

Study population.

This study included forty patients with secondary pulmonary hypertension. The mean total age was 56 ± 9 years (range 37 – 70) , 56 ± 9 years in sildenafil group versus 55 ± 7 years in placebo group (p value >0.05) , 18 patients were males (45%) and 22 patients were females (55%).

The mean heart rate at baseline was 83 ± 8 b pm, the mean heart rate in sildenafil group was 83 ± 8 b pm versus 83 ± 8 b pm in placebo group (p value >0.05) .

The mean total systolic blood pressure at baseline was 119 ± 8 mmHg, the mean systolic blood pressure in sildenafil group was 121 ± 8 mmHg versus 117 ± 8 mmHg in placebo group (p value >0.05) .

The mean total diastolic blood pressure at baseline was 74 ± 7 mmHg, the mean diastolic blood pressure in sildenafil group was 76 ± 6 mmHg versus 73 ± 7 mmHg. in placebo group (p value >0.05) . (Table 4)(Figure 7)

Results

Table (4): Baseline characteristic

			mean	Std. deviation	P value
Age years	total		56years	9	>0.05
	sildenafil		56 years	9	
	placebo		55 years	7	
Sex No(%)	Male	sildenafil	9 (45%)		
		placebo	9 (45%)		
	Female	sildenafil	11(55%)		
		placebo	11(55%)		
Heart rate b pm	Total		83 b pm	8	>0.05
	sildenafil		83 b pm	8	
	placebo		83 b pm	8	
Systolic blood P mmHg	total		119 mmHg	8	>0.05
	sildenafil		121mmHg	8	
	placebo		117mmHg	8	
Diastolic blood P mmHg	total		74 mmHg	7	>0.05
	sildenafil		76 mmHg	6	
	placebo		72 mmHg	7	

The mean heart rate after six weeks was 84 ± 9 b pm ,the mean heart rate in sildenafil group was 86 ± 9 b pm versus 83 ± 9 b pm in placebo group (p value >0.05).

The mean systolic blood pressure after six weeks was 119 ± 7 mmHg, the mean systolic blood pressure in sildenafil group was 115 ± 7 mmHg versus 117 ± 8 mmHg in placebo group (p value >0.05).

The mean diastolic blood pressure after six weeks was 71 ± 5 mmHg, the mean diastolic blood pressure in sildenafil group was 71 ± 6 mmHg versus 72 ± 5 mmHg in placebo group(p value >0.05)(table 5)(figure 7).

Results

Table (5): Hemodynamic parameters after six weeks.

		mean	Std. deviation	P value
Heart rate bpm	total	84 b pm	9	>0.05
	sildenafil	86 b pm	9	
	placebo	83 b pm	9	
Systolic blood P mmHg	total	119 mmHg	7	>0.05
	sildenafil	115 mmHg	7	
	placebo	117 mmHg	8	
Diastolic blood P mmHg	total	71mmHg	5	>0.05
	sildenafil	71 mmHg	6	
	placebo	72 mmHg	5	

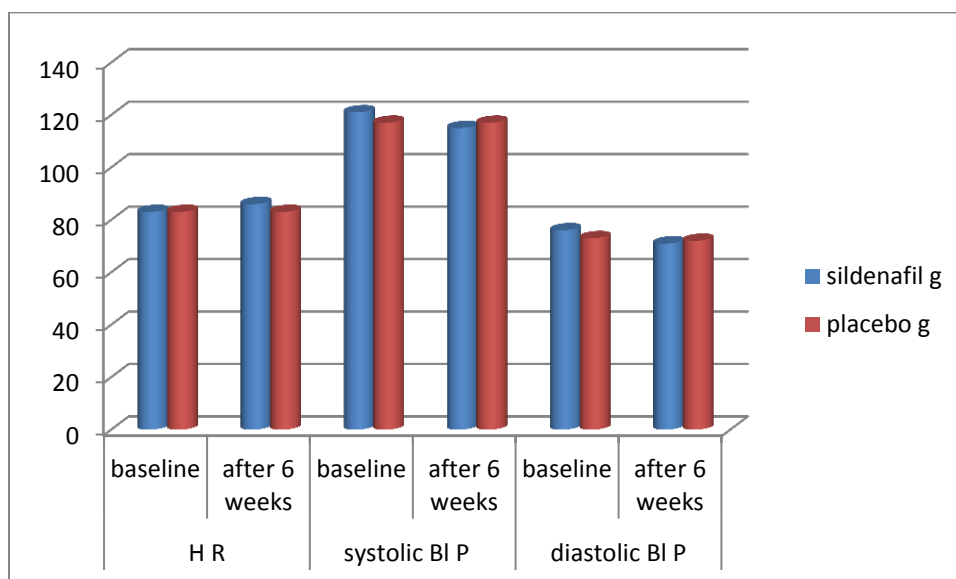


Figure (7) Hemodynamic parameters at baseline and after 6 weeks

Aetiology of pulmonary hypertension

The aetiologies of pulmonary hypertension were rheumatic valvular heart disease in 8 patients (20%) ,chronic thromboemblic pulmonary hypertension 8 patients (20%), chronic obstructive pulmonary disease in 8 patients (20%) ,interstitial pulmonary fibrosis in 8 patients (20%) and non ischemic dilated cardiomyopathy in 8 patients (20%).

Each group was divided to equal subgroup according to the aetiology of secondary pulmonary hypertension.(table 6)

Table 6: Etiology of pulmonary hypertension:

Aetiology of pulmonary hypertension	Study patients%
rheumatic valvular heart disease	20%
chronic thromboemblic pulmonary hypertension	20%
chronic obstructive pulmonary disease	20%
interstitial pulmonary fibrosis	20%
non ischemic dilated cardiomyopathy	20%

Echocardiographic data.

The mean pulmonary artery systolic pressure (PASP) significantly decreased in sildenafil group from base line 59 ± 7 mmHg to 43 ± 4 mmHg after six weeks (p value < 0.01), in addition, ejection fraction increased from baseline $53\% \pm 13$ to $59\% \pm 12$ after six weeks but did not reach statistically significant difference (p value > 0.05). (table 7)(figure 8)(figure 9).

The pulmonary artery systolic pressure did not change in placebo group from baseline 54 ± 7 mmHg to 53 ± 7 mmHg after six weeks (p value > 0.05), in addition, ejection fraction did not change from baseline 54 ± 7 at baseline versus 54 ± 14 after six weeks (p value > 0.05) (table 7)(figure 8)(figure 9).

Between groups analysis showed a significant decrease of pulmonary artery systolic pressure in sildenafil patients after 6 weeks compared to placebo patients (p value < 0.01), Ejection fraction was higher in sildenafil group compared to placebo group, but did not reach statistical significance. (p value > 0.05) (table 7)(figure 8)(figure 9).

Results

Table (7): Echocardiography data at base line and after six weeks on sildenafil and placebo group:

			mean	Std. deviation	P valu
Pulmonary artery systolic pressure mmHg	Base line	total	56 mmHg	7	>0.05
		sildenafil	59 mmHg*	7	
		placebo	54 mmHg	7	
	After 6 weeks	total	48 mmHg	7	<0.05
		sildenafil	43 mmHg*	4	
		placebo	53 mm Hg	7	
Ejection fraction%	Base line	total	54%	13	>0.05
		sildenafil	53%	13	
		placebo	54%	13	
	After 6 weeks	total	56%	13	>0.05
		sildenafil	59%	12	
		placebo	54%	14	

*within group comparison from baseline and after 6 weeks show significant decrease in pulmonary artery systolic pressure in sildenafil group .P value <0.01.

