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Comparison between Flibanserin and Vardenafil in The Treatment of Female Sexual Dysfunction

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Abstract

Background:*Sexual functioning is an integral part of human life and has been shown in researches to be important to both men and women. The aim was to compare efficacy of flibanserin and vardenafil on female sexual dysfunction.* ***Methods:****This comparative study was done at gynecology and obstetrics department and dermatology and Venereology department, Faculty of Medicine, Zagazig University Hospitals.patients were divided into:Group 1 includes 16 patients who were treated by vardenafil and group II includes 16 patients who were treated by fiibanserin.* ***Results:****there were no statistical significance differences between the two studied groups all scores pre ttt. But there was statistical significance increase in desire, orgasm and total score among Group II (flibanserin) compared to Group I (vardenafil) post ttt. Regarding comparing pre and post scores in each group: In Group I there were highly statistical significance increase in index scores of lubrication and satisfaction (by 37.5% & 42.7% respectively) post ttt and statistical significance increase in orgasm and total score (25% & 23.36 % respectively) post ttt compared to pre. While in Group II there was highly statistical significance increase in desire, orgasm, satisfaction and total (by 33.3%,41.76% & 25.66 % respectively) post ttt and statistical significance decrease in arousal score (by 23.75%) post ttt compared to pre.* ***Conclusion:****Flibanserin is a controversial drug approved for a controversial disorder amid huge controversy. While it may serve as the lamp in the light in the long search for female sexual problems, it has still a long way to go. Women taking this drug must well be educated about the adverse events associated with this drug and the possible interactions. Flibanserin treated women reported improvements on most measures of sexual dysfunction during the study, and trend was observed on most study measures in favor of flibanserin and significant differences were noted to compare with vardenafil.*

Key words: *flibanserin -vardenafil -female sexual dysfunction.*

I. Introduction:

Sexual functioning is an integral part of human life and has been shown in researchs to be important to both men and women. In the Study of Women's Health across the Nation, more than 75% of women reported sex to be moderately to extremely important **(1).**

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Around 43% of women report sexual problems with 22.2% reporting sexually related personal distress. Hypoactive sexual desire disorder (HSDD) has been regarded to be the most common female sexual dysfunction (FSD) and affects nearly 1 in 10 women[(2)].

For a diagnosis of HSDD, the desire problem must not be better accounted for by another psychiatric disorder such as depression, substance abuse, or medical condition. Not only does FSD negatively affect health-related quality of life but also general well-being [(3)].

Human sexual function is an essential component of life. Sexual dysfunction can lead to reduced quality of life and potentially procreative advancement. Female sexual dysfunction is more complicated than male sexual dysfunction[(4)].

Female sexual dysfunction is a multifaceted disorder, comprising anatomical, psychological, physiological, as well as social-interpersonal components [(5)].

Flibanserin is a nonhormonal, centrally acting molecule that acts as an agonist at postsynaptic 5-HT1A receptors and as an antagonist at 5-HT2A receptor [(6)]. Dopamine and norepinephrine are involved in the 'excitement' phase of the sexual response (e.g., desire and arousal) while 5-HT is involved in the 'inhibitory' phase (e.g., satiety or refractory period) [(7)].

A balance between excitatory activity driven by dopamine and norepinephrine and inhibitory activity driven by 5-HT is believed to be necessary for a healthy sexual response [(7)].

One hypothesis suggests that an imbalance between these systems may be present in sexual dysfunction. By selectively modulating these neuro transmitters in specific brain areas, flibanserin may act to re-balance these systems in women with HSDD[(8)].

Vardenafil, In smooth muscle cells, nitric oxide activates the guanylatecyclase enzyme which converts guanosine triphosphate into cyclic guanosine monophosphate. This molecule promotes the relaxation of the smooth muscle cells, causes vasodilatation, and increases blood flow in genital organs.The engorgement of clitoris and labia minora in women are the main modifications of genital organs during sexual arousal. The ultrafiltration of plasma through capillary vaginal vessels contributes to vaginallubrication[(9)].

Phosphodiesterase type 5 (PDE5) inhibitors (eg, tadalafil, vardenafil) physiologically enhance the production of guanosine monophosphate from cyclic guanosine monophosphate, PDE5 is expressed in vaginal, clitoral, and labial smooth muscles. Thus, PDE5 inhibitors could be used as an easily available medical treatment for genital FSADs[(10)].

