
Day symptoms< 2 time / week	10	66.7	13	86.7	11	73.3	34	76.6
Total	15	100	15	100	15	100	45	100

$X^2 = 1.86$ P = 0.43 > 0.05

This table shows that there was decrease day symptoms in group I by 66.7%, decrease in group II by 86.7% and decrease in group III by 73.3% with P > 0.05 so there were no statistical significant difference between the 3 groups.

Table (8): $Beta_2$ agonist use / week

Study group / Beta agonist	Group I		Group II		Group III		Total	
	No.	%	No.	%	No.	%	No.	%
> 2 time / week	9	60.0	5	33.3	5	33.3	19	42.2
< 2 time / week	6	40.0	10	66.7	10	66.7	26	57.8
Total	15	100.0	15	1000	15	100.0	45	100.0

$X^2 = 2.92$ $P = 0.233$ > 0.05

This table shows that there was decrease in β2 agonist use by 40% in group I and decrease in β2 agonist use in group II by 66.7% and in group III by also 66.7% with no statistical significant difference in the 3 groups.

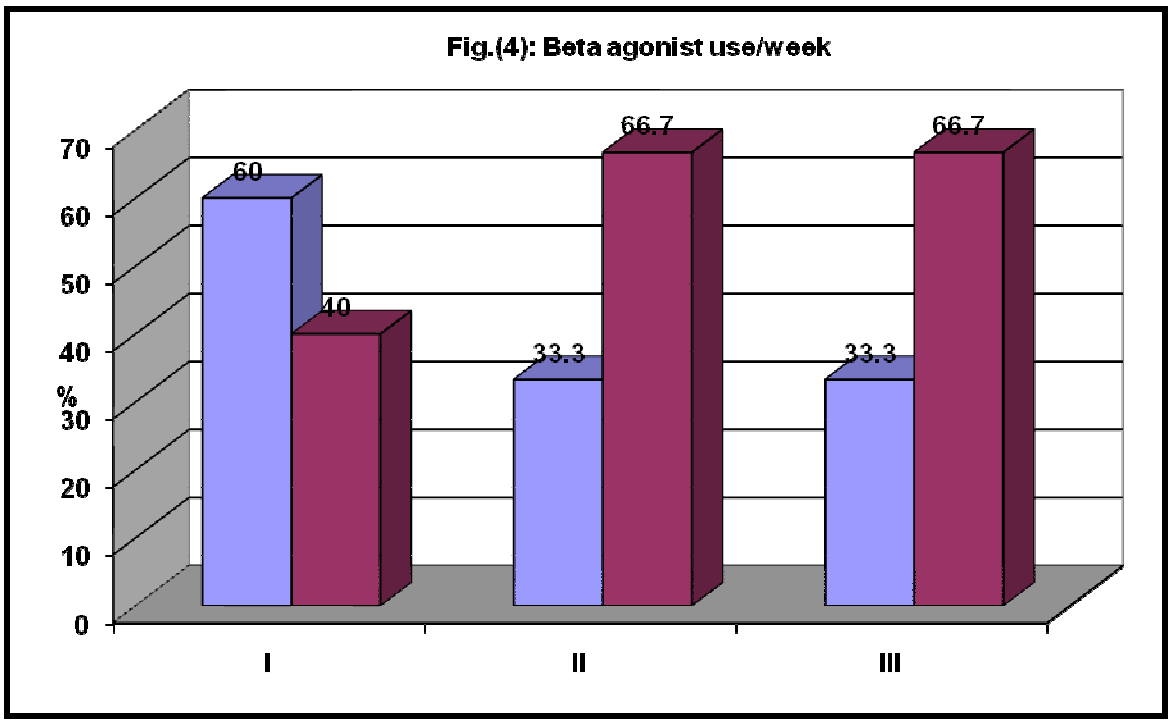


Table (9): Nocturnal symptoms / week during three months of treatment

Study group / Nocturnal Sy.	Group I		Group II		Group III		Total	
	No.	%	No.	%	No.	%	No.	%
No	6	40.0	10	66.7	9	60.0	25	55.6
Yes	9	60.0	5	33.3	6	40.0	20	44.4
Total	15	100.0	15	1000	15	100.0	45	100.0

$X^2 = 2.34$ P = 0.31 > 0.05

Comparing the 3 groups as regard patients nocturnal symptoms / week, we found that 40% of group I and 66.7% of group II and 60% of group III were free from nocturnal awakening of asthma symptoms. The difference between three groups were insignificant (P > 0.05).