Results

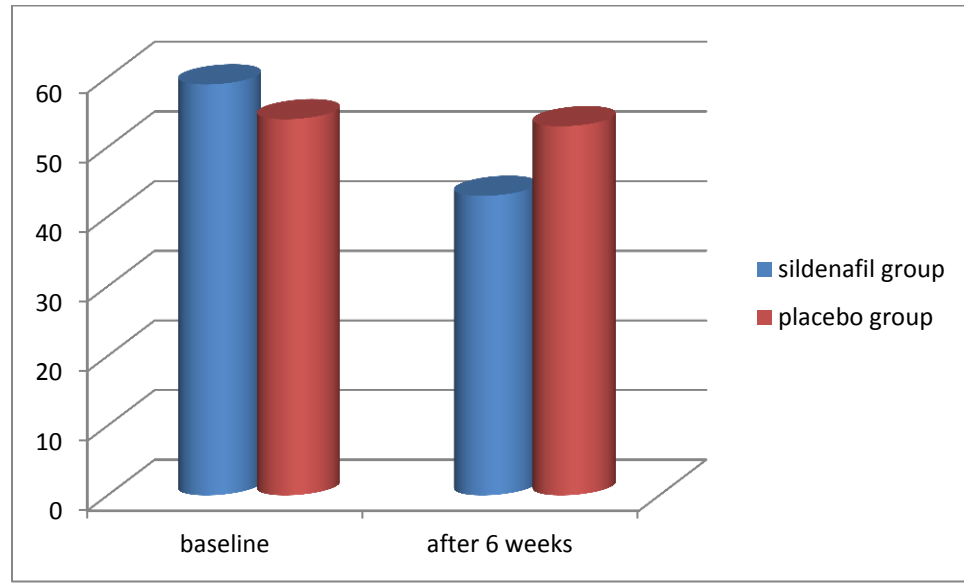
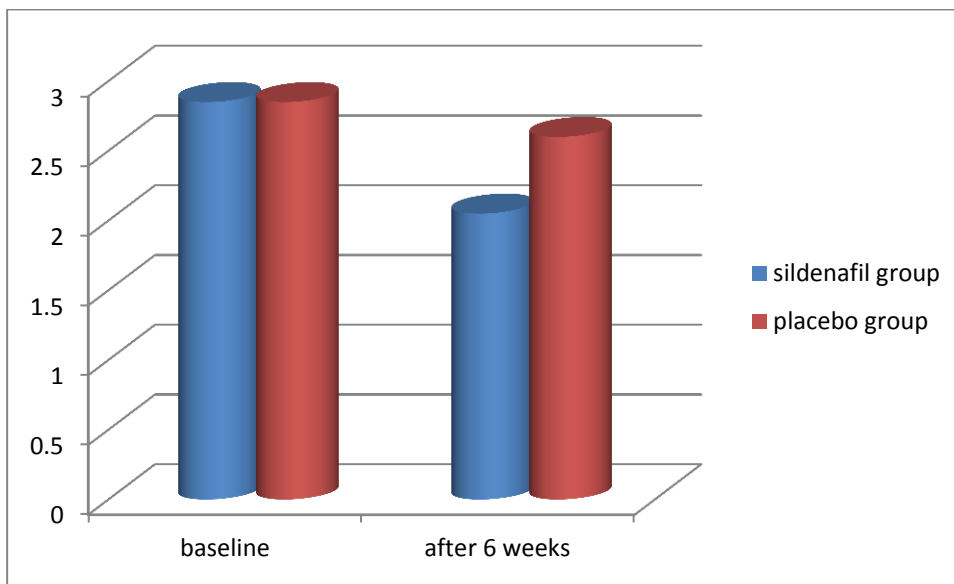


Figure (8)PASP at baseline and after 6 weeks on sildenafil and placebo groups



Figure(9)Ejection fraction % at baseline and after 6 weeks on sildenafil and placebo group

Functional status: The New York Heart Association classification data (NYHA)

The mean NYHA class in sildenafil group and placebo group at baseline was 2.85 ± 0.36 (p value >0.05), the mean NYHA after six weeks in sildenafil group was 2.05 ± 0.5 versus 2.6 ± 0.6 in placebo group (p value $=0.02$).

At baseline in sildenafil group 17(85%) patients had NYHA class 3, and 3(15%) patients had NYHA class 2, after six weeks there was 3 patients had NYHA class 3(15%), 15 patients had NYHA class 2(75%) and 2 patients had NYHA class 1(10%). 75% of patients had ≥ 1 class improvement from baseline. (Table 8)(Figure 10).

At base line in placebo group 17 patients had NYHA class 3 (85%) and 3 patients NYHA class 2(15%), after six weeks there was 13 patients had NYHA class 3(65%), 6 patients NYHA class 2(30%) and 1 patient NYHA class 1(5%), 20% of patients had ≥ 1 class improvement from baseline. (table 8)(figure 10).

Results

Table (8):NYHA changes from baseline to six weeks.

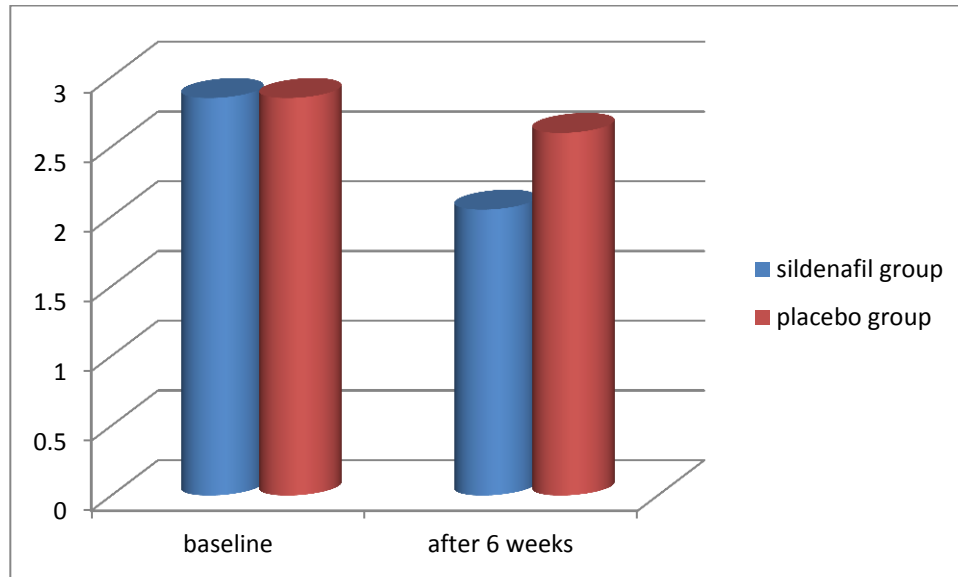
variable	sildenafil	placebo	p
Mean NYHA class at base line	2.85*±0.36	2.85±0.36	>0.05
Mean NYHA class after 6 weeks	2.05*±0.5	2.6±0.6	=0.02
Class at base line			
Class 3 No.&%.	17(85%)**	17(85%)	
Class 2 No. &%	3(15%)*	3(15%)	
Class after 6 weeks			
Class3 No. &%	3(15%)*	13(65%)	<0.01
Class2 No. &%	15(75%)*	6(30%)	<0.05
Class 1 No. &%	2(10%)	1(5%)	<0.05
One or more class improvement %	75%	20%	<0.01

*In sildenafil group significant decrease in mean N Y H A class from baseline (p value <0.05).

** In sildenafil group significant decrease on number N Y H A class 3 from 17 at baseline to 3 after 6 weeks (p value <0.01).

*** In sildenafil group significant increase on number N Y H A class 2 from 3 at baseline to 15 after 6 weeks (p value <0.01).

Results



Figure(10)Mean N Y H A class at baseline and after 6 weeks on sildenafil and placebo groups.

Subgroup analysis :

According to the etiology of secondary pulmonary hypertension patients divided to equal subgroups.

