

THE EFFECT OF
ANTIDEPRESSANT USAGE ON
THE EFFICACY OF ZESTRA FOR
WOMEN™ IN WOMEN WITH,
AND WITHOUT, FEMALE
SEXUAL AROUSAL DISORDER

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Zestra for Women™

- Feminine massage oil developed under the Cosmetics Act
- Enhance sexual pleasure
- Facilitate female sexual arousal
- Ingredients: FDA food additives list , FDA GRAS list, all natural (botanicals)

Zestra for Women™

- Proprietary blend of:
 - Borage seed oil
 - Evening primrose oil
 - Angelica root extract
 - Coleus forskohlii extract
 - Ascorbyl palmitate
 - dl-alpha tocopherol
 - Natural fragrances
- (Patent Pending)

Placebo for Zestra for Women™

- Soybean oil + coloring + fragrance; matches:
 - Odor
 - Color
 - Lubricity
 - Viscosity
 - Absorbency

Methods: study design

- 10 Women with FSAD; 10 women with no FSDs
- Visit 1: Screening, Begin period 1,
 - 5 applicators at home
- Visit 2: Assessment, Begin period 2,
 - 5 applicators at home
- Visit 3: Assessment, Exit

Female Sexual Arousal Disorder

- Persistent or recurrent inability to attain or maintain sufficient sexual excitement, causing personal distress. It may be expressed as a lack of subjective excitement or a lack of genital (lubrication/swelling) or other somatic responses.

Methods: inclusion criteria

- Written, informed consent
- 21 to 65 years
- Without risk of conception
- Stable heterosexual relationship for 1 year
- FSAD: Consensus Panel FSAD for 6 months; previously functional; Normals: No FSDs
- FSAD: $40 \leq \text{FSDS} \leq 60$
- Normals: $\text{FSDS} \leq 40$

Methods: exclusion criteria

- Unresolved sexual trauma or abuse
- Primary anorgasmia, vaginismus, sexual pain disorder, or sexual aversion disorder
- Pregnant or nursing
- Active STD
- Dyspareunia not attributable to vaginal dryness
- Neuroleptics, lithium, bupropion, coumadin

Methods: assessments

Visit 1	Visit 2	Visit 3
FSFI© FSDS©	FSFI© FSDS© FSEP© GAQ© QCTS©	FSFI© FSDS© FSEP© GAQ© QCTS©

Methods: safety endpoints

- Occurrence of any Adverse Events

Methods: efficacy endpoints

- # Satisfactory arousals/adequate attempts (FSEP Q3/Q7)
- Remaining FSEP questions
- FSFI
- FSDS(20)
- GAQ
- QCTS

Female Sexual Encounter Profile (FSEP)©

1. Please circle all activities that apply:
 - A. Genital stimulation by partner
 - B. Masturbation
 - C. Intercourse

Female Sexual Encounter Profile (FSEP)©

2. How would you rate your level of sexual desire during this sexual activity?
 - A. No desire
 - B. Slight desire
 - C. Moderate desire
 - D. High desire

Female Sexual Encounter Profile (FSEP)©

3. Were you satisfied with your arousal
(excitement) during this sexual activity?

Yes

No

Female Sexual Encounter Profile (FSEP)©

4. Did you achieve enough lubrication (wetness) to allow comfortable intercourse (even if you didn't actually have intercourse)?

Yes

No

Female Sexual Encounter Profile (FSEP)©

5. Did you achieve orgasm?

Yes

No

Female Sexual Encounter Profile (FSEP)©

6. How would you rate your level of sexual arousal (excitement) during this sexual activity?
- A. Not at all aroused
 - B. Slightly aroused
 - C. Moderately aroused
 - D. Highly aroused

Female Sexual Encounter Profile (FSEP)©

7. Were conditions appropriate for a satisfactory sexual encounter? (Adequate time, no distractions, etc.)

Yes

No

Methods

- Since Normal and FSAD women showed positive responses to Zestra, the two groups were pooled, then separated by SSRI use. All comparisons were SSRI vs. No SSRI.

Results: demographics

Descriptor	No SSRI	SSRI
N	13	7
Age	44.0 \pm 7.4	43.4 \pm 7.3
Height	164.7 \pm 6.1	165.8 \pm 4.7
Weight	77.4 \pm 19.2	77.7 \pm 16.3
Menarche	12.8 \pm 1.8	13.1 \pm 1.2
1 st Intercourse	18.7 \pm 2.5	16.9 \pm 1.6
Postmenopausal	4/13	2/7
HRT	4/13	2/7
Hormonal Contraception	2/13	3/7

