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Evaluation of clinical efficacy of the Vigomax Forte Tablet in Male Sexual Dysfunction

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ABSTRACT

Aim of the study: To study the effects of Vigomax Forte Tablet in male sexual dysfunction following certain physical and mental exhaustion states. **Materials and Methods:** Male patients complaining of sexual dysfunction as a result of stress, alcohol, diabetes or anti-hypertensive drugs were considered for the study. 64 patients satisfying the above-mentioned inclusion criteria were selected for the study. Patients of each group were randomly administered Vigomax Forte Tablet / Placebo Tablets in the dose of 1 Tablet twice a day. Each patient was asked to follow up every 4 weeks, when he was examined and the beneficial or adverse effects of the drug treatment were noted. **Results:** There was a statistically significant improvement in all the parameters evaluated. **Conclusion:** Thus, in this study, Vigomax Forte Tablet enhanced libido as well as erectile function in patient population with varied etiology of erectile dysfunction. Vigomax Forte Tablet was also well tolerated. Based on these data, Vigomax Forte Tablet may have the potential to become a safe & effective treatment option for erectile dysfunction.

Key words: *Erectile Dysfunction, Ejaculation, Erection, Impotence, Premature Ejaculation*

INTRODUCTION

Erectile dysfunction (ED) has been defined by the National Institutes of Health (NIH) Consensus Development Panel on Impotence and the American Urological Association (AUA) as the inability to achieve or maintain an erection sufficient for satisfactory sexual performance.[1,2] ED is a common medical disorder that has a negative impact on quality of life and self-esteem and can create difficulties in partner relationships.[1] A variety of organic, psychogenic, and lifestyle factors have been implicated in the etiology of ED.

In India, as in other populations, its exact prevalence is unknown. However, if comparable to the United States, where erectile dysfunction of some degree has been estimated to affect 52% of men 40 to 70 years of age,[3] the scale of the problem in Asian countries is probably very large.

Erectile dysfunction is commonly associated with aging and with a variety of medical and psychological conditions.[1] In Singapore, a study of the causes of erectile dysfunction showed the condition to be of organic origin in 72.5% of men and psychogenic in 27.5%. Diabetes mellitus and vascular disease accounted for most (81%) cases of organic origin.[4]

The range of therapies for treating erectile dysfunction has expanded rapidly in recent years, with a trend toward understanding the scientific basis of erectile function and implementing therapies that are strategically based on this new knowledge. Treatment options in the field have evolved from penile prostheses that unnaturally provide a rigid erectile organ for sexual intercourse to various pharmacotherapies that are designed to restore or

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promote the biochemical mechanisms required for natural erectile function. As pharmacotherapies have evolved, their routes of administration have also been advanced ranging from local (e.g., intracavernosal, intraurethral and tropical) to systemic (e.g., subcutaneous and oral) forms. Among these, the oral route has consistently been highly attractive, particularly since this form offers a noninvasive route of delivery. The patient preference for oral forms of therapy for erectile dysfunction has been well demonstrated, with recent treatment outcome analyses revealing that patients persist in their preferences for some traditional oral therapies despite the poor efficacies and hence cause for significant dissatisfaction.

Several orally administered agents such as yohimbine, trazodone and combinations of yohimbine and trazodone have also been evaluated but have limited effectiveness.[5-9] Recently, sildenafil, an oral, active inhibitor for cyclic guanosine monophosphate-specific phosphodiesterase type 5 (the predominant form in the corpus cavernosum)[10] was introduced. Clinical studies in men in Western countries have demonstrated sildenafil to be effective in treating erectile dysfunction of various causes, and also to be well tolerated.[11-13]

However, despite these favorable indications, several concerns remain. Among the guidelines for its use,[14,15] an absolute contraindication to the use of sildenafil is the concomitant use of nitrate drugs, which may result in severe and possibly fatal consequences, owing to a profound systemic vasodilatory effect of the drugs acting synergistically.[15] Caution may also be advised in administering the medication to patients with retinal disorders such as the rare congenital eye disease, retinitis pigmentosa, in view of the unknown long-term risk of retinal damage associated with effects of the drug on type 6 phosphodiesterase expressed in the retina.[14]

These concerns emphasize the need for responsibility in the administration of the medication and carry out additional objective evaluations of potential toxicities that have not yet been identified.