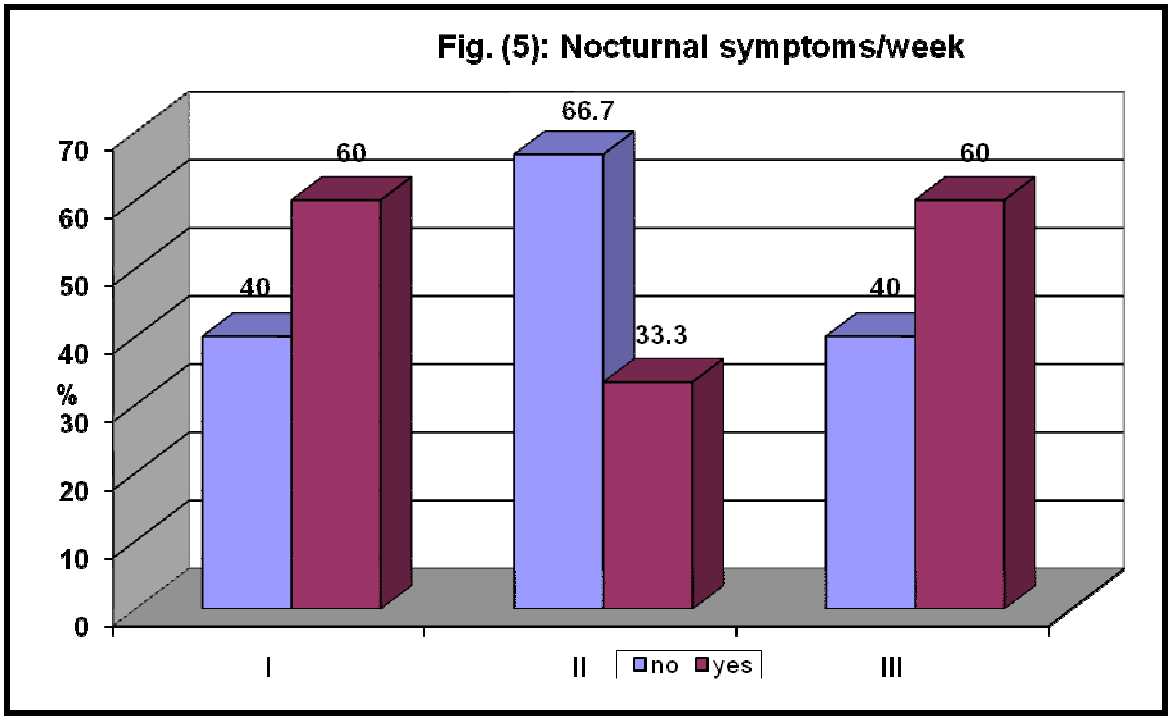


Table (10): Level of asthma severity according to clinical symptoms, PEF rate recording and PEF variability .

Study group / BEF	Group I		Group II		Group III		Total	
	No.	%	No.	%	No.	%	No.	%
Mild	7	46.7	8	53.3	7	46.7	22	48.9
Moderate	8	53.3	7	46.7	8	53.3	23	51.1
Total	15	100.0	15	1000	15	100.0	45	100.0

$X^2 = 0.178$ P = 0.915 > 0.05

This table shows that the patients with mild persistent asthma (PEFR > 80%, variability 20 – 30%) was in the three groups 48.9% and patients with moderate persistent asthma (PEFR ≥ 60 – 80%, variability > 30%) was 51.1% the difference between the 3 groups were insignificant .