Results: demographics

Descriptor	No SSRI	SSRI
FSDS (20)	27.3 \pm 20.0	29.9 \pm 17.0
FSFI Total	27.5 \pm 6.1	22.5 \pm 5.3
FSFI Desire	3.6 \pm 1.4	2.5 \pm 1.4
FSFI Arousal	4.2 \pm 1.5	2.8 \pm 1.4
FSFI Lubrication	5.5 \pm 1.1	4.0 \pm 1.3*
FSFI Orgasm	4.3 \pm 1.8	2.7 \pm 1.5*
FSFI Satisfaction	4.2 \pm 1.3	4.5 \pm 1.3
FSFI Pain	5.8 \pm 0.5	6.0 \pm 0.0

* P < .05

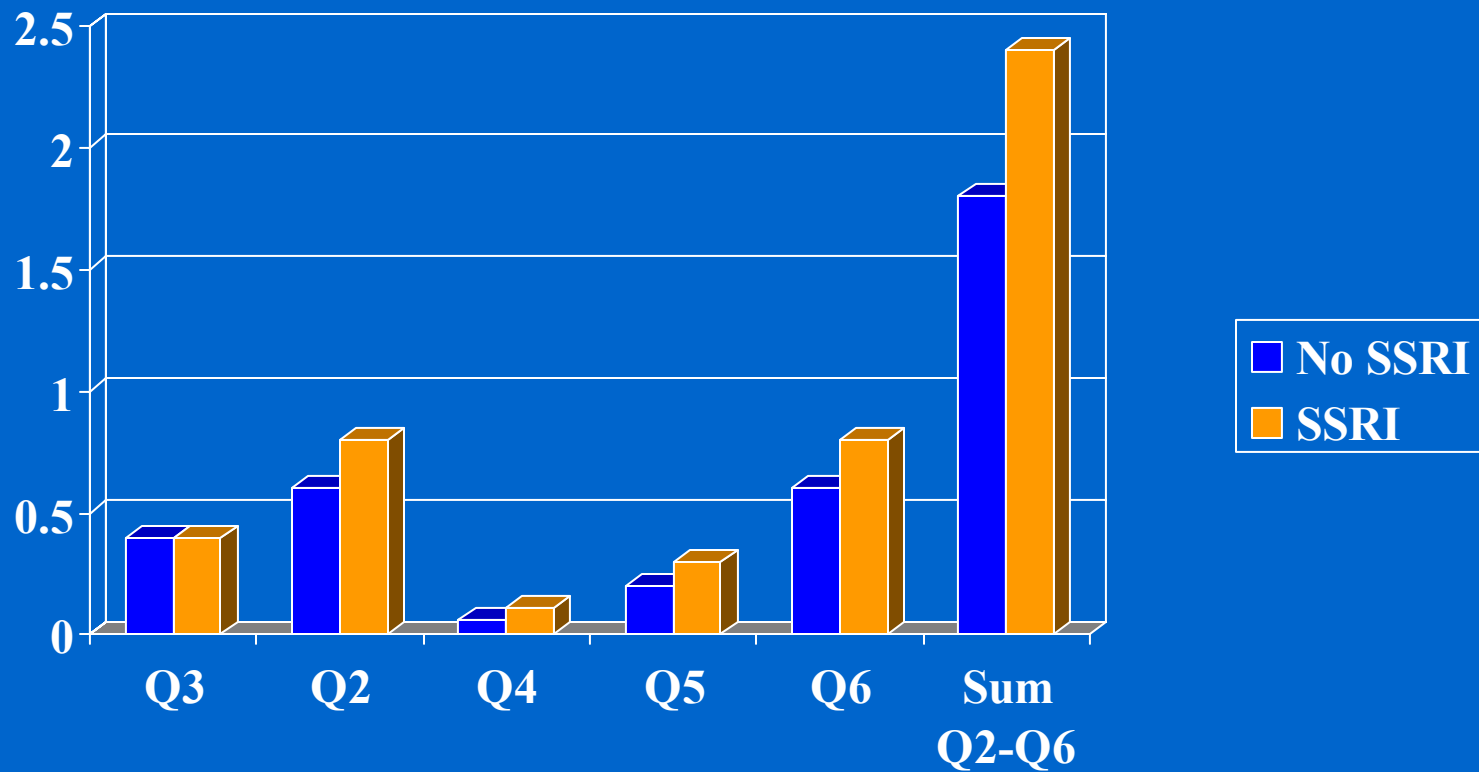
Results: Efficacy, Paired Analyses

Mean Change (Zestra – Placebo)		
Endpoint	No SSRI	SSRI
FSEP Q3/Q7	0.4 ± 0.4**	0.4 ± 0.3*
FSEP Q2/Q7	0.6 ± 0.4***	0.8 ± 0.3***
FSEP Q4/Q7	0.06 ± 0.15	0.11 ± 0.30
FSEP Q5/Q7	0.2 ± 0.3*	0.3 ± 0.2*
FSEP Q6/Q7	0.6 ± 0.6**	0.8 ± 0.5***
FSEP TOTAL	1.8 ± 1.4***	2.4 ± 1.2**

