

RESULTS

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Fifty females were included in this study. Their ages ranged from 19 to 43 years (Mean 31 ± 5.93).

Table (6) shows statistical calculation of demographic data. Single females represented 28% of the sample, while married females represented 72% of them.

Married females who had no children represented 10% of the study sample, while 62% who had children were classified as :

P1 = 12 % , P2 = 12 % , P3 = 28 % and P4 = 10 % of cases.

Demographic data:

Demographic data	No.	Age	Marital State		Parity											
			Single		Married		P ₀		P ₁		P ₂		P ₃		P ₄	
			No.	%	No	%	No	%	No.	%	No	%	No.	%	No	%
	50	Mean age = 31.1±5.93	14	28%	36	72%	5	10%	6	12%	6	12%	14	28%	5	10%

Table (6) statistical calculation of demographic data

Women who started with spironolactone:-

As regards the *somatic symptoms* : The percentage of improvement of somatic symptoms on spironolactone for the first three months was 76% which gave **significant** statistical correlation with the pretreatment. Then after placebo crossover the percentage of improvement decreased to be 58% but it gave no significant statistical difference than spironolactone.

Spironolactone use for the first three months gave **highly significant** statistical correlation with pretreatment as regard breast swelling , breast tenderness and easy fatigability, but placebo crossover for the next three months gave no significant statistical correlation to spironolactone. 64 % of patients who suffered from breast swelling improved on spironolactone this percentage decreased after placebo crossover to be 50%, 69% of patients who suffered from breast tenderness improved on spironolactone this percentage decreased to be 62% after placebo crossover and 77% of patients who suffered from easy fatigability improved on spironolactone decreased to be 67% after placebo crossover.

Also, spironolactone use for the first three months gave **significant** statistical correlation with pretreatment as regard skin changes appeared in form of greasy skin or acne vulgaris (according to the patient own words), abdominal bloating , ankle swelling, pelvic pain , headache and altered

appetite, but placebo crossover for the next three months gave no significant statistical correlation to spironolactone use. 75% of patients suffered from skin affection improved on spironolactone, decreased to 63% after placebo crossover, 100% of patients suffered from abdominal bloating improved on spironolactone, placebo crossover gave 75% improvement percentage for abdominal bloating, 100% of patients suffered from ankle swelling improved on spironolactone decreased to 50% after placebo crossover, 67% of patients suffered from pelvic pain improved on spironolactone to be decreased to 50% after placebo crossover, 60% of patients suffered from headache improved on spironolactone decreased to be 40% after placebo crossover and lastly improvement occurred on spironolactone in 100% of patients suffered from altered appetite then after placebo crossover the percentage of improvement decreased to be 80%.

Spironolactone use for the first three months gave **no significant** statistical correlation with pretreatment as regard generalized bone pain and nausea and vomiting, also placebo crossover for the next three months gave no significant statistical correlation to spironolactone. 75% of patients suffered from generalized bone pain improved on spironolactone this percentage remained as it was after placebo

crossover and 50% of patients suffered from nausea and vomiting improved on spironolactone, then after placebo crossover the percentage of improvement decreased to be 25% (Table 7) (Figure 7).

WOMEN STARTED WITH SPIRONOLACTONE

Somatic symptoms	Pretreatment	After treatment with spironolactone		% of improvement	Statistical correlation bet. Spironolactone and pretreatment		After crossover to placebo		% of improvement	Statistical correlation bet. Placebo crossover and spironolactone	
		Improved	Not improved		X ²	P	Improved	Not improved		X ²	P
Breast Swelling	14	9	5	64%	10.48	<0.001**	7	7	50%	0.15	>0.1
Breast tenderness	24	17	7	69%	24.56	<0.001**	15	9	62%	0.08	>0.1
Skin affection	8	6	2	75%	2.80	<0.05*	5	3	63%	0.00	>0.1
Abdominal bloating	4	4	0	100%	4.50	<0.01*	3	1	75%	0.00	>0.1
Ankle swelling	4	4	0	100%	4.50	<0.01*	2	2	50%	0.67	>0.1
pelvic pain	6	4	2	67%	3.38	<0.05*	3	3	50%	0.00	>0.1
Generalized bone pain	4	3	1	75%	2.13	>0.1	3	1	75%	0.67	>0.1
Headache	5	3	2	60%	3.75	<0.05*	2	3	40%	0.42	>0.1
Easy fatigue	9	7	2	77%	8.42	<0.001**	6	3	67%	0.00	>0.1
Nausea and vomiting	4	2	2	50%	0.67	>0.1	1	3	25%	0.00	>0.1
Altered appetite	5	5	0	100%	6.40	<0.01*	4	1	80%	0.00	>0.1
% of improvement of somatic symptoms				76%	3.33	<0.05*			58%	0.01	>0.05

Table (7) Somatic symptoms statistical calculations of spironolactone treatment significance in relation to pretreatment and then placebo crossover significance in relation to spironolactone. (X²-Chi-square, P- probability = 0.05, * Significant, ** Highly significant).