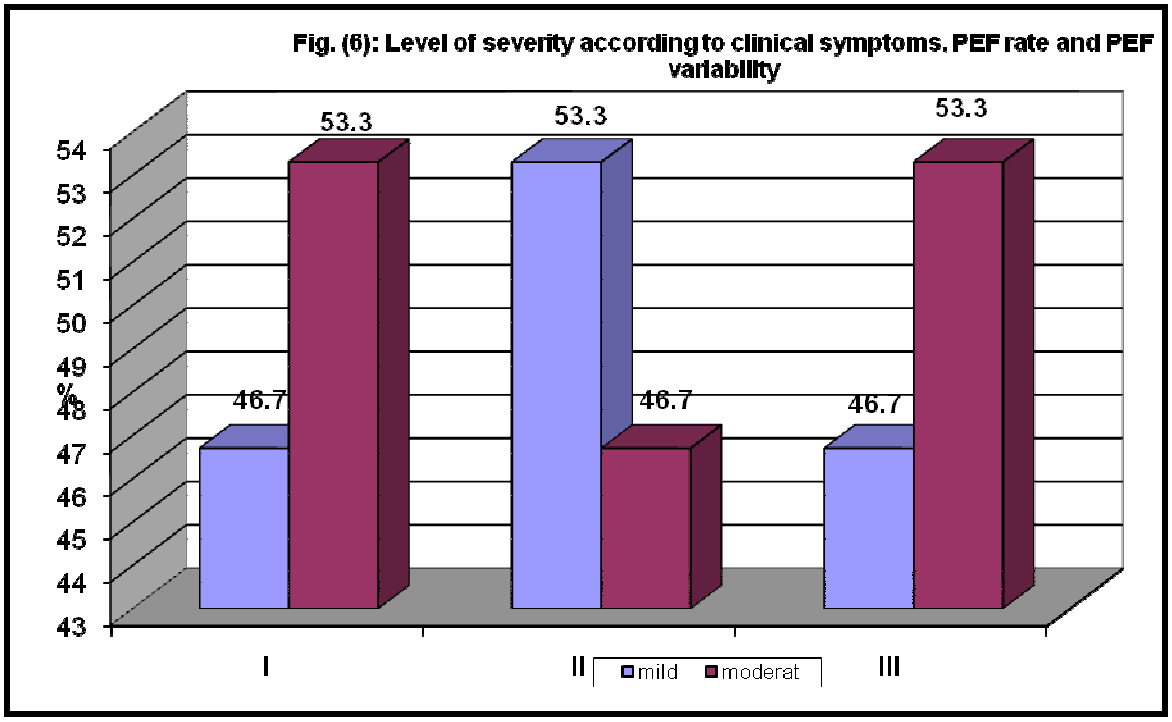


Table (11): Level of control

Study group / control level	Group I		Group II		Group III		Total	
	No.	%	No.	%	No.	%	No.	%
Uncontrolled	5	33.3	2	13.3	2	26.7	11	24.4
Controlled	6	40.0	10	66.7	11	60.0	25	55.6
Partially	4	26.7	3	20.0	2	13.3	9	20.0
Total	15	100.0	15	1000	15	100.0	45	100.0
	Z = 0.77 P > 0.05		Z = 1.81 P = < 0.05		Z = 1.71 P < 0.05			

This table shows that there was statistically significant difference in level of control of asthma in group II (P < 0.05) and also there was statistically significant difference in the control level in group III (P < 0.05). There was no significant difference in level of asthma control in group I patients (P > 0.05).