*P < .05 **P < .01 ***P < .001

No Between Group Comparisons were significant

Results: Efficacy: Mean Changes in FSEP Scores



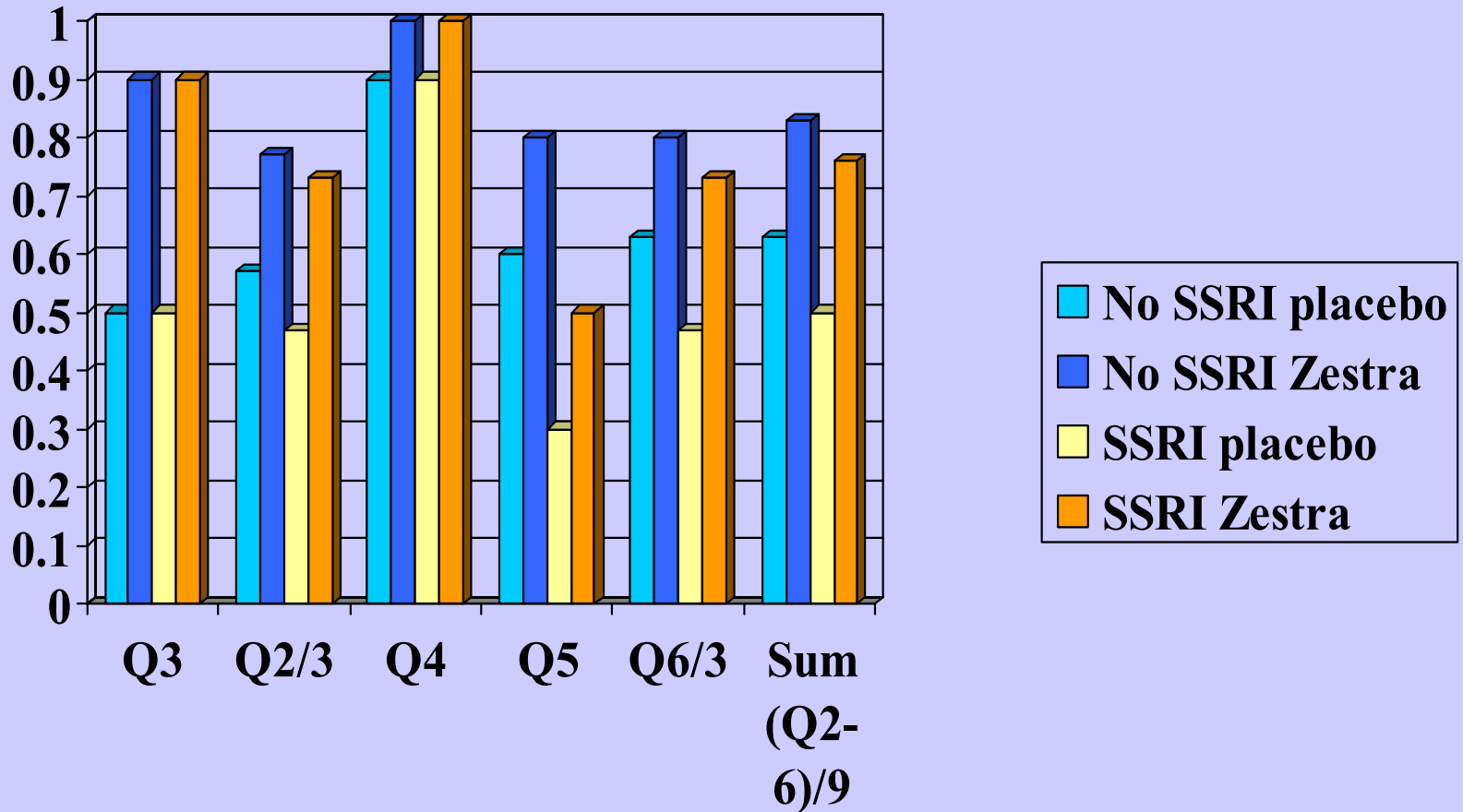
Results: Efficacy: Mean FSEP Scores

	Q2	Q3	Q4	Q5	Q6	ΣQ2-6
No SSRI: Placebo	1.7 ± .6	.5 ± .4	.9 ± .2	.6 ± .4	1.9 ± .7	5.7 ± 1.9
No SSRI: Zestra	2.3 ± .5***	0.9 ± .2**	1.0 ± .0	.8 ± .3*	2.4 ± .5**	7.5 ± 1.2***
SSRI: Placebo	1.4 ± .5	.5 ± .4	.9 ± .3	.3 ± .4	1.4 ± .6	4.5 ± 1.5
SSRI: Zestra	2.2 ± .6***	.9 ± .4*	1.0 ± .0	.5 ± .5*	2.2 ± .8**	6.8 ± 2.1**