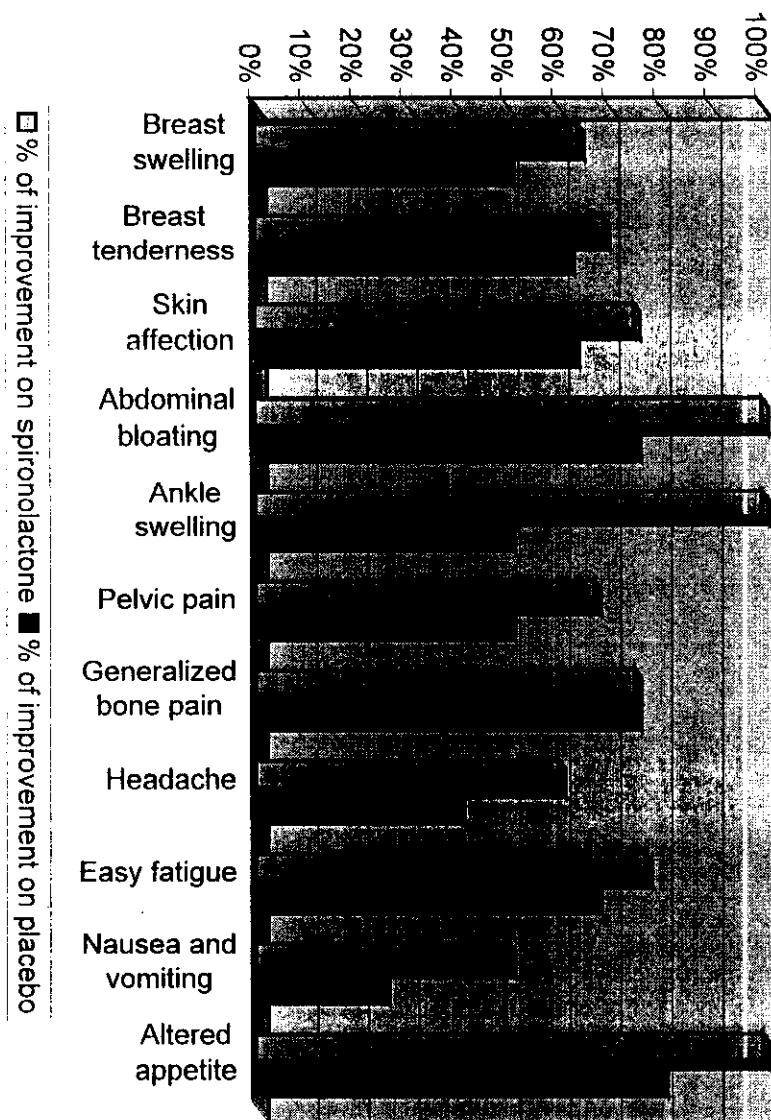


Figure (7) Comparison of somatic symptoms improvement percentages after tit with spironolactone for three months and then after placebo crossover for another three months.

Regarding *depressive symptoms*; The percentage of improvement of depressive symptoms on spironolactone for the first three months was 87% which gave statistical significant correlation with the pretreatment. Then after placebo crossover this percentage decreased to be 73% but it gave no significant statistical difference than spironolactone.

Spironolactone use for the first three months gave **highly significant** correlation with pretreatment as regard crying and anger, sad and about to burst, but placebo crossover gave no significant statistical correlation to spironolactone as regards the same symptoms. 78% of patients suffered from crying improved on spironolactone to be 56% after placebo crossover and 94% of patients suffered from anger, sad and about to burst improved on spironolactone, then after placebo crossover for the next three months the percentage of improvement decreased to be 88%.

Also, spironolactone use for the first three months, gave **significant** statistical correlation with pretreatment as regard social isolation, self depreciation, difficult concentration and hypersomnia but placebo crossover for the next three months gave no significant statistical correlation to spironolactone. The percentage of improvement of patients with social isolation on spironolactone was 100% to be decreased after

placebo crossover to be 80%, the percentage of improvement of self depreciation on spironolactone was 80% and remained as it was after placebo crossover, the percentage of improvement of difficult concentration was 67% on spironolactone decreased to 50% after placebo crossover, also the percentage of improvement of hypersomnia was 100% on spironolactone use decreased to 75% after placebo crossover (Table 8) (Figure 8).

Depressive symptoms	Pretreatment	After treatment with spirinolactone		% of improvement	Statistical correlation bet. spirinolactone and pretreatment.		After cross over to placebo.		% of improvement	Statistical correlation bet. Placebo crossover and spirinolactone	
		Improved	Not improved		X ²	P	Improved	Not improved		X ²	P
Social isolation	5	5	0	100%	6.40	<0.01*	4	1	80%	0.00	>0.1
Crying	9	7	2	78%	8.42	<0.001**	5	4	56%	0.25	>0.1
Anger, sad and about to burst	17	16	1	94%	26.56	<0.001**	15	2	88%	0.00	>0.1
Self depreciation	5	4	1	80%	3.75	<0.05*	4	1	80%	0.63	>0.1
Difficult concentration	6	4	2	67%	3.38	<0.05*	3	3	50%	0.00	>0.1
hypersomnia	4	4	0	100%	4.50	<0.01*	3	1	75%	0.00	>0.1
% of improvement of depressive symptoms		87%			5.99	<0.05*			73%	0.04	>0.05

Table (8) Depressive symptoms statistical calculations of spirinolactone treatment significance in relation to pretreatment and then placebo crossover significance in relation to spirinolactone. (X²- Chi-square, P- probability =0.05, * Significant, ** Highly significant).