Rheumatic valvular heart disease

The total mean age was 48 ± 7 years old, the mean age in sildenafil group was 47 ± 6 versus 48 ± 9 in placebo group (p value >0.05), all patients were females.

At baseline the mean heart rate in sildenafil group was 83 ± 8 bpm versus 85 ± 7 bpm in placebo group (P value >0.05), the mean systolic blood pressure in sildenafil group was 119 ± 9 mmHg versus 121 ± 9 mmHg in placebo group (P value >0.05), the mean diastolic blood pressure in sildenafil group was 76 ± 5 mmHg versus in placebo group 74 ± 5 mmHg (P value >0.05). (Table 9).

After six weeks the mean heart rate in sildenafil group was 87 ± 8 bpm versus 84 ± 7 bpm on placebo group (P value >0.05), the mean systolic blood

Results

pressure in sildenafil group was 113 ± 6 mmHg versus 120 ± 12 mmHg in placebo group (P value >0.05), the mean diastolic blood pressure in sildenafil group was 73 ± 5 mmHg versus 74 ± 5 mmHg in placebo group (P value >0.05). (Table 9)(Figure 11).

The pulmonary artery systolic pressure decreased significantly in sildenafil group from baseline (63 ± 8 mmHg) to (42 ± 5 mmHg) at 6 weeks (p value <0.01), in addition, ejection fraction increased significantly in sildenafil group from baseline ($60\% \pm 6$) to ($65\% \pm 4$) at 6 weeks (p value <0.05).

In placebo group there was no significant changes in pulmonary artery systolic pressure from baseline (59 ± 10 mmHg) to (57 ± 10 mmHg) at 6 weeks (p value >0.05), in addition, ejection fraction decreased from baseline ($63\% \pm 5$) to ($62.5\% \pm 8$) at 6 weeks but did not reach statistically significant difference (p value >0.05). (Table 9)(Figure 11).

After six weeks pulmonary artery systolic pressure was significantly lower in sildenafil group (42 mmHg) compared to placebo group (57 mmHg) (P value <0.05). Although EF% was higher on sildenafil group (65%) but did not reach statistical significance compared to placebo group (63%) (p value >0.05). (table 9)(figure 11).

The mean NYHA class was 2.625 ± 0.2 in all patients, sildenafil group was 2.75 ± 0.5 versus 2.75 ± 0.5 in placebo group (p value >0.05). After six weeks mean NYHA class decreased in sildenafil group to (2 ± 0.5) compared to placebo group (2.5 ± 0.6) but did not reach statistical significance (p value >0.05). Compared to baseline NYHA class improved on sildenafil group (p value <0.05), but not in placebo group (p value >0.05).

75% of patients in sildenafil group versus 25% of patients in placebo group improved ≥ 1 functional class compared to baseline (p value <0.05). (Table 9)(Figure 12)

Results

Table (9): Hemodynamic, echocardiography and functional parameters in patients with pulmonary hypertension secondary to valvular disease.

		group	N	Mean	Std. Deviation	P value
Base line	HR b pm	placebo	4	85	7	>0.05
		Sildenafil	4	83	8	
	Systolic BP mmHg	placebo	4	12	9	>0.05
		Sildenafil	4	119	9	
	Diastolic BP mmHg	placebo	4	74	5	>0.05
		Sildenafil	4	76	5	
	NYHA class	placebo	4	2.75	0.5	>0.05
		Sildenafil	4	2.75*	0.5	
	PASP mmHg	placebo	4	59.	10	>0.05
		Sildenafil	4	63**	8	
	EF %	placebo	4	63	5	>0.05
		Sildenafil	4	60***	6	
After 6 weeks	HR b pm	placebo	4	84	7	>0.05
		Sildenafil	4	87	8	
	Systolic BP mmHg	placebo	4	120	12	>0.05
		Sildenafil	4	113	6	
	Diastolic BP mmHg	placebo	4	74	5	>0.05
		Sildenafil	4	73	5	
	NYHA class	placebo	4	2.50	0.6	>0.05
		Sildenafil	4	2*	0.5	
	PASP mmHg	placebo	4	57	10	<0.05
		Sildenafil	4	42**	5	
	EF %	placebo	4	63	8	>0.05
		Sildenafil	4	65***	4	

*significant decrease in NYHA class in sildenafil group. (P value <0.05)