With the foregoing reasons a study was designed to evaluate the efficacy and safety of Vigomax Forte Tablet, a polyherbal formulation, in Indian men with erectile dysfunction of broad-spectrum etiology.

This was a double blind placebo controlled study sponsored by M/s. Charak Pharma Pvt Ltd. who also supplied the necessary medication.

AIM OF THE STUDY

To study the effects of Vigomax Forte Tablet in male sexual dysfunction following certain physical and mental exhaustion states.

MATERIALS AND METHODS

Inclusion Criteria

Male patients complaining of sexual dysfunction as a result of stress, alcohol, diabetes or anti-hypertensive drugs were considered for the study. The following inclusion criteria were followed:

1. Male patients more than 21 years and less than 60 yrs of age.
2. Sexual dysfunction presents for at least 3 months.

Exclusion Criteria

The following patients were excluded:

1. Patients with organic disorders for sexual dysfunction like paralysis, injury to spinal cord or having a penile anatomical defect.
2. Patient with renal or hepatic dysfunction
3. Patients with a history of stroke or myocardial infarction within the last 6 months.
4. Patients taking other drugs which could interfere with sexual function.

64 patients satisfying the above mentioned inclusion criteria were selected for the study. They were explained about the nature of the study and a written informed consent was obtained from all the patients.

They were then divided into 4 groups of 16 patients each depending upon the etiological factor responsible for sexual dysfunction as determined from history as follows:

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1. Group I - 16 patients - Alcoholics
2. Group II - 16 patients - Diabetics
3. Group III - 16 patients - Anti-hypertensive treatment
4. Group IV - 16 patients - Stress or idiopathic

The patients thus selected were subjected to a detailed history taking with special emphasis on the sexual history and a thorough clinical examination including genital examination as per a standard protocol.

Patients of each group were randomly administered Vigomax Forte Tablet / Placebo Tablets in the dose of 1 Tablet at twice a day for a period of 6 months (8 patients in each subgroup). Each patient was asked to follow up every 4 weeks, when he was examined and the beneficial or adverse effects of the drug treatment were noted.

In the unlikely event of a serious adverse effect, the treatment would be stopped and necessary corrective steps were taken with information to M/s. Charak Pharma Pvt Ltd.

Evaluation of Patients

A) Morbidity Index

The patient's sexual dysfunction status was graded on 5 parameters as follows:

Desire for intercourse

0 = No desire

1 = Desire less than normal

2 = Desire present but unable to perform

3 = Normal

Erection

0 = None at all

1 = Poor erection

2 = Erection without ejaculation

3 = Normal

Ejaculation

0 = No ejaculation

1 = Immediately on intercourse

2 = Shortly after intercourse

3 = Normal

Duration of intercourse

0 = No increase

1 = Slight increase

2 = Moderate increase

3 = Normal

Intercourse satisfaction

0 = Not satisfied

1 = Fair satisfaction

2 = Moderate satisfaction

3 = Completely satisfied

The morbidity index of a patient could thus vary from 0 (normal) to 15 (severe).

B) Laboratory Investigations

C.B.C., E.S.R., S. Testosterone levels were determined at the beginning and at the end of the study period.

C) Patient Evaluation

The patients were asked to judge the beneficial effect of drug treatment after the end of the study period on a 10-point scale.

D) Partner Satisfaction

The patient's partner was questioned to assess the performance of the patient and the satisfaction obtained by her on a 3-point scale as Not satisfied, Satisfied and Very Satisfied.

E) Doctor Evaluation

The investigator would evaluate the effect of drug treatment at the end of the study period as No improvement, Fair improvement, Good improvement and Excellent improvement.

The results were analyzed statistically using Wilcoxson's signed rank test for Morbidity index and Students ‘t’ test for Serum testosterone levels.

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RESULTS

A) Morbidity Index

Group I - (Alcoholics)

The patients were divided into 2 subgroups I-a (Vigomax Forte Tablet) and I-b (Placebo). The baseline morbidity index in the Vigomax Forte Tab group was 12.6±1.51, which reduced to 8.90±0.99, and 4.80±1.40 at the end of 3 months and 6 months respectively. The baseline morbidity index in the Placebo group was 13.30±0.95, which reduced to 12.90±0.99, and 11.90±1.97 at the end of 3 months and 6 months respectively.