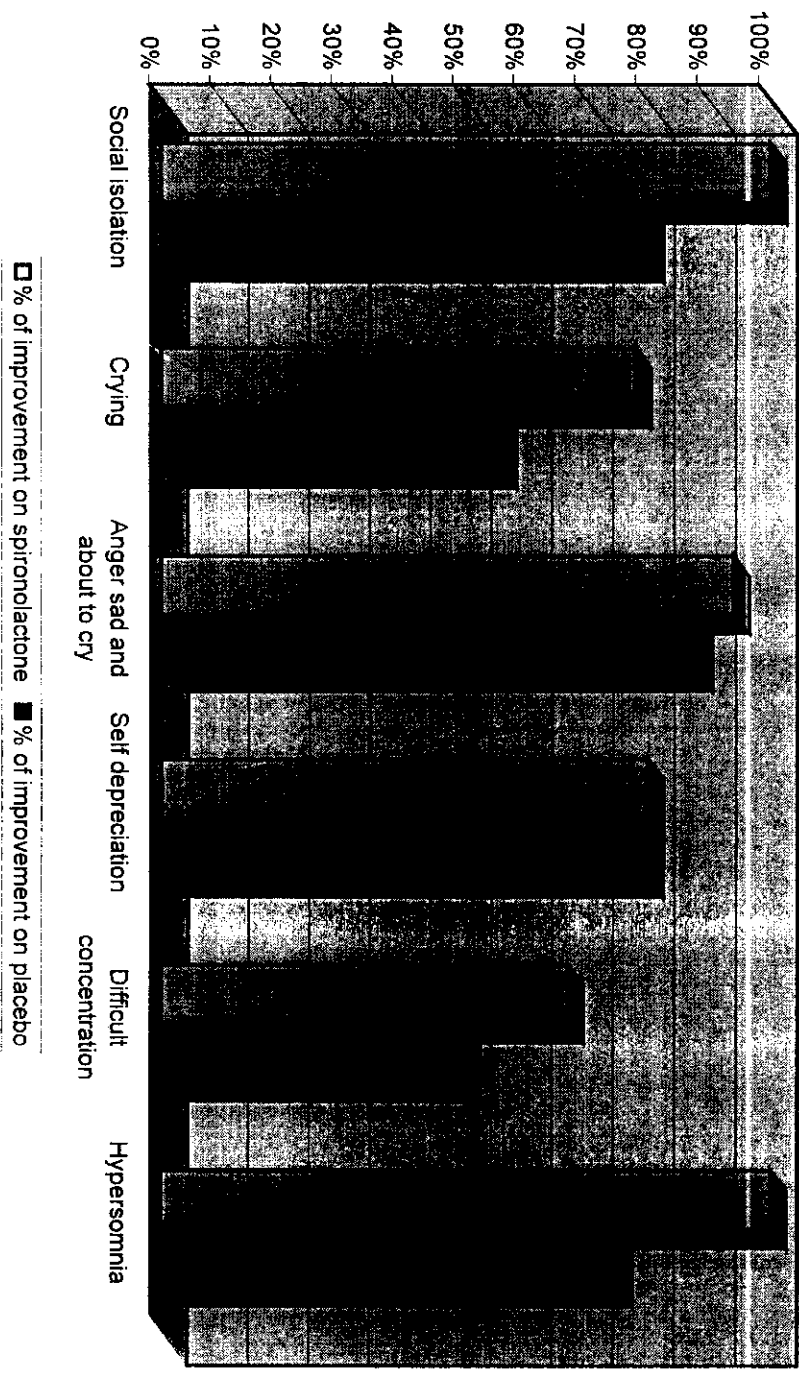


Figure (8) Comparison of depressive symptoms improvement percentages after 3 months with spironolactone for three months and then after placebo crossover for another three months.

Regarding *anxiety symptoms*; The percentage of improvement of anxiety symptoms on spironolactone for the first three months was 81% which gave **significant** statistical correlation with the pretreatment. Then, after placebo crossover this percentage decreased to be 64% but it gave no significant statistical correlation to spironolactone use.

Spironolactone use for the first three months gave **significant** statistical correlation with pretreatment for all anxiety symptoms detected compared with pretreatment but placebo crossover for the next three months gave no significant statistical correlation to spironolactone. 67% of patients suffered from irritability improved on spironolactone, the percentage decreased to be 56% after placebo crossover for the next three months, 80% of patient suffered from inability to relax improved on spironolactone but this percentage decreased to be 60% after placebo crossover, 100% for insomnia, decreased after placebo crossover to 80%, 80% of patients suffered from confusion decreased to 60% after placebo crossover for the next three months and 80% of patients suffered from noticeable restless behavior improved on spironolactone, then after placebo crossover for the next three months the percentage of improvement decreased to be 60% (Table 9) (Figure 9).

<i>Anxiety symptoms</i>	Pretreatment	After treatment with spironolactone		% of improvement	Statistical correlation bet. spironolactone and pretreatment		After cross over to placebo		% of improvement	Statistical correlation bet. Placebo crossover and spironolactone	
		Improved	Not improved		X ²	P	Improved	Not improved		X ²	P
Irritability	9	6	3	67%	6.25	<0.01*	5	4	56%	0.00	>0.1
Inability to relax	5	4	1	80%	3.75	<0.05*	3	2	60%	0.00	>0.1
Insomnia	5	5	0	100%	6.40	<0.01*	4	1	80%	0.00	>0.1
Confusion	5	4	1	80%	3.75	<0.05*	3	2	60%	0.00	>0.1
Noticeable restless behavior	5	4	1	80%	3.75	<0.05*	3	2	60%	0.00	>0.1
% of improvement of anxiety symptoms				81%	2.54	<0.05*			64%	0.00	>0.05

Table (9) Anxiety symptoms statistical calculations of spironolactone treatment significance in relation to pretreatment and then placebo crossover significance in relation to spironolactone. (X²- Chi. Square, P- Probability =0.05, * Significant, ** Highly significant).