Results

** Significant decrease in PASP in sildenafil group. (P value <0.01)

***Significant increase in E F % in sildenafil group. (P value <0.05)

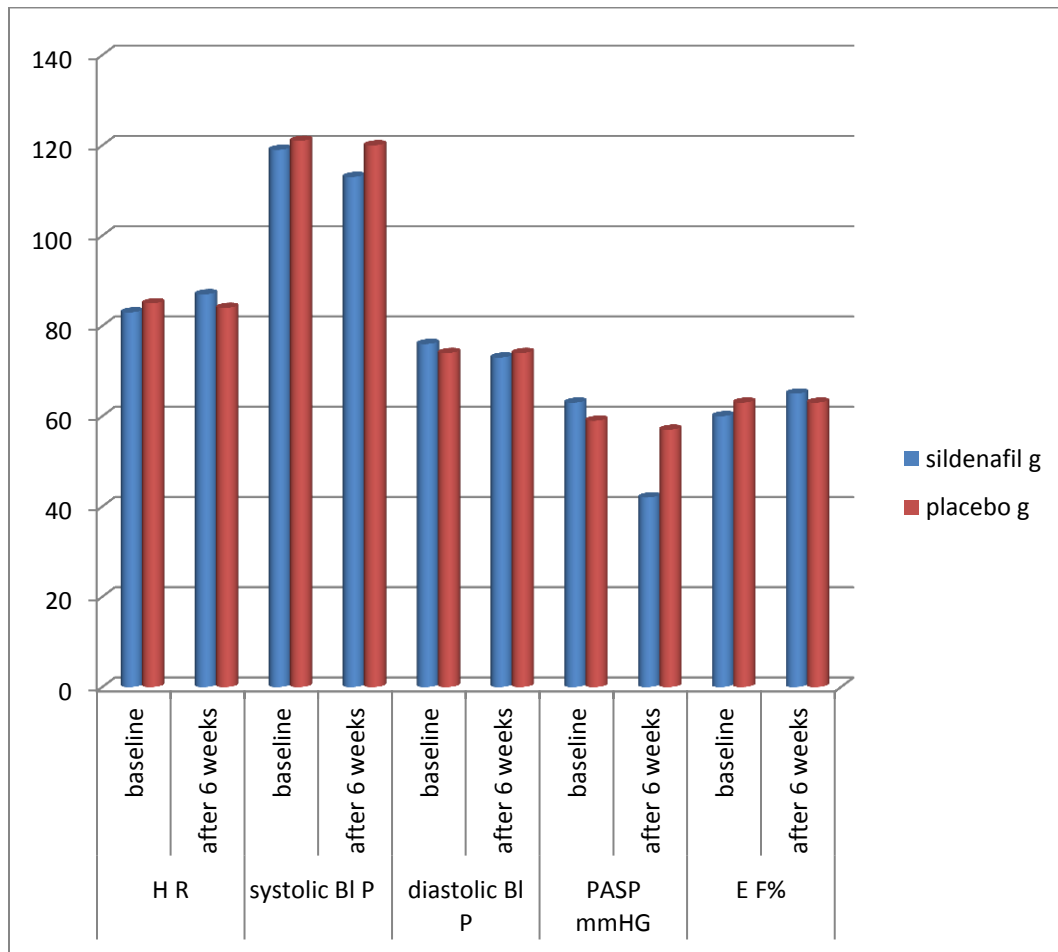


Figure (11) Hemodynamic and echocardiography parameters at baseline to 6 weeks

Results

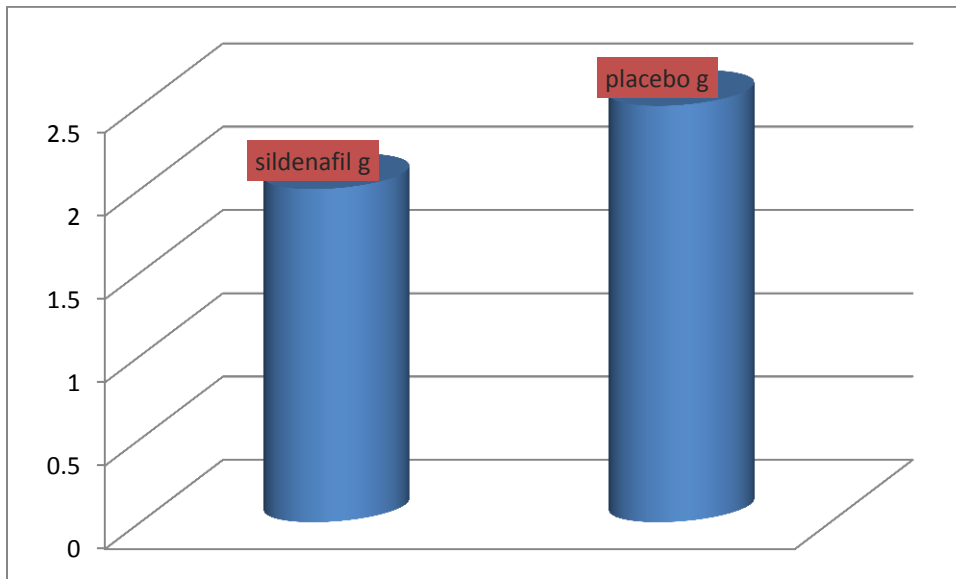


Figure (12) Functional class at six weeks

Chronic thromboembolic pulmonary disease

The mean total age was 59 years old, the mean age in sildenafil group was 60 ± 4 years old versus 58 ± 4 in placebo group (p value > 0.05), 50% were female and 50% were male.

At base line the mean heart rate in sildenafil group was $80 \text{ bpm} \pm 6$ versus 83 ± 6 bpm in placebo group (P value > 0.05), the mean systolic blood pressure on sildenafil group was $124 \pm 5 \text{ mmHg}$ versus $122 \pm 5 \text{ mmHg}$ in placebo group (P value > 0.05), the mean diastolic blood pressure on sildenafil group was $73 \pm 3 \text{ mmHg}$ versus $75 \pm 7 \text{ mmHg}$ in placebo group (P value > 0.05). (Table 10)(Figure 13)

After six weeks the mean heart rate in sildenafil group was $80 \pm 5 \text{ bpm}$ versus $82 \pm 9 \text{ bpm}$ in placebo group (P value > 0.05), the mean systolic blood pressure in sildenafil group was $114 \pm 5 \text{ mmHg}$ versus $116 \pm 5 \text{ mmHg}$ on placebo group (P

Results

value >0.05) , the mean diastolic blood pressure on sildenafil group was 71 ± 3 mmHg versus 70 ± 6 mmHg on placebo group (P value >0.05). (Table 10)(Figure 13).

The pulmonary artery systolic pressure decreased significantly in sildenafil group from base line 59 ± 3 mmHg to 43 ± 3 mmHg after six weeks (p value <0.01), in addition, ejection fraction increased in sildenafil group from base line $59\%\pm 2$ to $62\%\pm 2$ after six weeks but not reach statistically significant difference (p value >0.05) . (Table 10)(Figure 13)

In placebo group there was no significant changes in pulmonary artery systolic pressure from base line 54 ± 3 mmHg to 54 ± 4 mmHg after six weeks (p value >0.05), in addition, ejection fraction decreased from base line ($59\%\pm 3$) to ($56\%\pm 4$) at 6 weeks but did not reach statistically significant difference (p value > 0.05). (Table 10)(Figure 13)

After six weeks pulmonary artery systolic pressure was significantly lower in sildenafil group (43 mmHg) compared to placebo group (54 mmHg) (P value <0.01). Although EF% was higher on sildenafil group (62%) but did not reach statistical significant compared to placebo group (56%) (p value >0.05). (table 10)(figure 13)

The mean NYHA class was 2.75 ± 0.2 in all patients , sildenafil group was 2.75 ± 0.2 versus 2.75 ± 0.2 in placebo group (p value >0.05). After six weeks mean NYHA class decreased in sildenafil group to 2 ± 0.5 compared to 2.5 ± 0.5 in placebo group but not reach statistical significantly (p value >0.05). Compared to baseline NYHA class improved in sildenafil group (p value <0.05). but not in placebo group (p value >0.05). (Table 10)(Figure 14)

75% of patient in sildenafil group versus 25% of patient in placebo group improved ≥ 1 functional class compared to baseline (p value <0.05).

Results

Table (10): Hemodynamic, echocardiography and functional parameters in patients with pulmonary hypertension secondary to thromboembolic disease.

			N	Mean	Std. Deviation	P
Base line	HR b pm	placebo	4	83	6	>0.05
		Sildenafil	4	80	6	
	Systolic BP mmHg	placebo	4	122	5	>0.05
		Sildenafil	4	124	5	
	Diastolic BP mmHg	placebo	4	75	7	>0.05
		Sildenafil	4	73	3	
	NYHA class	placebo	4	2.75	0.5	>0.05
		Sildenafil	4	2.75*	0.5	
	PASP mmHg	placebo	4	54	3	>0.05
		Sildenafil	4	59**	3	
	EF %	placebo	4	59	3	>0.05
		Sildenafil	4	59	2	
After 6 weeks	HR b pm	placebo	4	82	9	>0.05
		Sildenafil	4	80	5	
	Systolic BP mmHg	placebo	4	116	5	>0.05
		Sildenafil	4	114	5	
	Diastolic BP mmHg	placebo	4	71	6	>0.05
		Sildenafil	4	70	3	
	NYHA class	placebo	4	2.5	.5	>0.05
		Sildenafil	4	2*	.5	
	PASP mmHg	placebo	4	54	4	<0.01
		Sildenafil	4	43**	3	
	EF %	placebo	4	56	4	>0.05
		Sildenafil	4	62	2	

* Significant decrease in NYHA class in sildenafil group .(p value <0.05)