The results were statistically significant (z = 3.21 and 3.70 for 0 v/s 90 days and 0 v/s 180 days respectively, Wilcoxson's rank sum test)

Group II - (Diabetics)

The patients were divided into 2 subgroups II-a (Vigomax Forte Tablet) and II-b (Placebo). The baseline morbidity index in the Vigomax Forte Tab group was 13.2 ± 1.47, which reduced to 9.1 ± 1.44, and 5.6 ± 1.95 at the end of 3 months and 6 months respectively. The baseline morbidity index in the Placebo group was 13.30 ± 1.25, which reduced to 12.40 ± 1.42, and 11.50 ± 1.71 at the end of 3 months and 6 months respectively.

The results were statistically significant (z = 3.13 and 3.66 for 0 v/s 90 days and 0 v/s 180 days respectively, Wilcoxson's rank sum test)

Group III - (Anti-hypertensive treatment)

The patients were divided into 2 subgroups III-a (Vigomax Forte Tablet) and III-b (Placebo). The baseline morbidity index in the Vigomax Forte Tab group was 11.6 ± 1.26, which reduced to 7.9 ± 1.59, and 3.7 ± 1.82 at the end of 3 months and 6 months respectively. The baseline morbidity index in the Placebo group was 11.5 ± 1.26, which reduced to 10.9 ± 1.72, and 10.8 ± 1.47 at the end of 3 months and 6 months respectively.

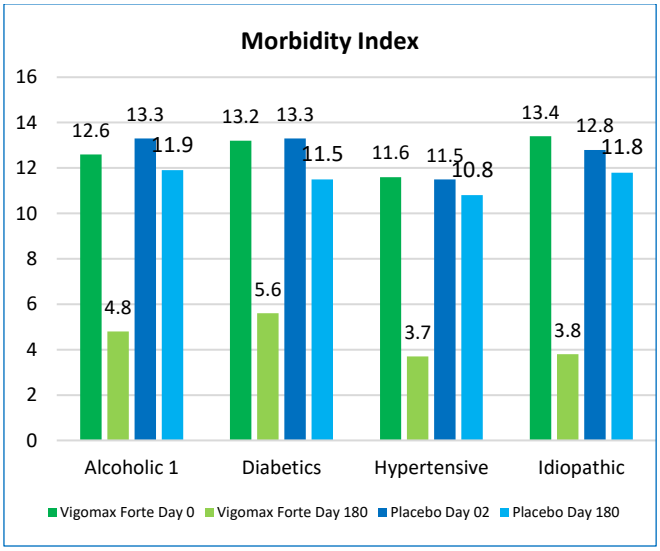
The results were statistically significant (z = 2.87 and 3.70 for 0 v/s 90 days and 0 v/s 180 days respectively, Wilcoxson's rank sum test)

Group IV - (Idiopathic)

The patients were divided into 2 subgroups IV-a (Vigomax Forte Tablet) and IV-b (Placebo). The baseline morbidity index in the Vigomax Forte Tab group was 13.4 ± 1.26, which reduced to 7.3 ± 1.56, and 3.8 ± 1.81 at the end of 3 months and 6 months respectively. The baseline morbidity index in the Placebo group was 12.8 ± 1.13, which reduced to 11.5 ± 1.90, and 11.8 ± 1.93 at the end of 3 months and 6 months respectively.

The results were statistically significant (z = 3.21 and 3.70 for 0 v/s 90 days and 0 v/s 180 days respectively, Wilcoxson's rank sum test)

Alcoholics		**Diabetics**		**Hypertensives**		**Idiopathic**	
Vigomax Forte Tablet	Placebo	Vigomax Forte Tablet	Placebo	Vigomax Forte Tablet	Placebo	Vigomax Forte Tablet	Placebo
12.6 ± 1.51	13.30 ± 0.95	13.2 ± 1.47	13.3 ± 1.25	11.6 ± 1.26	11.5 ± 1.26	13.4 ± 1.26	12.8 ± 1.13
8.90 ± 0.99	12.90 ± 0.99	9.1 ± 1.44	12.4 ± 1.42	7.9 ± 1.59	10.9 ± 1.72	7.3 ± 1.56	11.5 ± 1.90
4.80 ± 1.40	11.90 ± 1.97	5.6 ± 1.95	11.5 ± 1.71	3.7 ± 1.82	10.8 ± 1.47	3.8 ± 1.81	11.8 ± 1.93