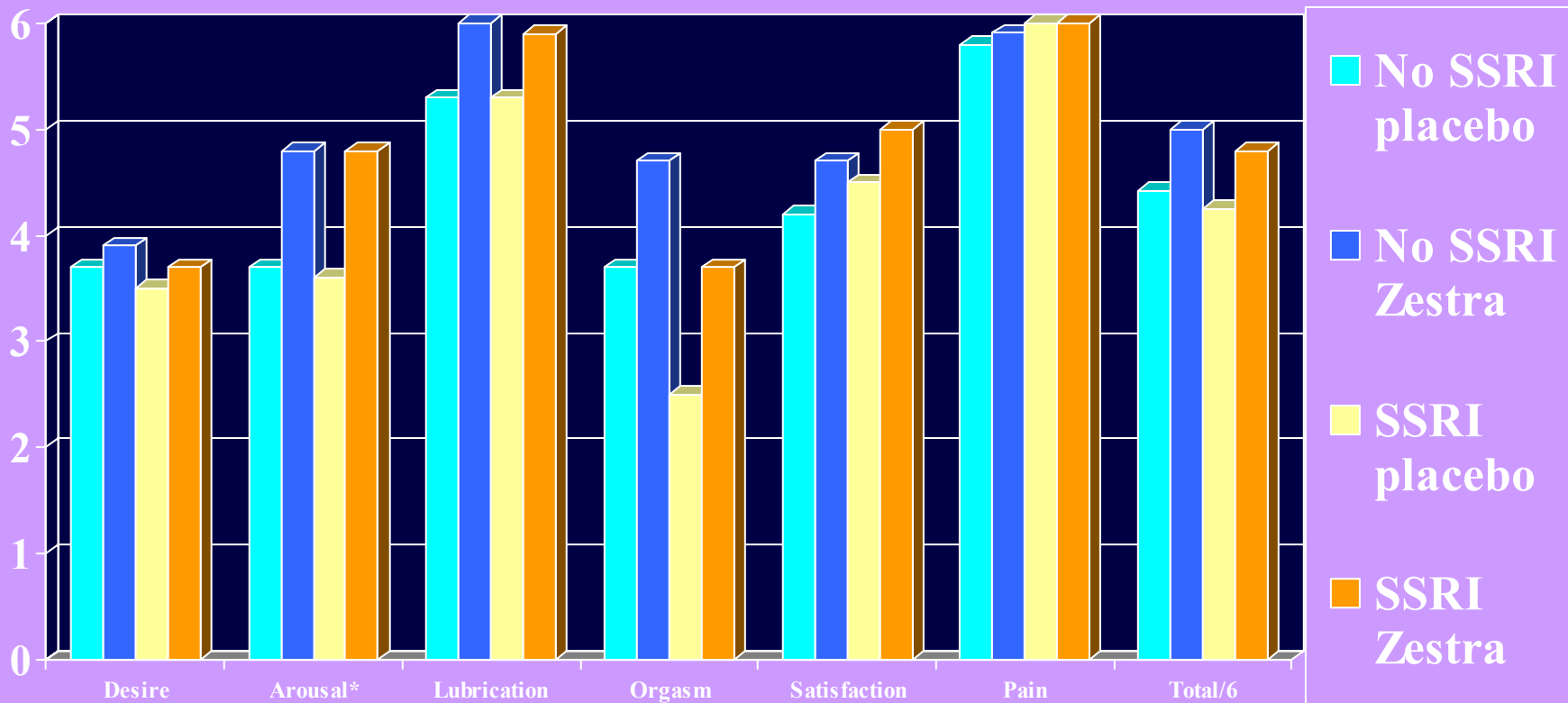
*P<.05 **P<.01 ***P<.001

No Between Group comparison was significant

Results: Efficacy: Normalized Mean FSEP Scores



Results: Efficacy: FSFI



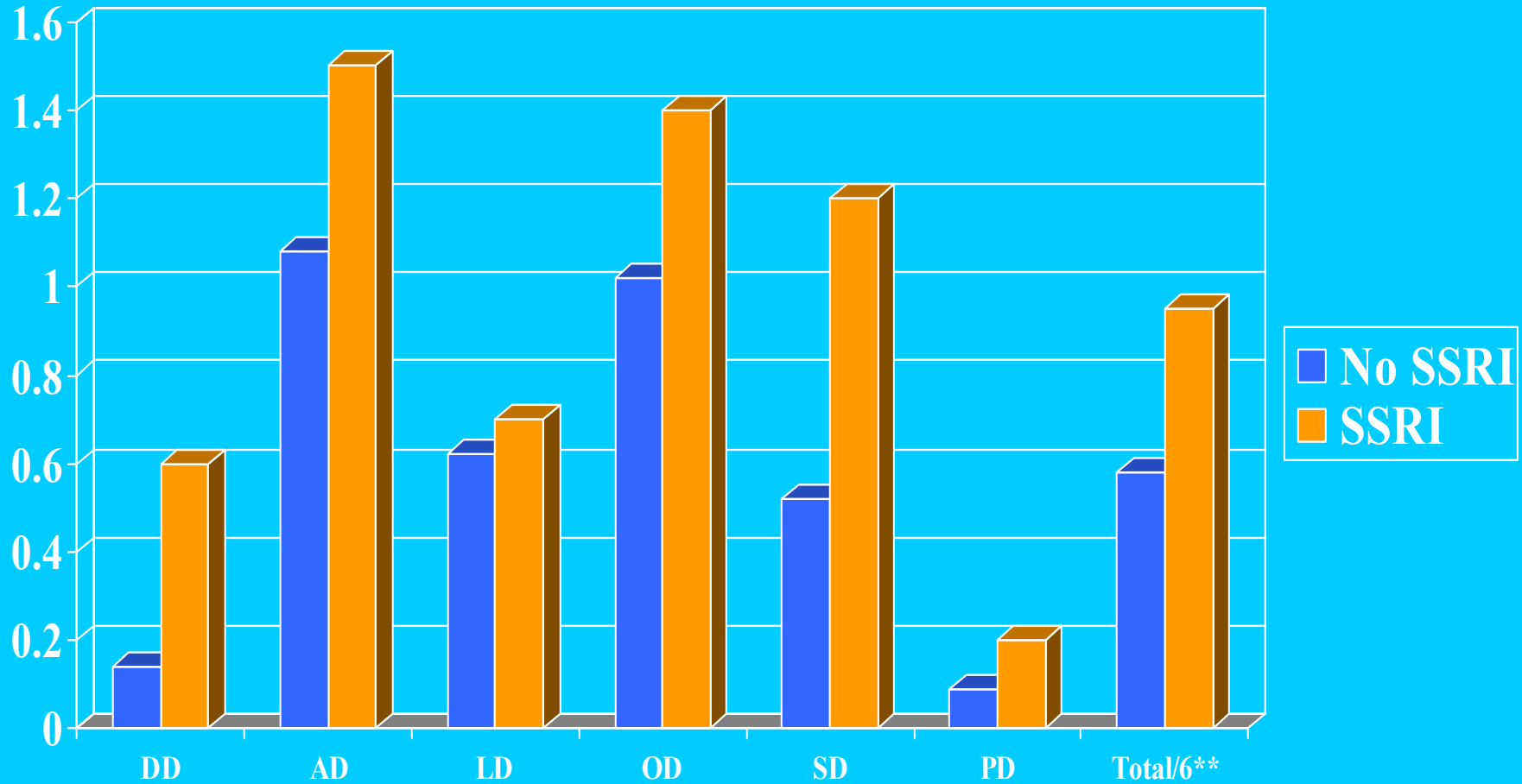
Results: Efficacy: Mean Changes in FSFI

Endpoint	No SSRI	SSRI
FSFI DESIRE	.14 \pm 1.4	.6 \pm 1.4
FSFI AROUSAL	1.08 \pm 1.3*	1.5 \pm 1.5*
FSFI LUBRICATION	.62 \pm 1.3	.7 \pm 1.5
FSFI ORGASM	1.02 \pm 1.4*	1.4 \pm 1.4*
FSFI SATISFACTION	.52 \pm 1.7	1.2 \pm 1.3
FSFI PAIN	.09 \pm 0.5	.2 \pm 0.4
FSFI TOTAL	3.48 \pm 5.5*	5.69 \pm 5.1*
FSDS	-6.2 \pm 14.9	-1.5 \pm 14.3

*P < .05

No Between Group Comparisons were significant

Results: Efficacy: Mean Changes in FSFI



Results: Efficacy: Global Assessment

Question 1

- GAQ 1: While using the study medication, did you feel that your level of sexual arousal (excitement) improved?
 - 0 Not at all
 - 1 A little, but barely noticeable
 - 2 Somewhat
 - 3 Quite
 - 4 Greatly