The study aimed tostudy compare efficacy of flibanserin and vardenafil on female sexual dysfunction.

II. Patients and Methods

The study was conducted in gynecology and obstetrics department and dermatology and Venereology department, Faculty of Medicine, Zagazig University Hospitals during the period from Feb 2019 to December 2019. Thirty two married female patients were included in this study. These patients were divided into two groups.Group 1 includes sixteen patients who were treated by vardenafil and group II includes the remainind

sixteen patients who were treated by fiibanserin. The protocol was approved by scientific and ethical committees, Faculty of Medicine Zagazig University.

Inclusion criteria: Married female patients complaining of sexual dysfunction more than 6 months with sexually active partner.

1) Operational design:

Type of study:

A clinical trial and all included patients will be classified into two groups;

- **Group I:** 16 patients with FSD received vardenafil tablets 10 mg at bed time as oral dose for 2 months.
- **Group II:** 16 patients with FSD received 100mg flibanserin at bed time as oral dose for 2 months.

Methods and objectives:

All patients in the 2 groups were subjected to:

1) Complete history taking: age, education, occupation, residence, age of marriage, special habits, history of medical diseases, surgical history and sexual history in the previous 6 months.

2) General and physical examination: pulse, blood pressure, routine laboratory investigations including CBC, LFT, RFT, RBS and lipid profils.

3) Evaluation questionnaire:

The questionnaire used included 25 items designed by the investigators [7]. Only some items were selected from the female sexual function index (FSFI)**,** other questions were added to suit the purpose of study.

The FSFI, a 19-item questionnaire, has been developed as a brief, multidimensional self-report instrument for assessing the key dimensions of sexual function in women including six domains (Desire, Arousal, Lubrication, Orgasm, Satisfaction and pain). It is psychometrically sound, easy to administer, and has demonstrated ability to discriminate between clinical and nonclinical populations. The questionnaire described was designed and validated for assessment of female sexual function and quality of life in clinical trials or epidemiological studies. Its further use in these areas remains to be investigated.

Domain	Questions	Score Range	Factor	Minimum Score	Maximum Score	Score
Desire	1,2	1-5	0.6	1.2	6.0	
Arousal	3,4,5,6	0-5	0.3	0	6.0	
Lubrication	7,8,9,10	0-5	0.3	0	6.0	
Orgasm	11,12,13	0-5	0.4	0	6.0	

Satisfaction	14,15,16	0 (or1)-5	0.4	0.8	6.0	
Pain	17,18,19	0-5	0.4	0	6.0	
Full Score Range				2.0	36.0	

4) Depression questionnaire to exclude the major psychological depressive disorder and its result put with the evaluation questionnaire as one item only.

Statistical analysis

The collected data were computerized and statistically analyzed using SPSS program (Statistical Package for Social Science) version 18.0.Qualitative data were represented as frequencies and relative percentages. Chi square test, Mann Whiteny (MW) test, Paired t test and Paired Wilixocon test were used The threshold of significance is fixed at 5% level (P-value)

III. Results:

Table (1): Comparison of demographic data of the two studied groups:

Variable	Total (n=32)		Group I (Vardenafil) (n=16)		Group II (Flibanserin) (n=16)		χ^2	P
	No	%	No	%	No	%		
Age: (years)								
<20	2	6.2	1	6.3	1	6.3	0.16	0.92
20 – 29	21	65.6	10	62.5	11	68.7		NS
≥ 30	9	28.1	5	31.3	4	25		
Education:								
Read & write	0	0	0	0	0	0	3.14	0.08
Basic education	15	46.9	10	62.5	5	31.2		NS
University	17	53.1	6	37.5	11	68.8		
Occupation:								
Yes	11	34.4	8	50	3	18.8	3.46	0.06
No	21	65.6	8	50	13	81.2		NS

Residence:								
Urban	16	50%	5	31.3	11	68.7	3.8	0.15 NS
Rural	16	50%	11	68.7	5	31.2		
Age of marriage:								
<20	9	28.1	5	31.3	4	25	2.54	0.28
20 – 29	21	65.6	9	56.2	12	75		NS
≥ 30	2	6.2	2	12.5	0	0		
Husband's age of marriage:								
<20	0	0	0	0	0	0	0.53	0.47
20 – 29	20	62.5	9	56.3	11	68.8		NS
≥ 30	12	37.5	7	43.8	5	31.2		

χ^2: Chi square test. NS: Non significant (P>0.05)

There were no statistical significance differences between the studied groups in any of demographic data.