Results

****Significant decrease in PASP in sildenafil group. (p value <0.01)**

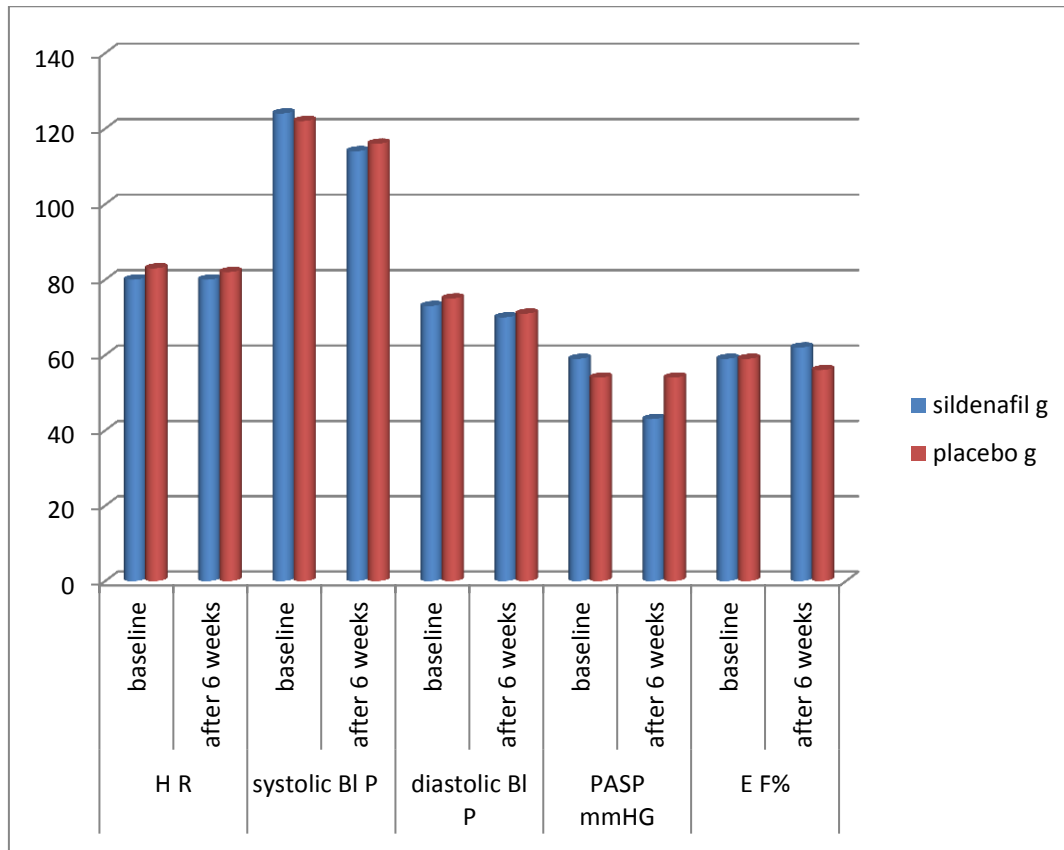
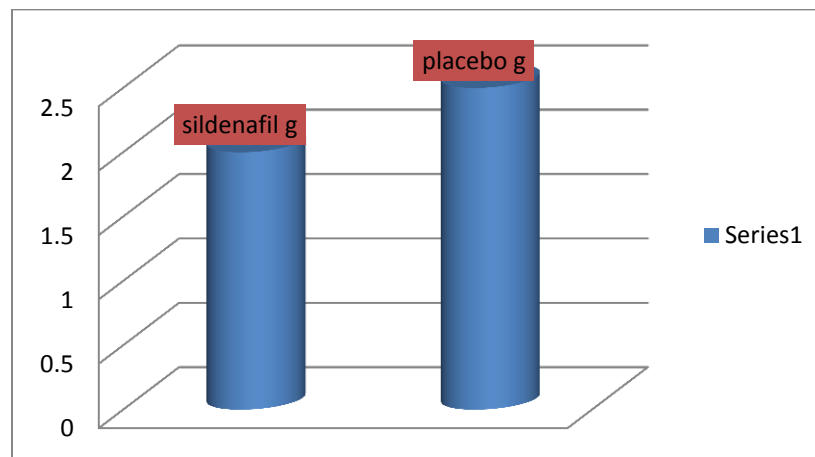


Figure (13) Hemodynamic and echocardiography parameters at baseline to 6 weeks



Figure(14) Functional class at six weeks

Results

Interstitial pulmonary fibrosis (I P F)

The mean total age was 56 ± 5 years old, the mean age in sildenafil group was 58 ± 5 versus 54 ± 6 in placebo group and 6(75%) were female, 2(25%) were male.

At baseline the mean heart rate in sildenafil group was 89 ± 6 b pm versus 85 ± 9 b pm in placebo group (P value > 0.05), the mean systolic blood pressure in sildenafil group was 128 ± 6 mmHg versus 120 ± 8 mmHg in placebo group (P value > 0.05), the mean diastolic blood pressure in sildenafil group was 80 ± 10 mmHg versus on placebo group 75 ± 11 mmHg (P value > 0.05). (table 11)(figure 15).

After six weeks the mean heart rate in sildenafil group was 92 ± 4 bpm versus 84 ± 10 bpm in placebo group (P value > 0.05), the mean systolic blood pressure in sildenafil group was 121 ± 5 mmHg versus 124 ± 9 mmHg in placebo group (P value > 0.05), the mean diastolic blood pressure in sildenafil group was 74 ± 8 mmHg versus 79 ± 3 mmHg in placebo group (P value > 0.05). (Table 11)(Figure 15).

The pulmonary artery systolic pressure decreased significantly in sildenafil group from baseline (66 ± 8) mmHg to (46 ± 5) mmHg after six weeks (p value < 0.01), in addition, ejection fraction increased in sildenafil group from base line ($63\% \pm 2$) to ($67\% \pm 2$) after six weeks not reach statistical significant (p value > 0.05). (Table 11)(Figure 15).

In placebo group there was no significant changes in PASP from baseline 59 ± 4 mmHg to 58 ± 5 mmHg after six weeks (p value > 0.05), in addition, ejection fraction increased from base line ($60\% \pm 4$) to ($61\% \pm 3$) after six weeks but did not reach statistically significant difference (p value > 0.05). (Table 11)(Figure 15).

After six weeks PASP was significantly lower in sildenafil group (46 mmHg) compared to placebo group (58.25 mmHg) (P value < 0.01). Although EF% was

Results

higher on sildenafil group (67%) but did not reach statistical significant compared to placebo group (61%) (p value >0.05). (Table 11)(Figure 15).

The mean NYHA class was 3 in all patients, sildenafil group was 3 ± 0.2 versus 3 ± 0.2 in placebo group (p value >0.05). After six weeks mean NYHA class decreased in sildenafil group to 2.25 ± 0.5 compared to placebo group 2.75 ± 0.65 but not reach statistical significantly (p value >0.05). Compared to baseline NYHA class improved on sildenafil group (p value <0.05). but not in placebo group (p value >0.05). (Table 11)(Figure 16).

75% of patients in sildenafil group versus 25% of patient in placebo group improved ≥ 1 functional class compared to baseline (p value <0.05).

Results

Table(11): Hemodynamic, echocardiography and functional parameters in patients with pulmonary hypertension secondary toIPF.

		group	N	Mean	Std. Deviation	P value
Base line	HR b pm	placebo	4	85	9	>0.05
		Sildenafil	4	89	6	
	Systolic BP mmHg	placebo	4	120	8	>0.05
		Sildenafil	4	129	6	
	Diastolic BP mmHg	placebo	4	75	11	>0.05
		Sildenafil	4	80	10	
	NYHA class	placebo	4	3	0.2	>0.05
		Sildenafil	4	3*	0.2	
	PASP mmHg	placebo	4	59	4	>0.05
		Sildenafil	4	66**	8	
	EF %	placebo	4	60	4	>0.05
		Sildenafil	4	63	2	
After 6 weeks	HR b pm	placebo	4	84	10	>0.05
		Sildenafil	4	92	4	
	Systolic BP mmHg	placebo	4	124	9	>0.05
		Sildenafil	4	121	5	
	Diastolic BP mmHg	placebo	4	79	3	>0.05
		Sildenafil	4	74	8	
	NYHA class	placebo	4	2.75	0.65	>0.05
		Sildenafil	4	2.25*	0.5	
	PASP mmHg	placebo	4	58	5	<0.05
		Sildenafil	4	46**	5	
	EF %	placebo	4	61.	3	>0.05
		Sildenafil	4	67	2	

Results

* Significant decrease in NYHA class in sildenafil group .(p value <0.05)