Results: Efficacy: Global Assessment

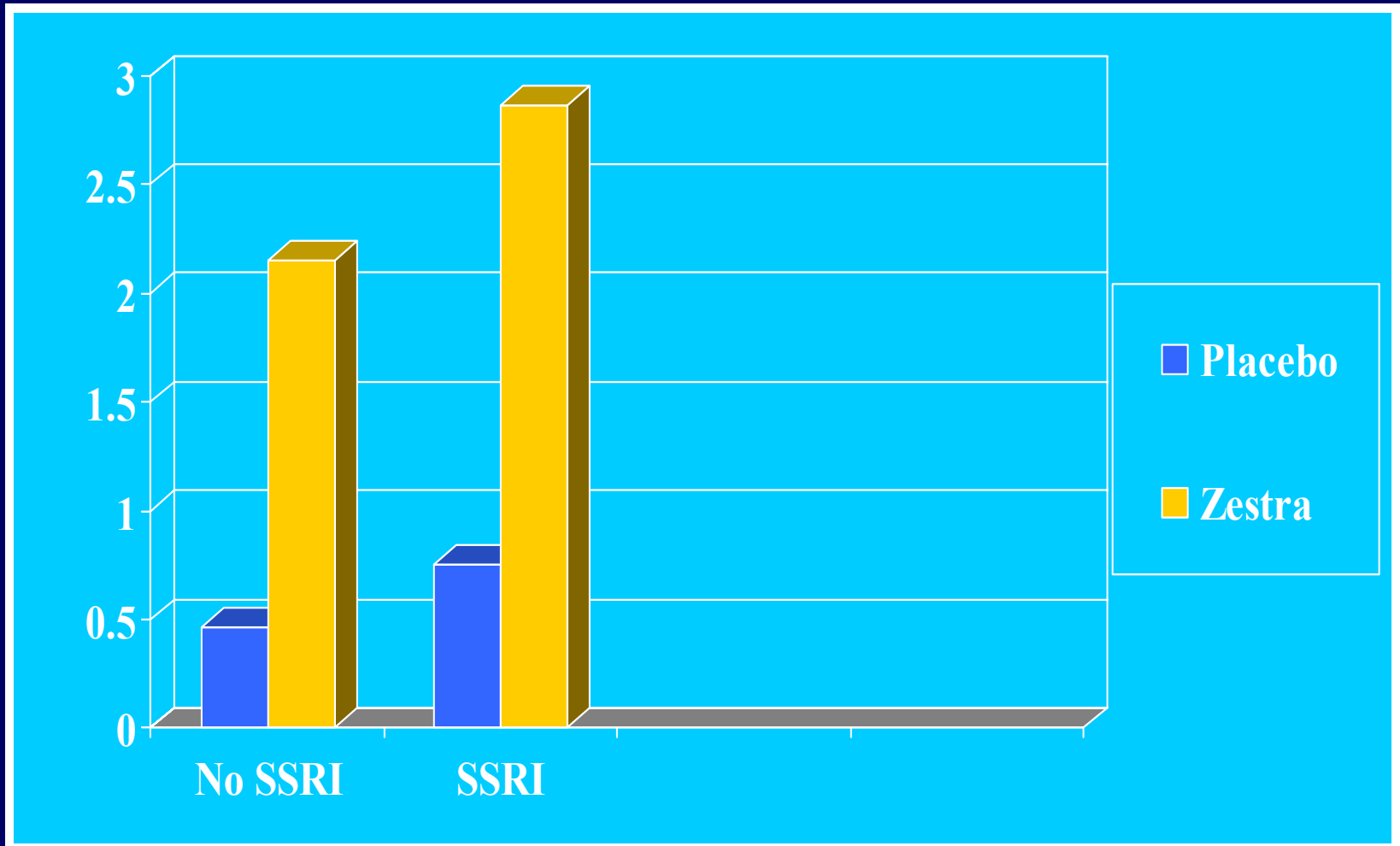
Question 1

Patients	Placebo	Zestra
No SSRI	0.46 \pm 0.66	2.15 \pm 1.41**
SSRI	0.75 \pm 0.96	2.86 \pm 1.07**