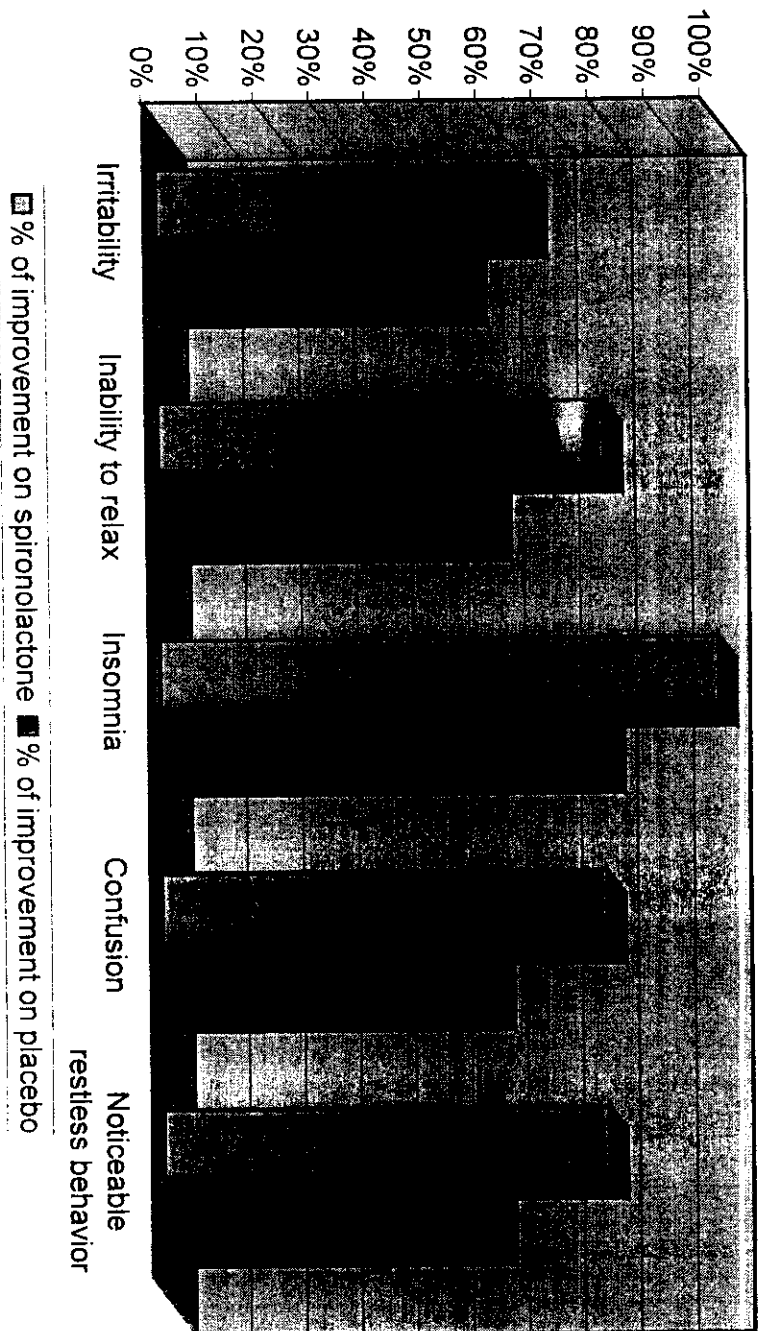


Figure (9) Comparison of anxiety symptoms improvement percentages after 3 months with spironolactone for 3 months and then after placebo crossover for another 3 months.

As regard *impact on life style symptoms*; The percentage of improvement on spironolactone for the first three months was 69%. This gave significant correlation with the pretreatment. Then after placebo crossover the percentage of improvement decreased to be 46% but it gave no statistical significant correlation to spironolactone.

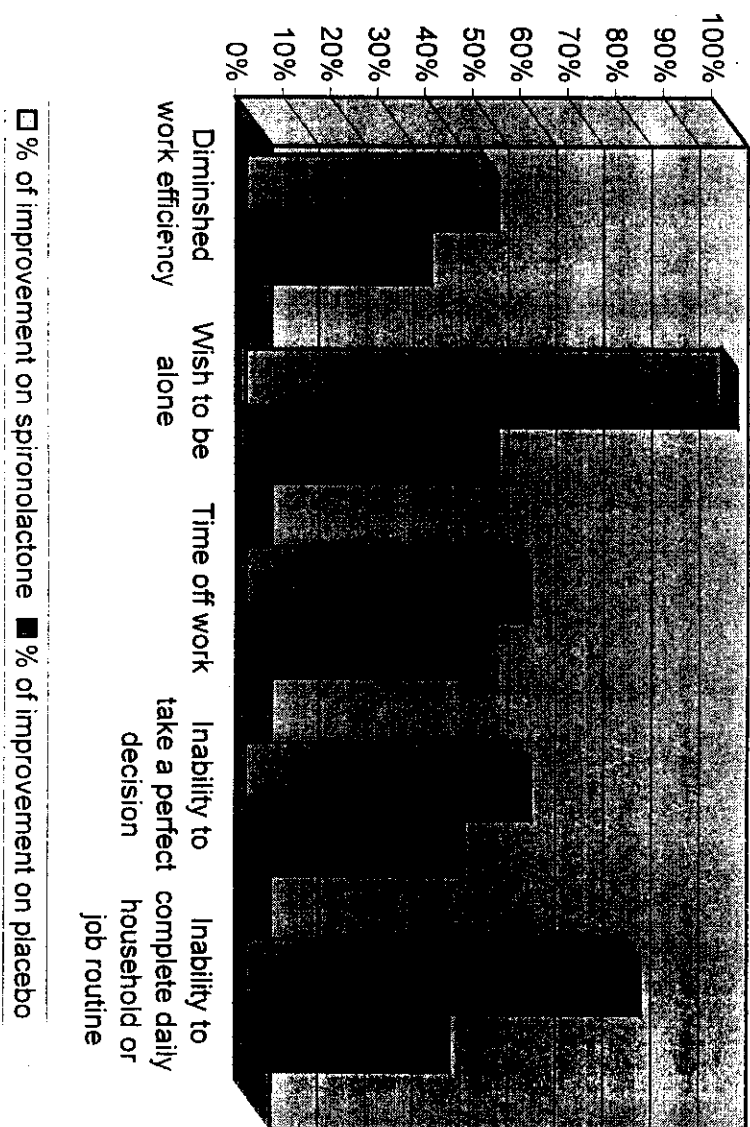
Spironolactone use for the first three months gave **highly significant** statistical correlation as regard “wish to be alone” in which the percentage of patients improved was 100%. Then after placebo crossover the percentage of improvement decreased to be 50% but it had no significant statistical correlation with spironolactone use.

Also, spironolactone use for the first three months gave **significant statistical** correlation with pretreatment as regard diminished work efficiency, time off work, inability to complete daily household or job routine. Then, after placebo crossover there was no significant statistical correlation to spironolactone. 50% of patients suffered from diminished work efficiency decreased to be 36% after placebo crossover. 57% of patients suffered from time off work improved on spironolactone. Then after placebo crossover the percentage decreased to be 43%. 57% of patients suffered from inability to take a perfect decision improved on spironolactone, it also decreased to 43% after placebo crossover. And

80% of patient suffered from inability to complete daily household or job routine improved on spironolactone. Then after placebo crossover the percentage of improvement decreased to be 40% (Table 10) (Figure 10).