Table (2): Previous sexual problems among the two studied groups:

Variable	Group I (Vardenafil)		Group II (Flibanserin)		χ^2	P
	No	%	No	%		
Having problems in 1st years of marriage:	(n=16)		(n=16)			
No					1.65	0.20
Yes	5	31.2	2	12.5		NS
	11	68.8	14	87.5		
If yes what: #	(n=11)		(n=14)			
No desire	4	36.4	8	57.1		
Dryness	6	54.5	5	35.7	1.13	0.77 NS
No orgasm	7	63.6	8	57.1		
Pain during intercourse	2	18.2	3	21.4		

The causes of these problems:	(n=11)		(n=14)			
Lack of knowledge	3	27.3	6	42.9	0.91	0.64
Shyness	4	36.4	5	35.7		NS
Fear	4	36.4	3	21.4		
Feel change in sexual relation after 1st year of marriage:	(n=16)		(n=16)			
Yes better	2	12.5	5	31.3	2.40	0.30
Yes worse	4	25	5	31.3		NS
No change	10	62.5	6	37.5		
Husband had sexual problems:	(n=16)		(n=16)			
No					0	1
Yes	11	68.8	11	68.8		NS
	5	31.2	5	31.2		
If yes what: #	(n=5)		(n=5)			
Weak erection	0	0	2	40	3.47	0.32
Ejaculation before orgasm	3	60	2	40		NS
Premature ejaculation	0	0	1	20		
Delayed ejaculation	2	40	1	20		

#: Question had more than 1 answer χ^2: Chi square test. NS: Non significant (P>0.05)

There were no statistical significance differences between the two studied groups in previous sexual problems.

Table (3): Sexual culture among the two studied groups:

Variable	**Group I (Vardenafil) (n=16)**		**Group II (Flibanserin) (n=16)**		**χ^2**	**P**
	No	**%**	**No**	**%**		
Had previous sexual information before marriage:					1.13	0.29 NS

No	9	56.2	6	37.5		
Yes	7	43.8	10	62.5		
Importance of pre-marital sexual information:						
Yes	7	43.8	7	43.8	0.28	0.87 NS
No	7	43.8	6	37.5		
To some degree	2	12.5	3	18.7		
Masturbation:						
Yes before marriage	1	6.3	1	6.3		
Yes before & after marriage	3	18.8	1	6.3	1.21	0.88 NS
No but my friends did it	3	18.8	4	25		
No never	7	43.8	8	50		
I don't know it	2	12.5	2	12.5		
Aim of marriage:#						
Social secure	8	50	12	75	2.27	0.32 NS
Sexual desire satisfaction	4	25	2	12.5		
Having children	11	68.8	7	43.8		
Suitable age of marriage:						
<20	0	0	0	0	---	---
20 – 29	16	100	16	100		
≥ 30	0	0	0	0		

#: Question had more than 1 answer χ^2: Chi square test. NS: Non significant (P>0.05)

There were no statistical significance differences between the two studied groups in sexual culture.

Table (4): Comparison between the two studied groups in pretreatment sexual dysfunction assessment:

Variable	**Group I (Vardenafil) (n=16)**		**Group II (Flibanserin) (n=16)**		**χ^2**	**P**
	No	**%**	**No**	**%**		

Coital frequency:	Every day	1	6.3	3	18.8		
	2 -3 times/week	1	6.3	2	12.5		
	Once/week	6	37.5	2	12.5		0.48
	1 – 2 times/month	5	31.3	5	31.3	3.48	NS
	Less than that	3	18.8	4	25		
Desire:	Many times/day	0	0	0	0		
	Once /day	1	6.3	0	0		
	Weekly	6	37.5	3	18.8		0.44
	Monthly	7	43.8	10	62.5	2.73	NS
	Never	2	12.5	3	18.8		
Lubrication:	All times	1	6.3	5	31.3		
	Half times	4	25	2	12.5		
	Less than have times	11	68.8	7	43.8	6.22	0.10
	Never	0	0	2	12.5		NS
Lubricant maintenance:	All times	1	6.3	2	12.5		
	Half times	2	12.5	3	18.8		
	Less than have times	13	81.3	9	64.3	3.26	0.35
	No lubrication	0	0	2	12.5		NS
Orgasm:	All times	0	0	1	6.3		
	Half times	1	6.3	1	6.3		
	Less than have times	8	50	7	43.8	1.07	0.79
	Not feel it at all	7	43.8	7	43.8		NS
Pain:	No	8	50	9	56.3	0.13	0.72
	Yes	8	50	7	43.8		NS
Pain had organic cause:	No	8	100	7	100	----	----
	Yes	0	0	0	0		
Sexual satisfaction:	Very satisfactory	0	0	0	0		