**P<0.01

No Between Group Comparisons were significant

Results: Efficacy: Global Assessment Question 1



Results: Efficacy: Global Assessment

Question 1

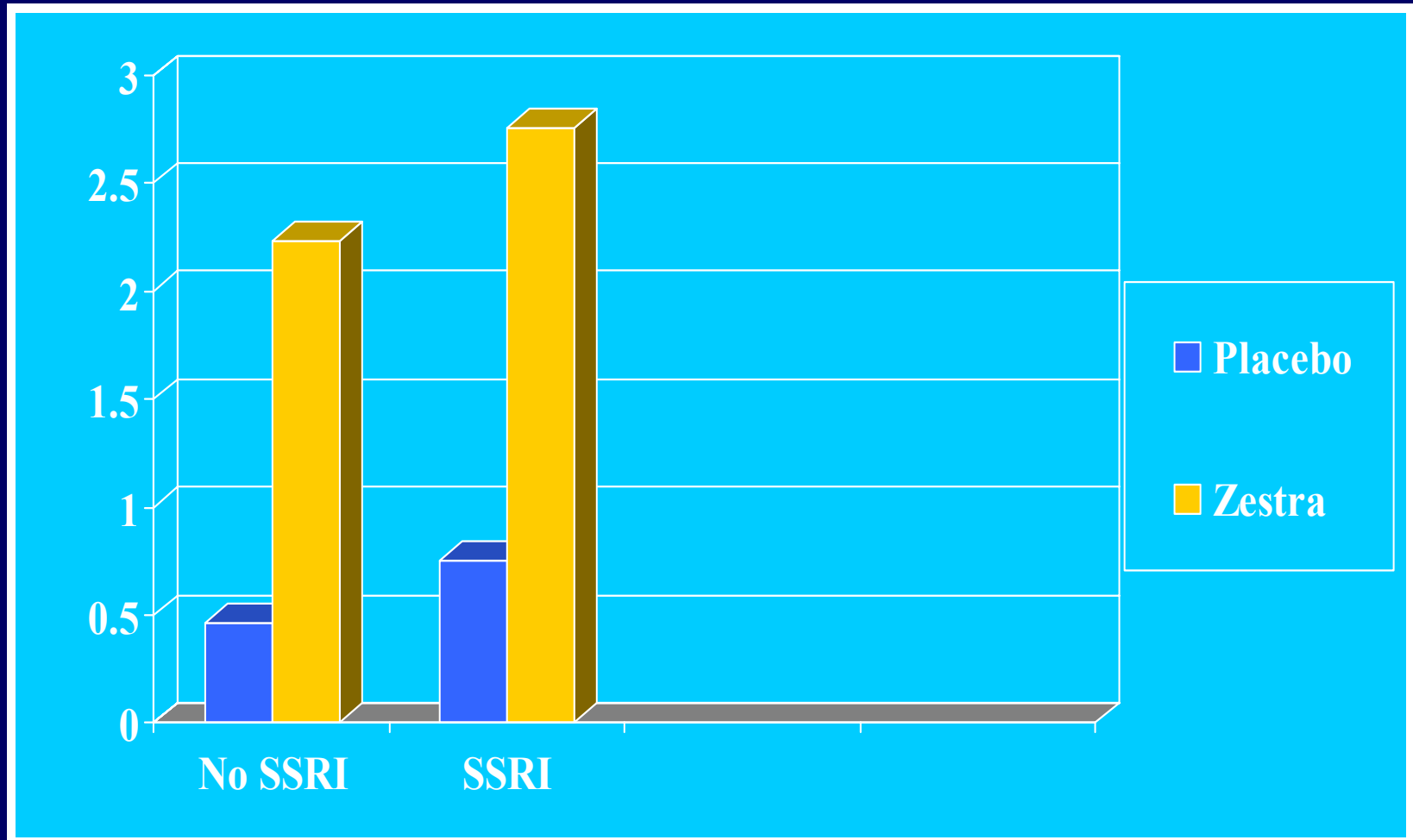
- GAQ 2: While using the study medication, did you feel that your sexual pleasure was enhanced?
 - 0 Not at all
 - 1 A little, but barely noticeable
 - 2 Somewhat
 - 3 Quite
 - 4 Greatly

Results: Efficacy: Global Assessment

Question 2

Patients	Placebo	Zestra
No SSRI	0.46 \pm 0.52	2.23 \pm 1.17***
SSRI	0.75 \pm 0.96	2.75 \pm 1.50**
P<0.01 *P<0.001 No Between Group Comparisons were significant		