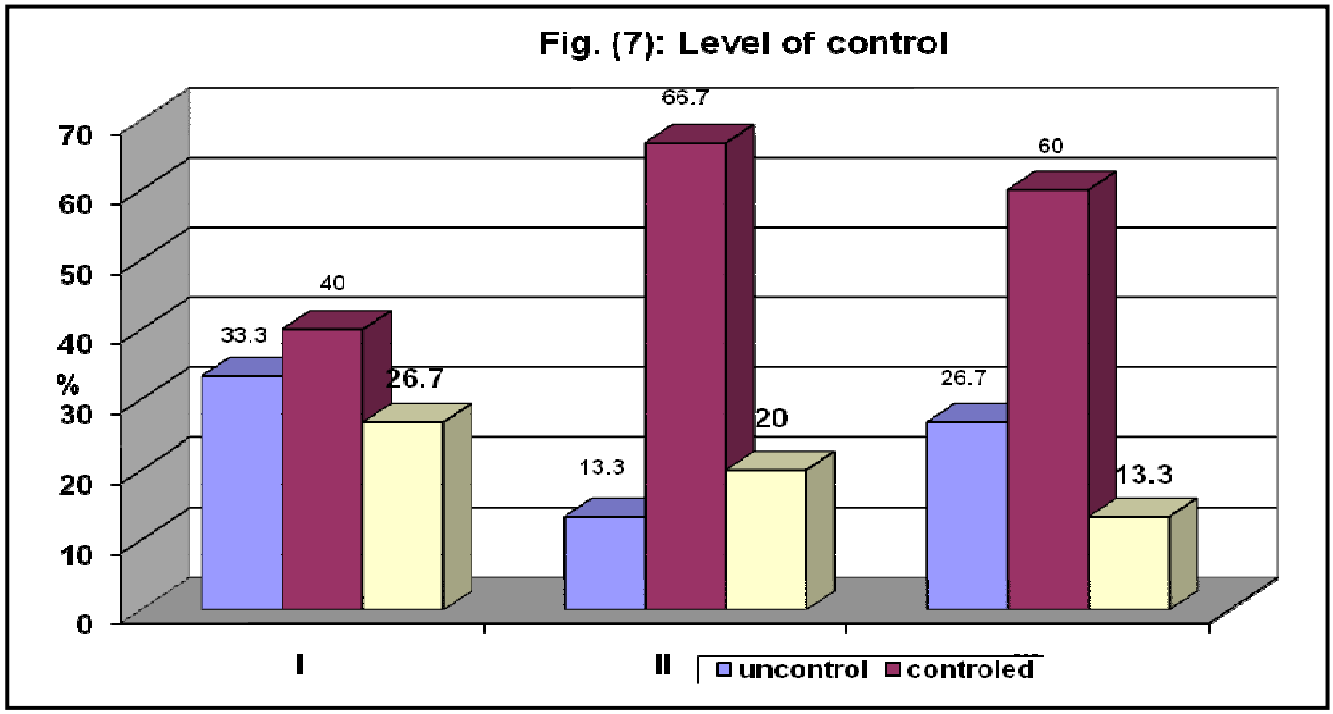


Table (12): Hospital admission / 3 months of treatment.

Study group / Hospital admi	Group I		Group II		Group III		Total	
	No.	%	No.	%	No.	%	No.	%
No	10	66.7	14	93.3	13	86.7	37	
+ ve hospital	5	33.3	1	6.37	2	13.3	8	
Total	15	100.0	15	1000	15	100.0	45	100.0

$X^2 = 3.95$ $P > 0.05$

This table shows that in group I the percentage of patients admitted to the hospital in 3 months was 33.3%, in group II was 6.7% and in group III was 26.7% with (P > 0.05).