**Significant decrease in PASP in sildenafil group. (p value <0.01)

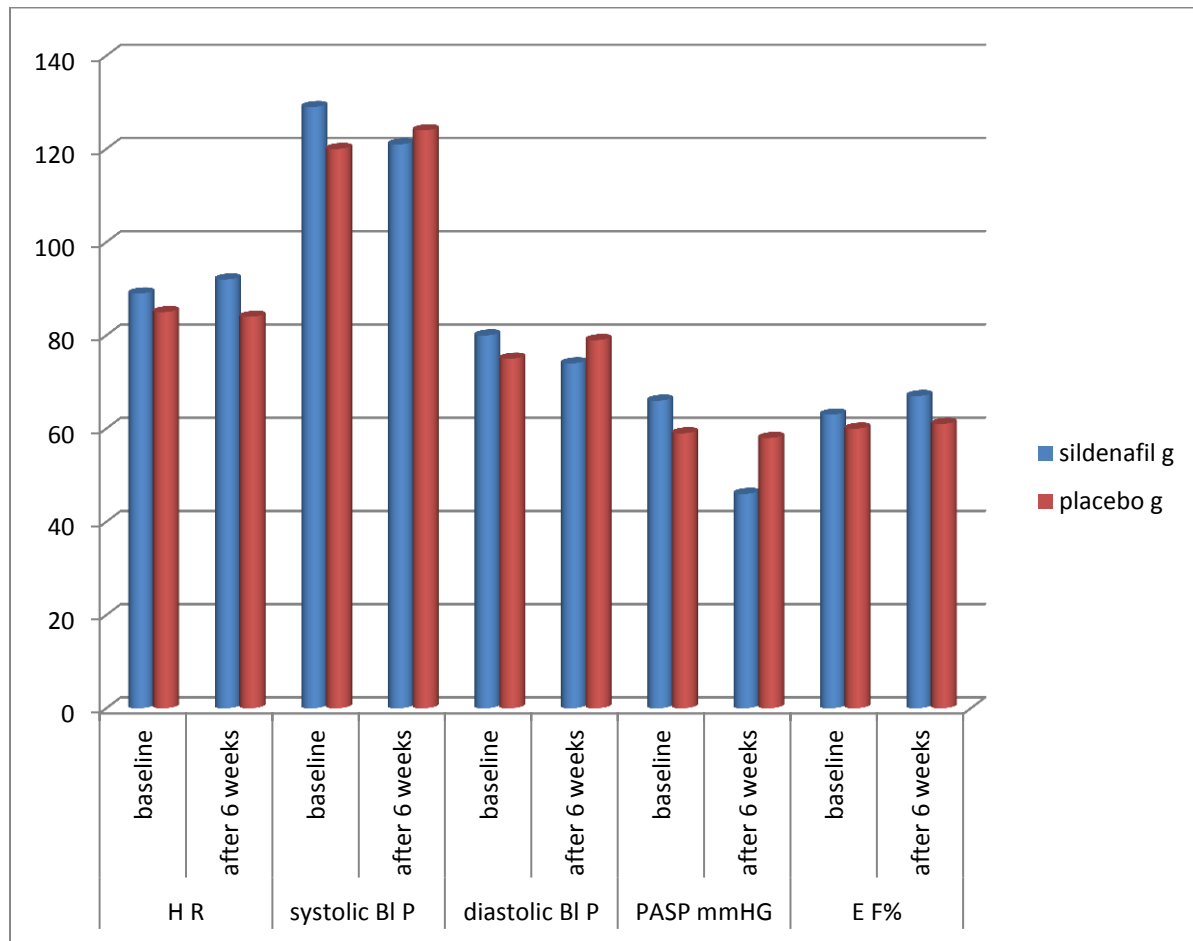


Figure (15) Hemodynamic and echocardiography parameters at baseline to 6 weeks

Results

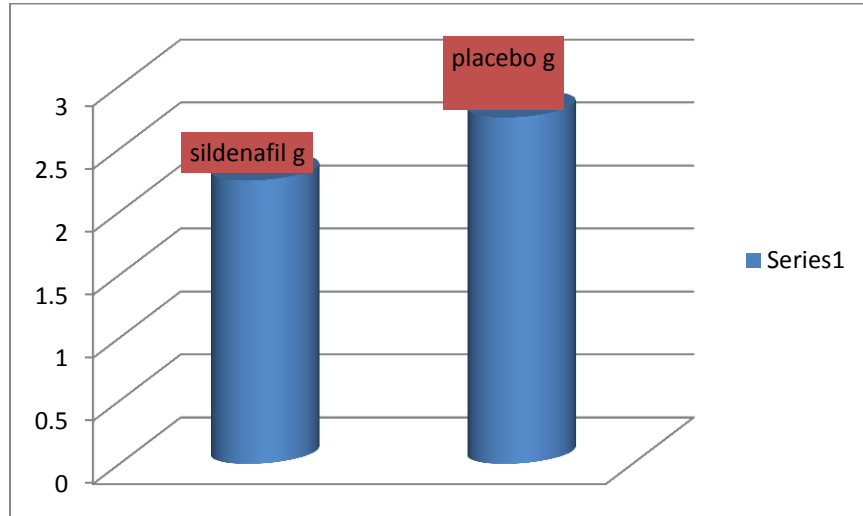


Figure (16) **Functional class at six weeks**

Chronic obstructive pulmonary disease(C O P D)

The mean total age was 60 ± 5 years old, the mean age in sildenafil group was 58 ± 4 versus 61 ± 5 in placebo group, 4(50%) female and 4 (50%) male.

At baseline the mean heart rate on sildenafil group was 87 ± 8 b pm versus 89 ± 5 b pm in placebo group (P value > 0.05), the mean systolic blood pressure in sildenafil group was 116 ± 5 mmHg versus 119 ± 9 mmHg in placebo group (P value > 0.05), the mean diastolic blood pressure in sildenafil group was 74 ± 5 mmHg versus in placebo group 73 ± 5 mmHg (P value > 0.05). (Table 12)(Figure 17)

After six weeks the mean heart rate in sildenafil group was 90 ± 7 b pm versus 90 ± 6 b pm in placebo group (P value > 0.05), the mean systolic blood pressure in sildenafil group was 110 ± 7 mmHg versus 118 ± 9 mmHg in placebo group (P value > 0.05), the mean diastolic blood pressure on sildenafil group was 69 ± 6 mmHg versus 71 ± 5 mmHg in placebo group (P value > 0.05). (Table 12)(Figure 17)

Results

The pulmonary artery systolic pressure decreased significantly in sildenafil group from baseline 57 ± 6 mmHg to 41 ± 4 mmHg after six weeks (p value < 0.01), in addition, ejection fraction increased in sildenafil group from baseline $56\% \pm 4$ after six weeks to $61\% \pm 3$ not reach statistical significant (p value > 0.05). (Table 12)(Figure 17)

In placebo group there was no significant changes in pulmonary artery systolic pressure from baseline 58 ± 6 mmHg to 54 ± 3 mmHg after six weeks (p value > 0.05), in addition, ejection fraction increased from base line $56\% \pm 5$ to $59\% \pm 7$ after six weeks but did not reach statistically significant difference (p value > 0.05). (Table 12)(Figure 17)

After six weeks pulmonary artery systolic pressure was significantly lower in sildenafil group (41 mmHg) compared to placebo group (54 mmHg) (P value < 0.01). Although EF% higher on sildenafil group (61%) but did not reach statistical significant compared to placebo group (59%) (p value > 0.05). (table 12)(figure 17)

The mean NYHA class was 2.75 ± 0.6 , sildenafil group was 2.75 ± 0.6 versus 2.75 ± 0.5 in placebo group (p value > 0.05). After six weeks mean NYHA class decreased in sildenafil group to 2 ± 0.5 compared to placebo group 2.5 ± 0.6 but not reach statistical significantly (p value > 0.05). Compared to baseline NYHA class improved on sildenafil group (p value < 0.05). but not in placebo group (p value > 0.05). (Table 12)(Figure 18)

75% of patients in sildenafil group versus 25% of patients in placebo group improved ≥ 1 functional class compared to baseline (p value < 0.05).