<i>Impact on life style symptoms</i>	Pretreatment	After treatment with spironolactone		% of improve ment	Statistical correlation bet. Spironolactone and pretreatment		After cross over to placebo		% of improve ment	Statistical correlation bet. placebo crossover and spironolactone	
		improved	Not improved		X ²	P	Improved	Not improved		X ²	P
Diminished work efficiency	8	4	4	50%	3.00	<0.05*	3	5	36%	0.00	>0.1
Wish to be alone	6	6	0	100%	8.33	<0.001**	3	3	50%	1.78	>0.1
Time off work	7	4	3	57%	3.15	<0.05*	3	4	43%	0.00	>0.1
Inability to take a perfect decision	7	4	3	57%	3.15	<0.05*	3	4	43%	0.00	>0.1
Inability to complete daily household or job routine	5	4	1	80%	3.75	<0.05*	2	3	40%	0.42	>0.1
% of improvement of impact on life style				69%	2.66	<0.05*			46%	0.1	>0.05

Table (10) Impact on life style symptoms statistical calculations of spironolactone titt significance in relation to pretreatment and then placebo crossover significance in relation to Spironolactone. (X²- Chi -square, P- probability = 0.05, * Significant, ** Highly significant).



Figure(10) Comparison of impact on life style symptoms improvement percentages after tit with spironolactone for three months and then after placebo crossover for another three months.

Women who started with PLACEBO:

As regard the *somatic symptoms*; The percentage of improvement of somatic symptoms on placebo for the first three months was 24% which revealed **non significant** statistical correlation with pretreatment. Then, after spironolactone crossover for the next three months, the percentage of improvement increased to be 87% and it revealed significant statistical correlation with placebo.

Placebo use for the first three months revealed **non significant** statistical correlation with pretreatment as regard breast swelling, breast tenderness, skin affection, abdominal bloating, ankle swelling, pelvic pain, generalized bone pain, headache, easy fatigue, nausea and vomiting and altered appetite. But spironolactone crossover for the next three months gave highly significant statistical correlation as regard breast swelling and breast tenderness. Significant statistical correlation to skin affection, abdominal bloating, ankle swelling, pelvic pain, generalized bone pain, headache, easy fatigue, nausea and vomiting and finally to altered appetite. 27% of patients suffered from breast swelling improved on placebo, this percentage increased to be 100% after spironolactone crossover. 33% of patients suffered from breast tenderness improved on placebo, this percentage increased to 75% after spironolactone crossover.

13% of patient suffered from skin affection improved on placebo, increased to 75% after spironolactone crossover. 33% of patients suffered from abdominal bloating improved on placebo, increased to 100% after spironolactone crossover. 20% of patients suffered from ankle swelling improved on placebo increased to 100% after spironolactone crossover. 17% of patients suffered from pelvic pain improved on placebo ,increased to 83% after spironolactone crossover. 17% of patients suffered from generalized bone pain improved on placebo , increased to 83% after spironolactone crossover. 17% of patients suffered from headache improved on placebo , increased to 83% after spironolactone crossover. 40% of patients suffered from easy fatigue improved on placebo , increased to 90% after spironolactone crossover. 20% of patients suffered from nausea and vomiting improved on placebo , increased after spironolactone crossover to 83% . And lastly 25% of patients suffered from altered appetite improved on placebo, increased to 88% after spironolactone crossover (Table 11) (Figure 11).

WOMEN STARTED WITH PLACEBO

Somatic symptoms	Pretreatment	After treatment with placebo		% of improvement	Statistical correlation bet. Placebo and pretreatment		After crossover to spironolactone		% of improvement	Statistical correlation between spironolactone crossover and placebo	
		Improved	Not improved		X ²	P	Improved	Not improved		X ²	P
Breast swelling	15	4	11	27%	2.05	>0.05	15	0	100%	10.16	<0.001**
Breast tenderness	24	8	16	33%	7.35	>0.1	18	6	75%	6.80	<0.001**
Skin affection	8	1	7	13%	0.00	>0.1	6	2	75%	4.06	<0.01*
Abdominal bloating	6	2	4	33%	0.60	>0.1	6	0	100%	3.38	<0.05*
Ankle swelling	5	1	4	20%	0.00	>0.1	5	0	100%	3.75	<0.05*
Pelvic pain	6	1	5	17%	0.00	>0.1	5	1	83%	3.00	<0.05*
Generalized bone pain	6	1	5	17%	0.00	>0.1	5	1	83%	3.00	<0.05*
Headache	6	1	5	17%	0.00	>0.05	5	1	83%	3.00	<0.05*
Easy fatigue	10	4	6	40%	2.81	>0.1	9	1	90%	3.52	<0.05*
Nausea and vomiting	6	1	5	20%	0.00	>0.1	5	1	83%	3.00	<0.05*
Altered appetite	8	2	6	25%	0.57	>0.1	7	1	88%	4.06	<0.01*
% of improvement of somatic symptoms				24%	0.08	>0.05			87%	3.88	<0.05*

Table (11) Somatic symptoms statistical calculations of placebo fit significance in relation to pretreatment and then spironolactone crossover significance in relation to Placebo. (X²- Chi. Square, P- Probability = 0.05, * Significant, ** Highly Significant).