Fig.(8): Hospital admission/3months

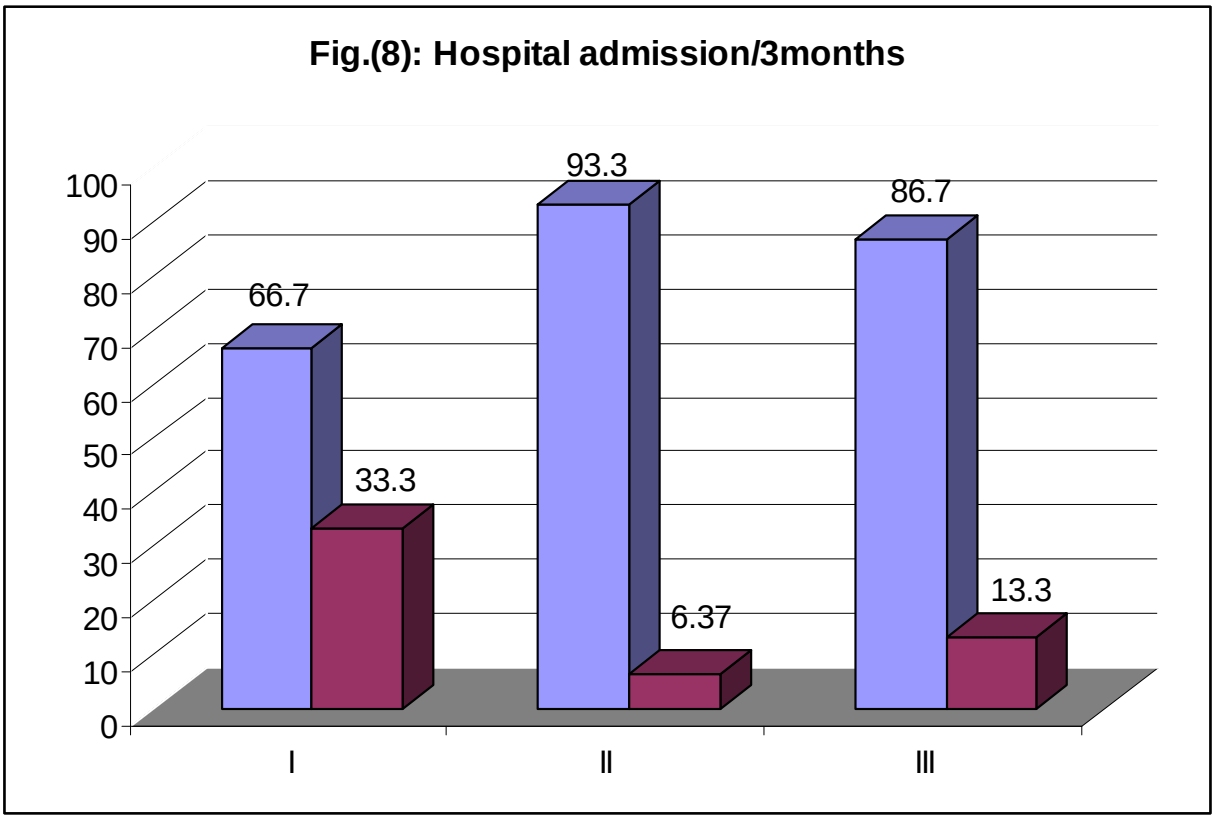


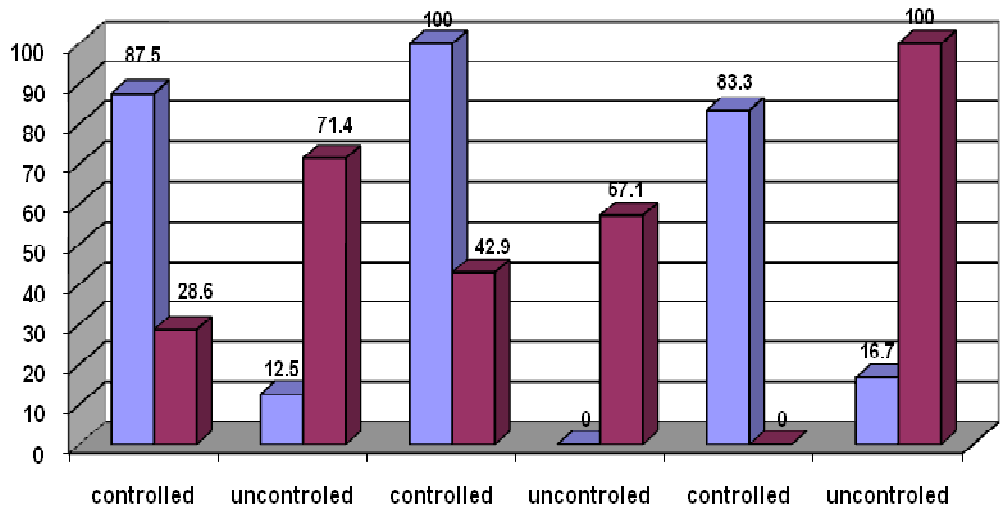
Table (13): Distribution of studied asthma patients according to asthma severity and level of control.

PEF / St. group	Mild		Moderate		Total		X^2	p
	No.	%	No.	%	No.	%		
G I								
Controlled	5	83.3	0	0.0	5	33.3	7.81	<0.001
Partially +Uncontrolled	1	16.7	9	100.0	10	66.7		0.00005
G II:								
Controlled	8	100.0	3	42.9	10	66.7	5.66	< 0.05
Partially +Uncontrolled	0	00.0	4	57.1	5	33.3		0.2002
G III:								
Controlled	7	87.5	2	28.6	10	66.7	3.34	>0.05
Partially + Uncontrolled	1	12.5	5	71.4	5	33.3		0.017

This table shows that there was highly statistically significant difference in control level between mild and moderate cases in group I ($P < 0.001$).

Also there was statistical significant difference in control level between mild and moderate cases in group II ($P < 0.05$) and in group III there was no statistical significant difference in control level between mild and moderate cases ($P > 0.05$).