Results

Table (12) Hemodynamic, echocardiography and functional parameters in patients with pulmonary hypertension secondary to COPD.

		group	N	Mean	Std. Deviation	p
Base line	HR b pm	placebo	4	89	5	>0.05
		Sildenafil	4	87	8	
	Systolic BP mmHg	placebo	4	119	9	>0.05
		Sildenafil	4	116	5	
	Diastolic BP mmHg	placebo	4	73	5	>0.05
		Sildenafil	4	74	5	
	NYHA class	placebo	4	2.75	0.6	>0.05
		Sildenafil	4	2.75*	0.5	
	PASP mmHg	placebo	4	58	6	>0.05
		Sildenafil	4	57**	6	
	EF %	placebo	4	58	5	>0.05
		Sildenafil	4	56	4	
After 6 weeks	HR b pm	placebo	4	90	6	>0.05
		Sildenafil	4	90	7	
	Systolic BP mmHg	placebo	4	118	9	>0.05
		Sildenafil	4	110	7	
	Diastolic BP mmHg	placebo	4	71	5	>0.05
		Sildenafil	4	69	6	
	NYHA class	placebo	4	2.50	0.6	>0.05
		Sildenafil	4	2*	0.5	
	PASP mmHg	placebo	4	54	3	<0.05
		Sildenafil	4	41**	4	
	EF %	placebo	4	59	7	>0.05
		Sildenafil	4	61	3	

* Significant decrease in NYHA class in sildenafil group .(p value <0.05)

Results

****Significant decrease in PASP in sildenafil group .(p value <0.01)**

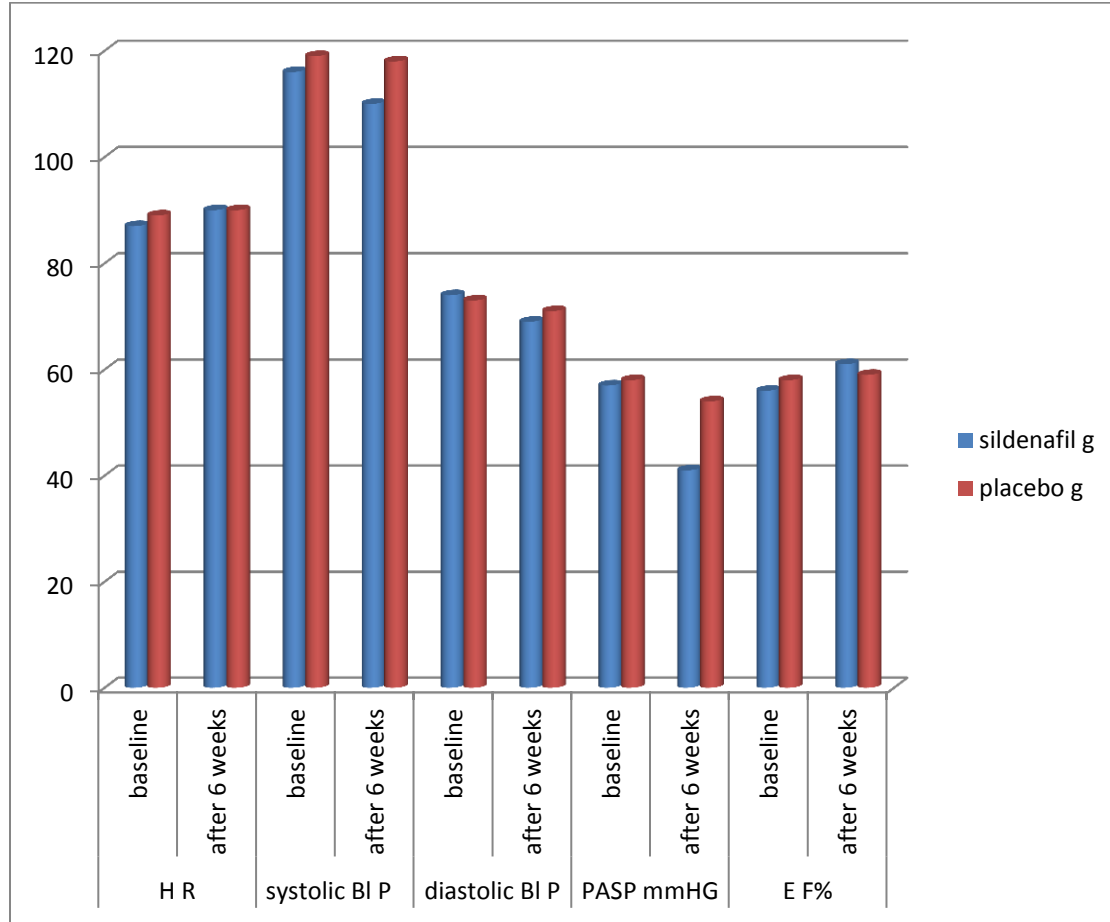


Figure (17) Hemodynamic and echocardiography parameters at baseline to 6 weeks

Results

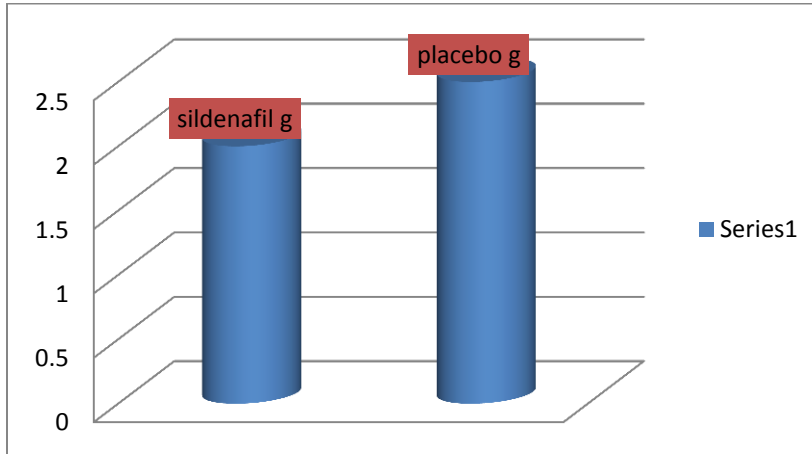


Figure (18) **Functional class at six weeks.**

Non ischaemic dilated cardiomyopathy(non I D C M)

The mean age was 59 ± 5 years old, the mean age at sildenafil group was 61 ± 5 versus 58 ± 6 on placebo group, and 2(25%) female, 6(75%) male.

At baseline the mean heart rate in sildenafil group was 78 ± 11 b pm versus 74 ± 7 b pm in placebo group (P value > 0.05), the mean systolic blood pressure in sildenafil group was 119 ± 12 mmHg versus 118 ± 5 mmHg on placebo group (P value > 0.05), the mean diastolic blood pressure in sildenafil group was 75 ± 7 mmHg versus in placebo group 70 ± 8 mmHg (P value > 0.05). (table 13)

After six weeks the mean heart rate in sildenafil group was 80 ± 12 b pm versus 75 ± 10 bpm in placebo group (P value > 0.05), the mean systolic blood pressure in sildenafil group was 113 ± 13 mmHg versus 110 ± 7 mmHg in placebo group (P value > 0.05), the mean diastolic blood pressure in sildenafil group was 71 ± 6 mmHg versus 68 ± 8 mmHg on placebo group (P value > 0.05). (Table 13)(Figure 19)

The mean pulmonary artery systolic pressure decreased significantly in sildenafil group from base line 54 ± 4 mmHg to 44 ± 2 mmHg after six weeks (p value < 0.05), in addition, ejection fraction increased in sildenafil group from

Results

baseline $27\% \pm 4$ to $35\% \pm 5$ after six weeks not reach statistical significant (p value > 0.05). (Table 13)(Figure 19)

In placebo group there was no significant changes in pulmonary artery systolic pressure from baseline 51 ± 3 mmHg to 49 ± 2 mmHg after six weeks (p value > 0.05), in addition, ejection fraction decreased from baseline $30\% \pm 4$ to $29\% \pm 6$ after six weeks but did not reach statistically significant difference (p value > 0.05). (Table 13)(Figure 19)

After six weeks pulmonary artery systolic pressure was significantly lower in sildenafil group (44 mmHg) compared to placebo group (49 mmHg) (P value < 0.05). Although EF% was higher on sildenafil group (35%) but did not reach statistical significant compared to placebo group (29%) (p value > 0.05). (table 12)(figure 13)

The mean NYHA class was 3 ± 0.2 , sildenafil group was 3 ± 0.2 versus 3 ± 0.2 in placebo group (p value > 0.05). After six weeks mean NYHA class decreased in sildenafil group to 2 ± 0.2 compared to placebo group 2.75 ± 0.3 but not reach statistical significantly (p value > 0.05). Compared to baseline NYHA class improved on sildenafil group (p value < 0.05). but not in placebo group (p value > 0.05) (table 13) (figure 20)

100% of patients in sildenafil group versus 25% of patients in placebo group improved ≥ 1 functional class compared to baseline (p value < 0.05).