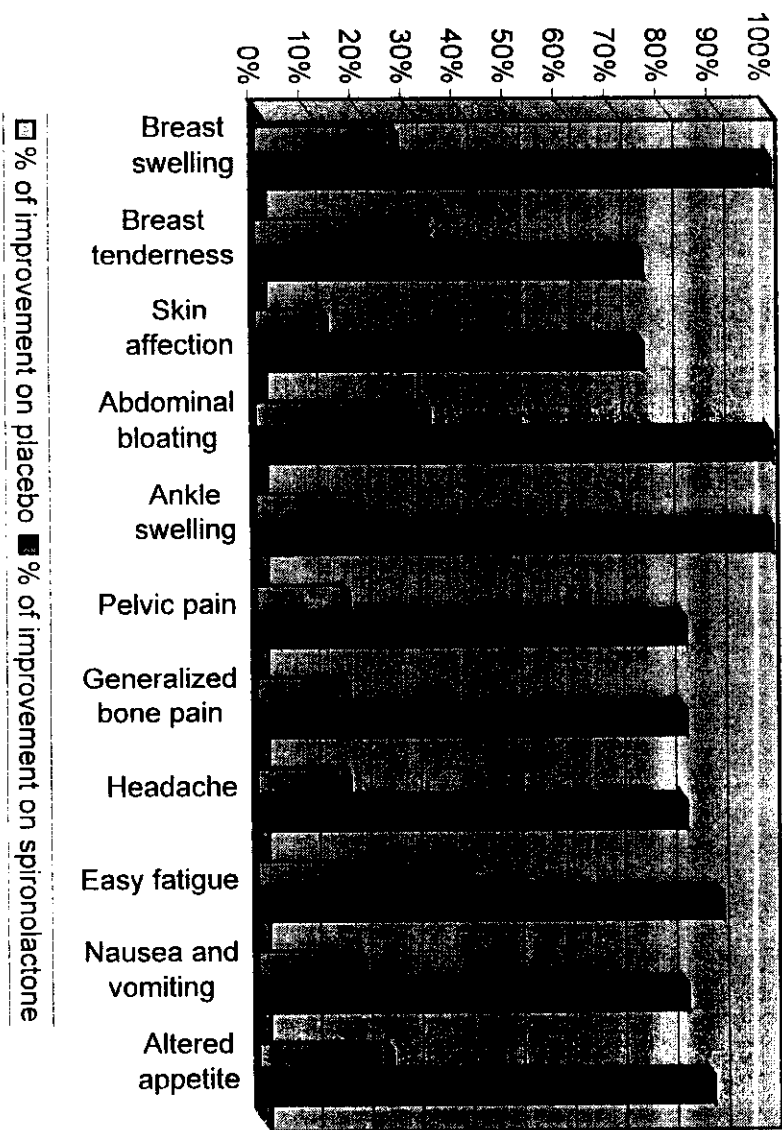


Figure (11) Comparison of somatic symptoms improvement percentages after 11 months with placebo for three months and then after spironolactone crossover for another three months.

As regard *depressive symptoms* ; The percentage of improvement of depressive symptoms on placebo for the first three months was 68% which revealed **significant** statistical correlation with pretreatment. Then, after crossover to spironolactone for the next three months the percentage of improvement changed to be 75% which revealed non significant statistical correlation to placebo use.

Placebo use for the first three months revealed **high significant** statistical correlation with pretreatment as regard anger, sad and about to burst and self depreciation. Then after spironolactone crossover there was no significant statistical correlation to placebo. 79% of patients suffered from anger, sad and about to burst improved on placebo increased to 89% after spironolactone crossover. 75% of patients suffered from self depreciation improved on placebo, increased to 88% after spironolactone crossover.

While placebo use for the first three months revealed that there was a **significant** correlation with pretreatment as regard social isolation, crying, difficult concentration and hypersomnia, but spironolactone crossover for the next three months revealed non significant statistical correlation to placebo. 57% of patients suffered from social isolation improved on placebo, changed to 71% after spironolactone crossover. 82% of patient

suffered from crying improved on placebo, decreased to 57% after spironolactone crossover. 67% of patients suffered from difficult concentration improved on placebo, increased to 83% after spironolactone crossover. 50% of patients suffered from hypersomnia improved on placebo, increased to 63% after spironolactone crossover (Table - 12) (Figure - 12).

Depressive Symptoms	Pretreatment	After treatment with placebo		% of improvement	Statistical correlation between placebo and pretreatment		After crossover to spironolactone		% of improvement	Statistical correlation bet. Spironolactone crossover and placebo	
		improved	Not improved		X ²	P	improved	Not improved		X ²	P
Social isolation	7	4	3	57%	3.15	<0.05*	5	2	71%	0.00	>0.1
Crying	7	5	2	82%	3.15	<0.05*	4	3	57%	0.00	>0.1
Anger, sad and about to burst	19	15	4	79%	21.59	<0.001**	17	2	89%	0.20	>0.1
Self depreciation	8	6	2	75%	6.67	<0.001**	7	1	88%	0.00	>0.1
Difficult concentration	6	4	2	67%	3.38	<0.05*	5	1	83%	0.00	>0.1
Hypersomnia	8	4	4	50%	3.00	<0.05*	5	3	63%	0.00	>0.1
% of improvement of depressive symptoms				68%	2.57	<0.05*			75%	0.21	>0.05

Table (12) Depressive symptoms statistical calculations of placebo treatment significance in relation to pretreatment and then spironolactone crossover significance in relation to Placebo. (X²- Chi-square, P- probability =0.05, * Significant, ** Highly significant).