	Moderately satisfactory	1	6.3	2	12.5		
	Equal between satisfactory and not	6	37.5	5	31.3	0.42	0.81 NS
	Unsatisfactory	9	56.3	9	56.3		

χ^2: Chi square test. . NS: Non significant (p>0.05)

This table shows there were no statistical significance differences between the two studied groups all parameters pre ttt.

Table (5): Comparison between the two studied groups in post-treatment sexual dysfunction assessment:

Variable		**Group I (Vardenafil) (n=16)**		**Group II (Flibanserin) (n=16)**		**χ^2**	**P**
		No	**%**	**No**	**%**		
Coital frequency:	Every day	1	6.3	3	18.8		
	2 -3 times/week	1	6.3	4	25		0.34 NS
	Once/week	7	43.8	5	31.3	4.53	
	1 – 2 times/month	6	37.5	4	25		
	Less than that	1	6.3	0	0		
Desire:	Many times/day	0	0	2	12.5		
	Once /day	0	0	1	6.3		0.43 NS
	Weekly	2	12.5	9	56.3	2.79	
	Monthly	8	50	4	25		
	Never	6	37.5	0	0		
Lubrication:	All times	4	25	8	50		
	Half times	11	68.8	3	18.8	**8.57**	**0.01***
	Less than have times	1	6.3	5	31.3		
	Never	0	0	0	0		
Lubricant maintenance:	All times	2	12.5	5	31.3	2.32	0.31

	Half times	3	18.8	4	25		NS
	Less than have times	11	68.8	7	43.8		
	No lubrication	0	0	0	0		
Orgasm:	All times	0	0	3	18.8	**7.07**	**0.04***
	Half times	5	31.3	5	31.3		
	Less than have times	7	43.8	8	50		
	Not feel it at all	4	25	0	0		
Pain:	No	8	50	9	56.3	0.13	0.72
	Yes	8	50	7	43.8		NS
Pain had organic cause:	No	8	100	7	100	----	----
	Yes	0	0	0	0		
Satisfaction:	Very satisfactory	2	12.5	1	6.3	2.14	0.54 NS
	Moderately satisfactory	5	31.3	9	56.3		
	Equal between satisfactory and not	7	43.8	5	31.3		
	Unsatisfactory	2	12.5	1	6.3		

χ^2: Chi square test. . NS: Non significant (p>0.05) *: Significant (P<0.05)

This table (5) shows that there was statistical significance increase in frequency of lubrication among Gr I compared to Gr II also there was statistical significance increase in frequency of orgasm among Group II compared to Group I post ttt.

Table (6): Comparison of sexual function index score before and after ttt in Group I :

Variable (vardenafil group):		**Pre (n=16)**	**Post (n=16)**	**P**	**% of**
Desire	Mean ± Sd	4.88 ± 1.82	5.44 ± 1.55	0.72 ^	1.54%
	Median (Range)	7 (2 – 9)	6.5 (3 – 9)	NS	
Arousal	Mean ± Sd	2.25 ± 0.58	2.44 ± 0.73	0.19^	9.38%
	Median (Range)	3 (2 – 4)	3 (2 – 4)	NS	

Lubrication	Mean ± Sd Median (Range)	2.38 ± 0.62 3 (2 – 4)	3.19 ± 0.54 2 (2- 4)	**<0.001^** **	**37.5%**
Orgasm	Mean ± Sd Median (Range)	1.63 ± 0.62 3 (1 – 3)	2.06 ± 0.77 3 (1- 3)	**0.02** # *	**25%**
Satisfaction	Mean ± Sd Median (Range)	2.5 ± 0.63 4 (2- 4)	3.44 ± 0.89 3 (2 – 5)	**0.001** **	**42.71%**
Pain	Mean ± Sd Median (Range)	0.5 ± 0.5 0.5 (0 -1)	0.5 ± 0.52 0.5 (0 -1)	1 # NS	0%
Full score	Mean ± Sd Median (Range)	14.13 ± 2.73 21 (10 – 20)	17.1 ± 2.46 17 (13 – 21)	**0.001^** **	**23.36%**