Results

Table (13): Hemodynamic ,echocardiography and functional parameters in patients with pulmonary hypertension secondary to non IDCM .

		group	N	Mean	Std. Deviation	p
Base line	HR b pm	placebo	4	74	7	>0.05
		Sildenafil	4	78	11	
	Systolic BP mmHg	placebo	4	118	5	>0.05
		Sildenafil	4	119	12	
	Diastolic BP mmHg	placebo	4	70	8	>0.05
		Sildenafil	4	75	7	
	NYHA class	placebo	4	3.00	0.2	>0.05
		Sildenafil	4	*3.00	0.2	
	PASP mmHg	placebo	4	51	3	>0.05
		Sildenafil	4	**54	4	
	EF %	placebo	4	30	4	>0.05
		Sildenafil	4	27	4	
After 6 weeks	HR b pm	placebo	4	75	10	>0.05
		Sildenafil	4	80	12	
	Systolic BP mmHg	placebo	4	110	7	>0.05
		Sildenafil	4	113	13	
	Diastolic BP mmHg	placebo	4	68	8	>0.05
		Sildenafil	4	71	6	
	NYHA class	placebo	4	2.75	.500	<0.05
		Sildenafil	4	*2.00	.000	
	PASP mmHg	placebo	4	49	2	<0.05
		Sildenafil	4	**44	2	
	EF %	placebo	4	29	6	>0.05
		Sildenafil	4	35	5	

* Significant decrease in NYHA class in sildenafil group .(p value <0.05)

Results

**Significant decrease in PASP in sildenafil group. (p value <0.01)

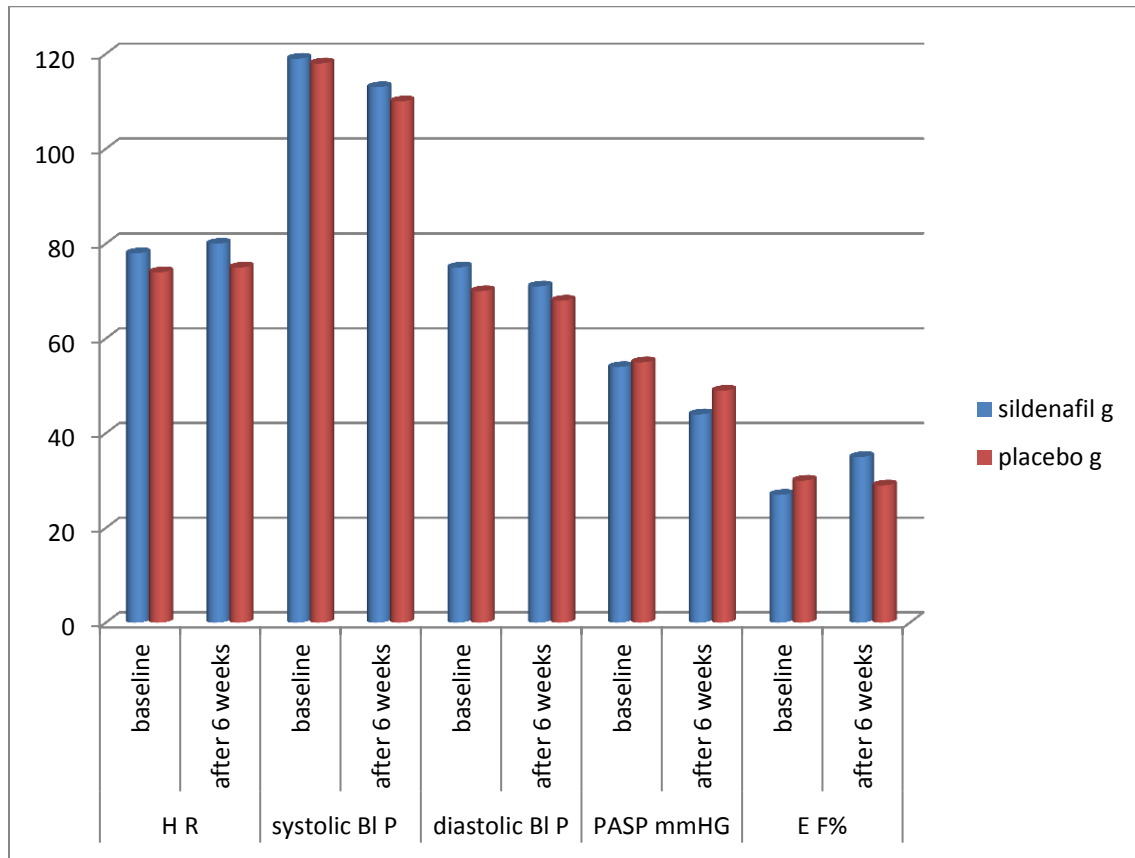


Figure (19) Hemodynamic and echocardiography parameters at baseline to 6 weeks

Results

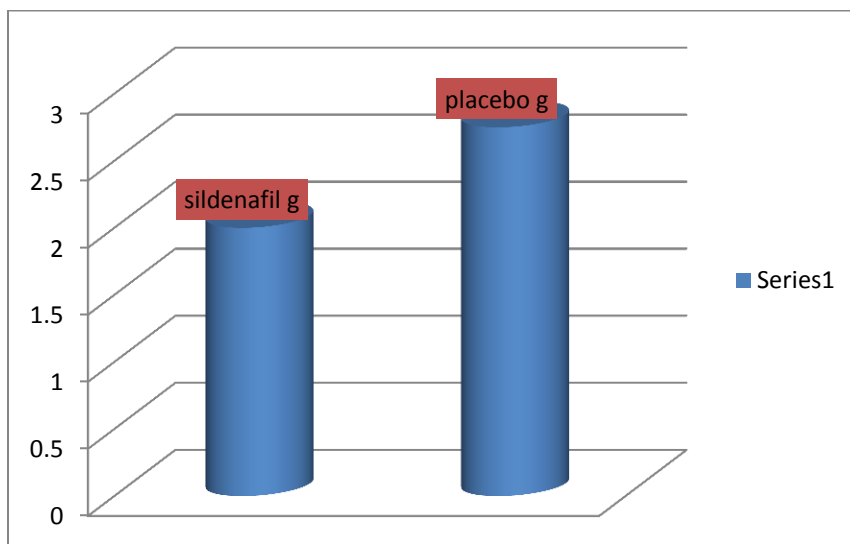


Figure (20) **Functional class at six weeks**

Side effects and tolerability of sildenafil

Two patients developed transient headaches but these symptoms resolved spontaneously, three patients experienced nausea resolved after one week of treatment spontaneously and no need to decrease the dose of sildenafil. No severe adverse events were reported.