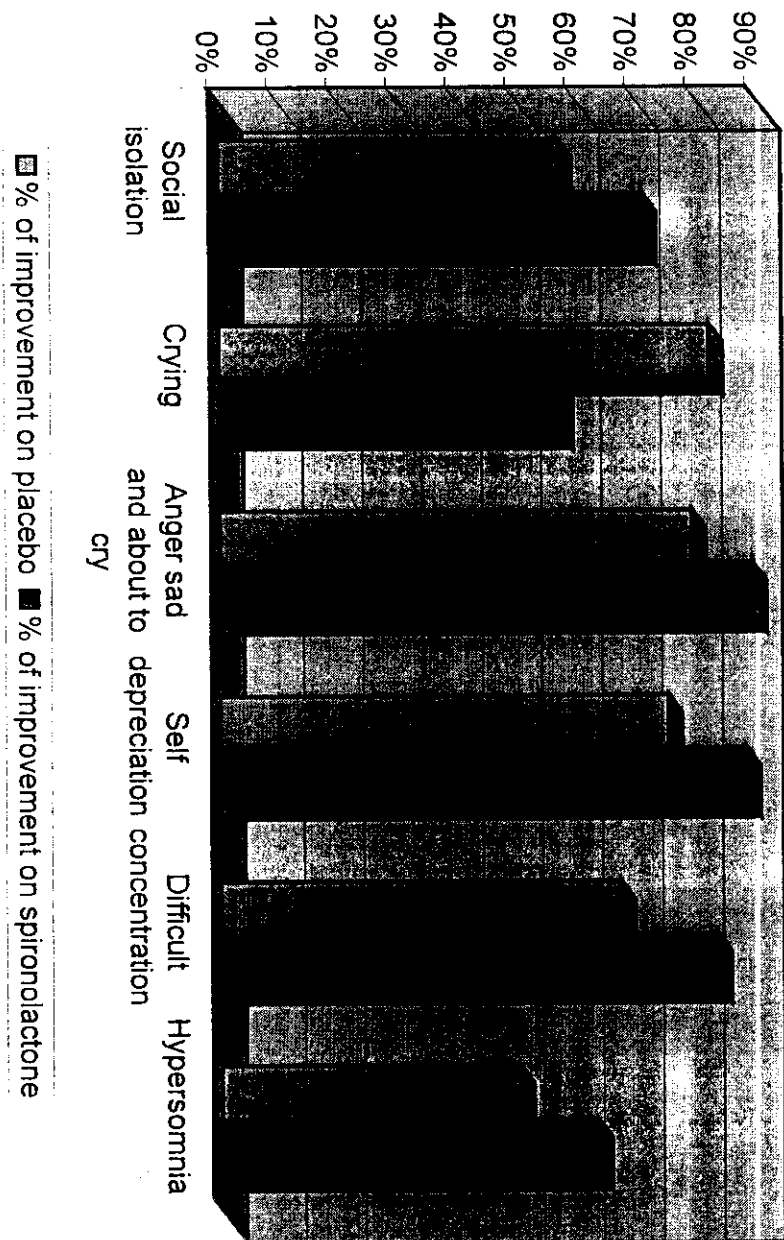


Figure (12) Comparison of depressive symptoms improvement percentages after titt with placebo for three months and then after spironolactone crossover for another three months.

As regard *anxiety symptoms*; The percentage of improvement of anxiety symptoms on placebo for the first three months was 57% which revealed **significant** statistical correlation with pretreatment. Then after spironolactone crossover for the next three months the percentage of improvement changed to 77% but with non significant statistical correlation with placebo.

Placebo use for the first three months revealed **significant** statistical correlation with pretreatment as regard irritability, inability to relax, insomnia, confusion and noticeable restless behavior, but spironolactone crossover for the next three months revealed non significant statistical correlation to placebo. 56% of patients suffered from irritability improved on placebo, increased to 67% after spironolactone crossover. 50% of patients suffered from inability to relax improved on placebo, this percentage increased to 63% after spironolactone crossover. 67% of patients suffered from insomnia improved on placebo, this changed to 100% after spironolactone crossover. 57% of patients suffered from confusion improved on placebo, increased to 86% after spironolactone crossover. Also 57% of patients with noticeable restless behavior improved on placebo, increased to 71% after spironolactone crossover (Table 13)(Figure 13).

Anxiety symptoms	pretreatment	After treatment with placebo		% of improvement	Statistical correlation bet. placebo and pretreatment		After crossover to spironolactone		% of improvement	Statistical correlation bet. spironolactone crossover and placebo	
		Improved	Not improved		X ²	P	Improved	Not improved		X ²	P
Irritability	9	5	4	56%	4.43	<0.01*	6	3	67%	0.00	>0.1
Inability to relax	8	4	4	50%	3.00	<0.05*	5	3	63%	0.00	>0.1
Insomnia	6	4	2	67%	3.38	<0.05*	6	0	100%	0.60	>0.1
Confusion	7	4	3	57%	3.15	<0.05*	6		86%	0.00	>0.1
Noticeable restless behavior	7	4	3	57%	3.15	<0.05*	5	2	71%	0.00	>0.1
% of improvement of anxiety symptoms				57%	3.86	<0.05*			77%	0.1	>0.05

Table (13) Anxiety symptoms statistical calculations of placebo tit significance in relation to pretreatment and then spironolactone crossover significance in relation to Placebo. (X² - Chi-square, P- probability =0.05, * Significant, ** Highly significant).

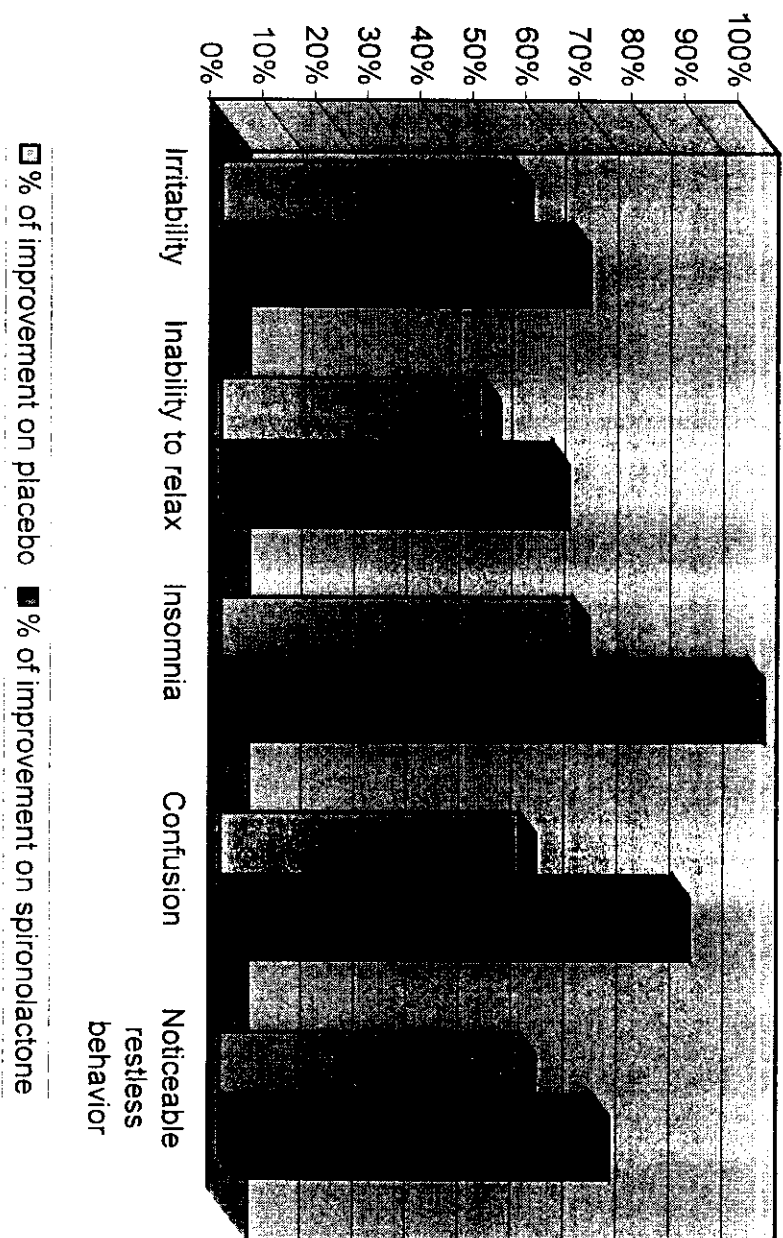


Figure (13) Comparison of anxiety symptoms improvement percentages after tit with placebo for three months and then after spironolactone crossover for another three months.