Fig.(9): Distribution of studied asthma patients according to asthma severity and level of control



Group III **Group II** **Group I**

Table (14) : Theophylline blood levels in group II patients according to level of asthma control.

Theophyll / Study group	X ± SD µg/day	t	p
Uncontrolled (n=2)	2.5 ± 0.7	t_1 = 1.98	>0.05
Partial controlled (n=3)	3.93 ± 0.9	t_2 = 4.31	<0.001
Controlled (n=10)	5.89 ± 1.9	t_3=2.44	<0.05

One way anove "F" test = 4.04 p = 0.046 (< 0.05)

t_1 = Uncontrolled vs partial controlled

t_2 = Uncontrolled vs controlled

t_3 = partial controlled vs controlled

There were significant difference in theophylline level between these with good control and partial controlled (P < 0.05) and high significant difference between serum level of theophylline between uncontrolled group and good controlled group (P < 0.001).

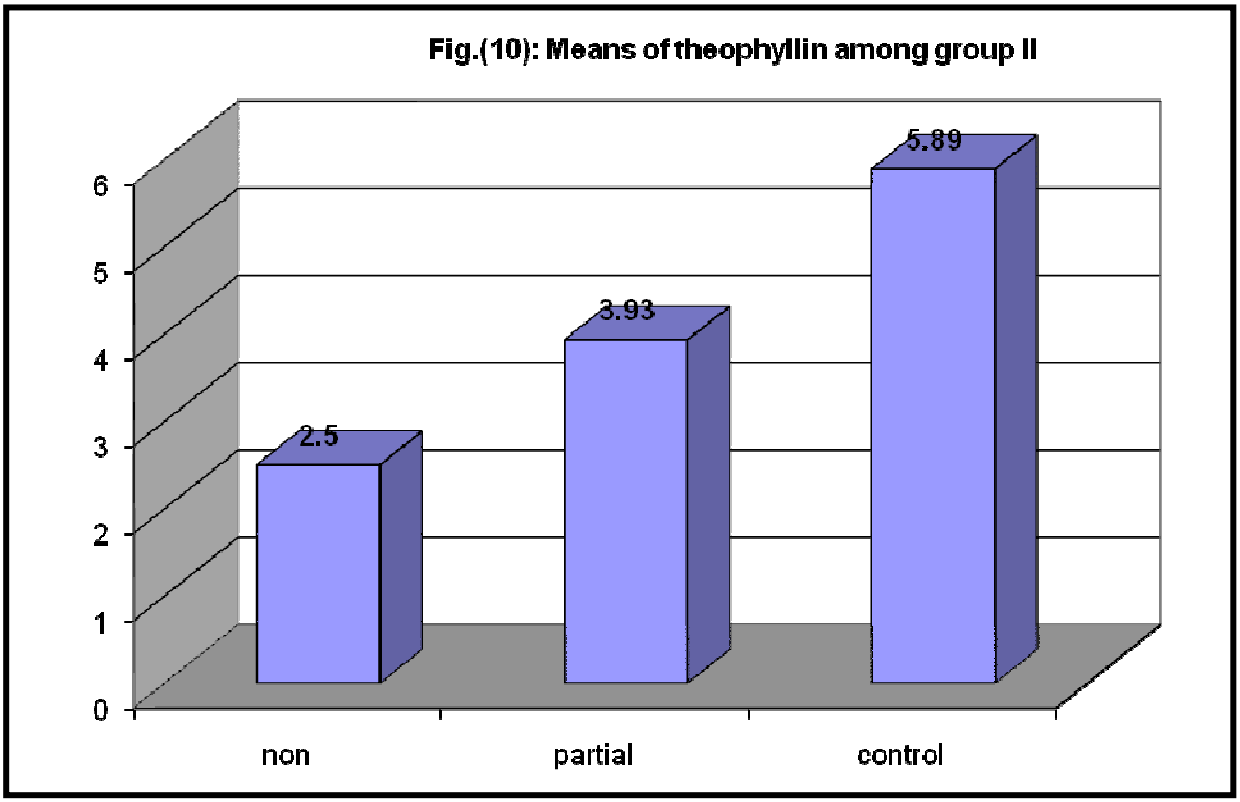


Fig.(10): Means of theophyllin among group II
6
5
4
3
2
1
0
2.5
3.93
5.89
non
partial
control