Results: Efficacy: Global Assessment Question 2



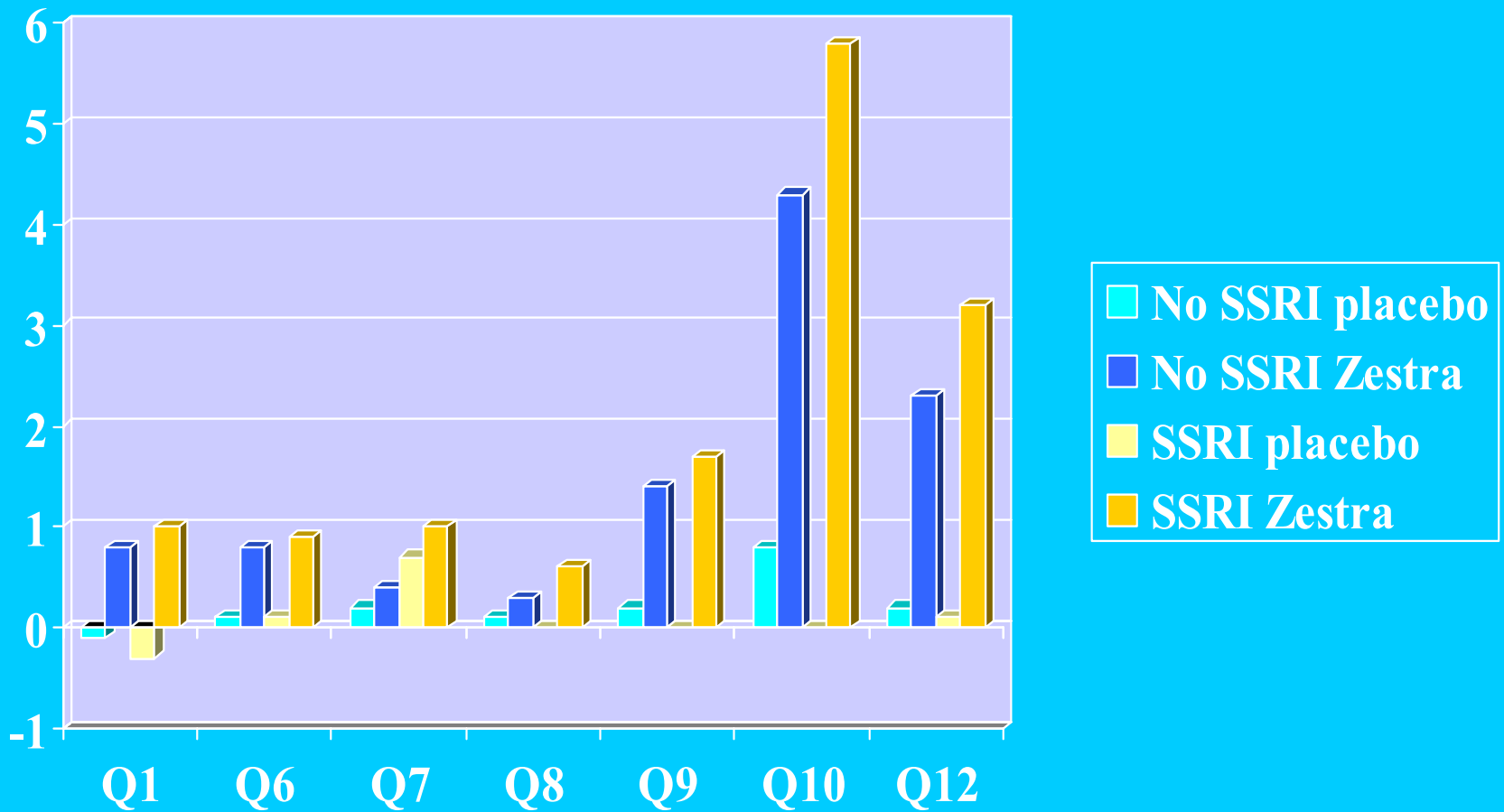
Results: Efficacy: QualiLife Consumer Testing Survey

- Questions 1, 6, 7, 8, 9, 10, and 12 are quantitative.
- Q1 addresses genital sensation.
- Q6 addresses pleasure with sexual activities.
- Q7 addresses lubrication.
- Q8 addresses ability to have orgasms.
- Q9 addresses enhancement of sexual experience.
- Q10 addresses willingness to purchase product.
- Q12 asks how much patient would pay for product.

Results: Efficacy: QualiLife Consumer Testing Survey

QCTS Question	No SSRI Placebo	No SSRI Zestra	SSRI Placebo	SSRI Zestra
Q1: sensation	$-.1 \pm .3$	$.8 \pm .4^{***}$	$-.3 \pm .5$	$1.0 \pm .0^{***}$
Q6: pleasure	$.1 \pm .3$	$.8 \pm .4^{***}$	$.1 \pm .4$	$.9 \pm .4^{**}$
Q7: lubrication	$.2 \pm .4$	$.4 \pm .6$	$.7 \pm .5$	$1.0 \pm .0$
Q8: orgasm	$.1 \pm .3$	$.3 \pm .5$	$.0 \pm .6$	$.6 \pm .5^*$
Q9: enhanced	$.2 \pm .6$	$1.4 \pm 1.0^{**}$	$.0 \pm .6$	$1.7 \pm .8^{**}$
Q10: purchase	$.8 \pm 1.7$	$4.3 \pm 1.9^{**}$	0.0 ± 0.0	$5.8 \pm .8^{***}$
Q12: price	$.2 \pm .3$	$2.3 \pm 3.1^*$	$.1 \pm .4$	3.2 ± 3.2
<p>*P<.05 **P<.01 ***P<.001</p> <p>No Between Group Comparisons were significant</p>				

Results: Efficacy: QualiLife Consumer Testing Survey



Conclusions

- Zestra for Women™ is effective in women with, and without FSAD, regardless of SSRI usage.
- Women using SSRIs start with lower efficacy variables, but experience greater improvements in response to Zestra than women not using SSRIs.
- Zestra for Women™ improves level of arousal in women with, and without FSAD, regardless of SSRI usage.
- Zestra for Women™ increases frequency of orgasm in women with, and without FSAD, regardless of SSRI usage.
- Zestra for Women™ improves desire in women with, and without FSAD, regardless of SSRI usage.
- Zestra for Women™ enhances sexual pleasure in women with, and without FSAD, regardless of SSRI usage.