Lastly, as regard *impact on life style symptoms*; the percentage of improvement on placebo for the first three months was 48% which revealed **significant** statistical correlation with pretreatment. Then, after spironolactone crossover for the next three months the percentage of improvement changed to 59% but with non significant statistical correlation with placebo.

Placebo use for the first three months revealed **significant** statistical correlation with pretreatment as regard diminished work efficiency, wish to be alone , time off work, inability to take a perfect decision and inability to complete daily household or job routine. 33% of patients suffered from diminished work efficiency improved on placebo increased to 67% after spironolactone crossover. 25% of patients suffered from wish to be alone improved on placebo use for the first three months, increased to 50% after spironolactone crossover . 33% of patients suffered from time off work improved on placebo, increased to 67% after spironolactone crossover. 50% of patients suffered from inability to take a perfect decision improved on placebo increased to 100% after spironolactone crossover. and 100% of patients suffered from inability to complete daily household or job routine improved on placebo ,remained 100% after spironolactone crossover (Table 14) (Figure 14).

<i>Impact on life style symptoms</i>	Pretreatment	After treatment with placebo		% of improvement	Statistical correlation bet. Placebo and pretreatment		After cross over to spironolactone		% of improvement	Statistical correlation bet. Spironolactone crossover and placebo	
		Improved	Not improved		X ²	P	Improved	Not improved		X ²	P
Diminished work efficiency	3	1	2	33%	2.75	<0.05*	2	1	67%	0.00	>0.1
Wish to be alone	4	1	3	25%	3.01	<0.05*	2	2	50%	0.00	>0.1
Time off work	3	1	2	33%	2.79	<0.05*	2	1	67%	0.00	>0.1
Inability to take a perfect decision	2	1	1	50%	2.65	<0.05*	2	0	100%	0.00	>0.1
Inability to complete daily household or job routine	1	1	0	100%	3.00	<0.05*	1	0	100%	0.00	>0.1
% of improvement of impact on life style				48%	3.01	<0.05*			59%	1.07	>0.05

Table (14) Impact on life style symptoms statistical calculations of placebo ttt significance in relation to pretreatment and then spironolactone crossover significance in relation to Placebo. (X²- Chi -square, P- probability =0.05, * Significant, ** Highly significant).

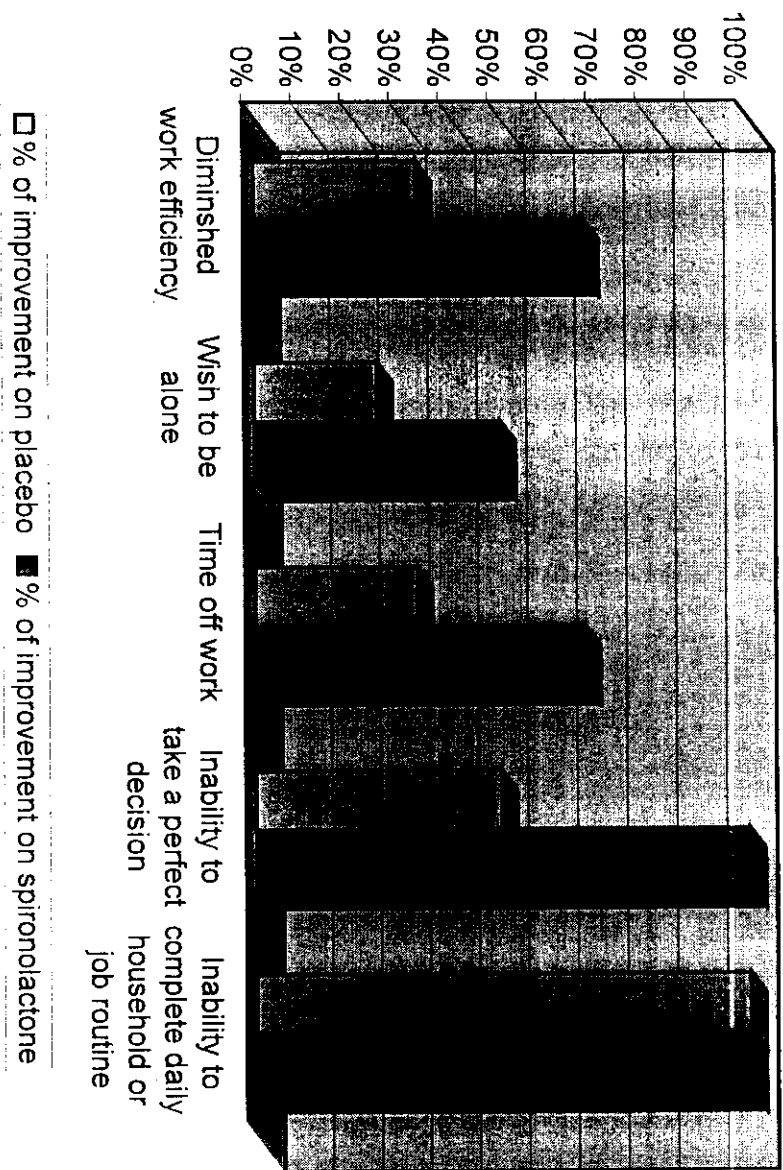


Figure (14) Comparison of impact on life style symptoms improvement percentages after ttt with placebo for three months and then after spironolactone crossover for another three months.