^: Paired t test #: Paired Wilcoxon test

NS: Non significant (p>0.05) *: Significant (P<0.05) **: Highly significant (p<0.01)

This table shows that there were highly statistical significance increase in scores of lubrication and satisfaction (by 37.5% & 42.7% respectively) post ttt and statistical significance increase in orgasm and total score (25% & 23.36 % respectively) post ttt compared to pre.

Table (7): Comparison of female sexual function index score before and after ttt in Group II (flibanserin group):

Variable		**Pre (n=16)**	**Post (n=16)**	**P**	**% of**
Desire	Mean ± Sd Median (Range)	4.69 ± 1.89 8 (2 – 8)	6.45 ± 1.17 5.5 (4 – 10)	**<0.001 ^** **	**33. 3%**
Arousal	Mean ± Sd Median (Range)	2.31 ± 0.87 3 (1- 4)	2.88 ± 0.89 2 (2 – 4)	**0.041 #** *	**23.75%**
Lubrication	Mean ± Sd Median (Range)	2.63 ± 1.09 3 (1 – 4)	3.19 ± 0.91 1.5 (2 – 4)	0.66 # NS	26.88%
Orgasm	Mean ± Sd Median (Range)	1.75 ± 0.86 3 (1- 4)	2.69 ± 0.79 2.5 (2 – 4)	**0.004 #** **	**38.13%**
Satisfaction	Mean ± Sd	2.56 ± 0.73	3.63 ± 0.72	**<0.001 ^**	**41. 67%**

	Median (Range)	4 (2 – 4)	2 (2 - 5)	****	
Pain	Mean ± Sd Median (Range)	0.56 ± 0.51 0 (0 – 1)	0.56 ± 0.51 0 (0 – 1)	1 # NS	0%
Full score	Mean ± Sd Median (Range)	14.5 ± 3.25 20 (10 – 20)	19.37 ± 3.81 14.5 (13 – 25)	**<0.001 ^ ******	**25.66%**

Sd: Standard deviation. ^: Paired t test #: Paired Wilcoxon test

NS: Non significant (p>0.05) *: Significant (P<0.05) **: Highly significant (p<0.01)

This table shows that there was highly statistical significance increase in desire, orgasm, satisfaction and total (by 33.3%,41.76% & 25.66 % respectively) post ttt and statistical significance increase in arousal score (by 23.75%, %) post ttt compared to pre.

Table (8): Comparison between the two studied groups in female sexual dysfunction index score before ttt:

Variable		**Group I (Vardenafil) (n=16)**	**Group II (Flibanserin) (n=16)**	**Test**	**P**
Desire	Mean ± Sd Median (Range)	4.88 ± 1.82 7 (2 – 9)	4.69 ± 1.89 8 (2 – 8)	t 1.76	0.09 NS
Arousal	Mean ± Sd Median (Range)	2.25 ± 0.58 3 (2 – 4)	2.31 ± 0.87 3 (1- 4)	MW -.16	0.87 NS
Lubrication	Mean ± Sd Median (Range)	2.38 ± 0.62 3 (2 – 4)	2.63 ± 1.09 3 (1 – 4)	MW -.59	0.56 NS
Orgasm	Mean ± Sd Median (Range)	1.63 ± 0.62 3 (1 – 3)	1.75 ± 0.86 3 (1- 4)	MW -.21	0.84 NS
Satisfaction	Mean ± Sd Median (Range)	2.5 ± 0.63 4 (2- 4)	2.56 ± 0.73 4 (2 – 4)	t 0.26	0.80 NS
Pain	Mean ± Sd Median (Range)	0.5 ± 0.5 0.5 (0 -1)	0.56 ± 0.51 0 (0 – 1)	MW -.35	0.73 NS
Full score	Mean ± Sd	14.13 ± 2.73	14.5 ± 3.25	t	0.73 NS

	Median (Range)	21 (10 – 20)	20 (10 – 20)	.35	

Sd: Standard deviation. t: Independent t test MW: Mann Whitney test

NS: Non significant (p>0.05) *: Significant (P<0.05) **: Highly significant (p<0.01)

There were no statistical significance differences between the two studied groups all scores pre ttt.

Table (9): Comparison between the two studied groups in sexual function index score afterttt:

Variable		**Group I (Vardenafil) (n=16)**	**Group II (Flibanserin) (n=16)**	**Test**	**P**
Desire	Mean ± Sd Median (Range)	5.44 ± 1.55 6.5 (3 – 9)	6.45 ± 1.17 5.5 (4 – 10)	**t** **2.08**	**0.04***
Arousal	Mean ± Sd Median (Range)	2.44 ± 0.73 3 (2 – 4)	2.88 ± 0.89 2 (2 – 4)	t 1.53	0.14 NS
Lubrication	Mean ± Sd Median (Range)	3.19 ± 0.54 2 (2- 4)	3.19 ± 0.91 1.5 (2 – 4)	t 00	1.00 NS
Orgasm	Mean ± Sd Median (Range)	2.06 ± 0.77 3 (1- 3)	2.69 ± 0.79 2.5 (2 – 4)	**MW** **2.26**	**0.03***
Satisfaction	Mean ± Sd Median (Range)	3.44 ± 0.89 3 (2 – 5)	3.63 ± 0.72 2 (2 - 5)	t .66	0.52 NS
Pain	Mean ± Sd Median (Range)	0.5 ± 0.52 0.5 (0 -1)	0.56 ± 0.51 0 (0 – 1)	MW -.35	0.73 NS
Full score	Mean ± Sd Median (Range)	17.1 ± 2.46 17 (13 – 21)	19.37 ± 3.81 14.5 (13 – 25)	**t** **2.1**	**0.04***

Sd: Standard deviation .t: Independent t test MW: Mann Whitney test

NS: Non significant (p>0.05) *: Significant (P<0.05) **: Highly significant (p<0.01)

This table shows that there was statistical significance increase in desire, orgasm and total score among Group II compared to Group I post ttt.

IV. Discussion

Female sexual dysfunction (FSD) is a highly prevalent condition that encompasses 4 primary domains: hypoactive sexual desire disorder (HSDD), arousal disorder, orgasmic disorder, and sexual pain disorder. Incidence and prevalence rates vary but have been reported to range from 30-50% of women. These rates are likely an underestimate given the social stigma still associated with acknowledging female sexual distress. It is perhaps because of this stigma that the literature surrounding FSD is lacking **(11).**

This study showed that there were no statistical significance differences between the two studied groups in sexual culture.

This is supported by study of **Chivers and Rosen, (12)** as they reported that the extent that subjective factors can maintain FSAD, a pharmacological intervention that has primarily vascular effects in local, genital tissues and does not act centrally may fail as an effective treatment for women with FSAD.

Rosen and Leiblum,(13), speculated, based on evidence available at that time, that subjective factors were more critical and necessary to women's experience and recognition of sexual arousal and pleasure than peripheral physiological changes, particularly vaginal vasocongestion or lubrication. Evidence for this position has increased substantially since the 1980s, and may underlie part of the lack of efficacy in using PDE5 to treat FSAD in women

The etiology of FSD is multi-factorial, with both biologic and psychosocial elements. In addition, many patients report concerns across a variety of symptom complexes. Given the multifactorial etiology of FSD, both pharmacologic and nonpharmacologic strategies have been investigated. Treatments in the past have aimed to address individual symptoms, but no single treatment modality addresses the entire spectrum of the disorder**(11).**

In the study in our hands, there were no statistical significance differences between the two studied groups all scores pre ttt. But there was statistical significance increase in desire, orgasm and total score among Group II (flibanserin) compared to Group I (vardenafil) post ttt. Regarding comparing pre and post scores in each group:

In Group I there were highly statistical significance increase in index scores of lubrication and satisfaction (by 37.5% & 42.7%respectively) post ttt and statistical significance increase in orgasm and total score (25% & 23.36 % respectively) post ttt compared to pre. While in Group II there was highly statistical significance increase in desire, orgasm, satisfaction and total (by 33.3%,41.76% & 25.66 % respectively) post ttt and statistical significance decrease in arousal score (by 23.75%) post ttt compared to pre.

Our results are supported by study of **Robinsonet al., (14)** as they reported that Flibanserin is effective in the treatment of HSDD. Flibanserin should be administered at bedtime to limit the risk for hypotension/syncope, accidental injury, and central nervous system (CNS) depression. Concomitant alcohol use contributes to significant CNS depression and hypotension/syncope with flibanserin and should be avoided according to the boxed warning. Careful patient assessment prior to the diagnosis of HSDD and the use of flibanserin is needed for safe use.

Regarding **Thorp et al.(15)** studied the efficacy of Flibanserin in the DAISY Study found that Flibanserin 100 mg once daily was associated with an increase in SSE ($P<0.01$ vs. placebo) All flibanserin regimens improved FSDS-R total, FSDS-R Item 13, FSFI total, and FSFI desire domain scores vs. placebo ($P<0.05$, for all). The most frequently reported adverse events in women receiving flibanserin were somnolence (11.8%), dizziness (10.5%), and fatigue (10.3%).

Katz et al., [16]intheir study of efficacy of flibanserin in women with HSDD: Results from the BEGONIA trial found that flibanserin 100 mg qhs resulted in significant improvements in the number of SSE and sexual desire (FSFI desire domain score) vs. placebo. Flibanserin was associated with significant reductions in distress associated with sexual dysfunction (FSDS-R total score) and distress associated with low sexual desire (FSDS-R Item 13) vs placebo.

DeRogatis et al., [17]studied the efficacy of 24 weeks'flibanserin 50 and 100g treatment in premenopausal women with HSDD Violet study,At the end of the study, mean (SE) increases from baseline in FSFI desire domain score were 0.5 (0.1) for placebo, 0.8 (0.1) for flibanserin 50 mg ($P < 0.05$ vs. placebo), and 0.9 (0.1) for flibanserin 100 mg ($P < 0.000,1$ vs. placebo) . The greater increases in FSFI desire domain score in both flibanserin groups vs. placebo were statistically significant at all-time points ($P < 0.05$ vs. placebo for all), except at week 4 for flibanserin50 mg.

Regarding**Lodise, [18]**reported that as the first approved medication for low sexual desire, even with counseling considerations and concerns regarding broad use and efficacy, flibanserin provides an option for patients desiring an FDA-approved medication to address low sexual desire. As described in the **[19]**'s article, additional study of flibanserin in diverse populations will be advantageous to further define flibanserin's role and the patients best suited for use to ensure optimal efficacy.

Frühauf et al., [20]suggested that the benefits of flibanserin treatment are marginal, particularly when taking into account the concurrent occurrence of AEs. It has been suggested that women with HSDD would benefit most from an integrative approach, including, medical, psychiatric, psychological, couple-relationship, and sociocultural domains: the biopsychosocial model. Before flibanserin can be recommended in guidelines and clinical practice, future studies should include women from diverse populations, particularly women with a history of somatic and psychological comorbidities, medication use, and surgical menopause.

V. Conclusion:

In conclusion,female sexual problems don't received more attention as male sexual problems among health care provider in our country and therefore warrants recognition as a significant public health issue, with a need for further research studies in different population and measuring different attributes. Also, we need to increase public awareness regarding sexual problems and its impact on their life and change culture view for the importance of sexual education especially for the new couples.

Treatment of FSD is multi-factorial; medications alone do not resolve FSD. Flibanserin is a controversial drug approved for a controversial disorder amid huge controversy. While it may serve as the lamp in the light in the long search for female sexual problems, it has still a long way to go. Women taking this drug must well be educated about the adverse events associated with this drug and the possible interactions.

Flibanserin treated women reported improvements on most measures of sexual dysfunction during the study, and trend was observed on most study measures in favor of flibanserin and significant differences were noted to compare with vardenafil. It seems that vardenafil may be effective in women with orgasm difficulty or lubrication defect.

VI. Recommendations

1) Flibanserin is an effective drug for treatment of HSDD. Design and implement community-wide study to evaluate the effect of flibanserin in the treatment of female sexual dysfunction.

2) Future studies should include more specific inclusion criteria such as only including women for whom FSAD is the primary diagnosis and exclude other sexual disorders.

3) Expand the concept of sex education for Arabic women**.**

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