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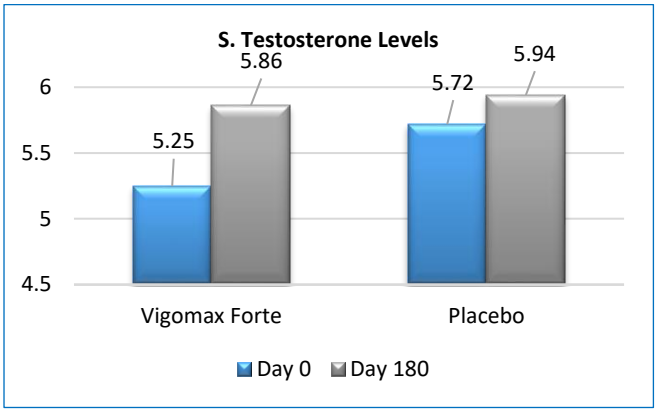
B) Serum Testosterone Levels

The mean S. Testosterone level at baseline in the Vigomax Forte Tablet group was 5.25 ± 1.58 mg/ml and the Placebo group was 5.72+1.36 mg/ml. The mean S. Testosterone level at the end of the study in the Vigomax Forte Tablet group was 5.86+1.79 and 5.94 ± 1.02 mg/ml in the the Placebo group respectively.

S. Testosterone Levels (ng/ml)		
	Vigomax Forte Tablet	**Placebo**
0 Day	5.25±1.58	5.72+1.36
180 Days	5.86+1.79	5.94+1.02



The results were statistically significant (z=3.21 and 3.70 for 0 v/s 90 days and 0 v/s 180 days respectively, Wilcoxson's rank sum test)

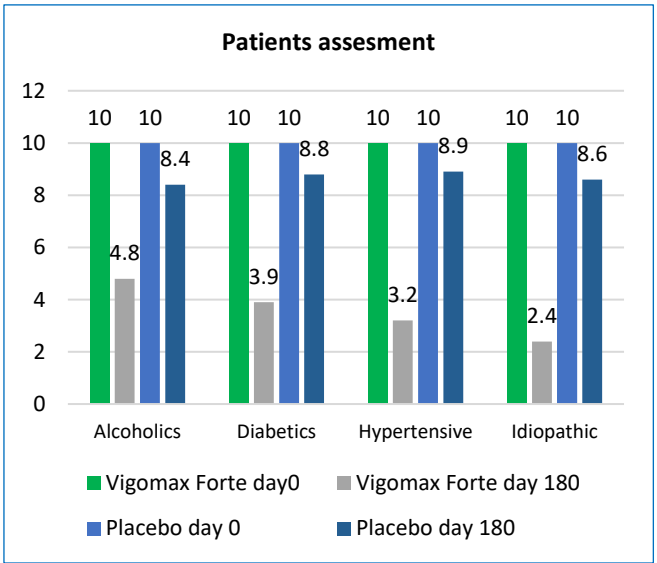
The results in the Vigomax Forte Tablet group were statistically significant ($p<0.05$) but those in the Placebo group were statistically insignificant. (Student's test)

C) Patient Assessment

The patients were asked to evaluate the benefit obtained by them after treatment on a scale of 10. The results were as follows:

Vigomax Forte Tablet				
	Alcoholics	**Diabetics**	**On Antihypertensives**	**Idiopathic**
Day 0	10	10	10	10
Day 90	6.10	6.7	4.8	3.9
Day 180	4.80	3.9	3.2	2.4

Placebo				
	Alcoholics	**Diabetics**	**On Antihypertensives**	**Idiopathic**
Day 0	10	10	10	10
Day 90	9.10	8.5	8.6	8.9
Day 180	8.4	8.8	8.9	8.6



D) Partner Satisfaction

The partners of the patients treated with either drug were questioned regarding the satisfaction obtained by them after sexual intercourse on a 3-point scale as Very Satisfied, Satisfied or Not Satisfied. Out of the total number of 32 patients 50% of the partners were Very satisfied with their partners after treatment with Vigomax Forte Tablet whereas 40% of them were Satisfied. Only 10% of the patients could not satisfy their partners after a 6-month treatment with Vigomax Forte Tablet.

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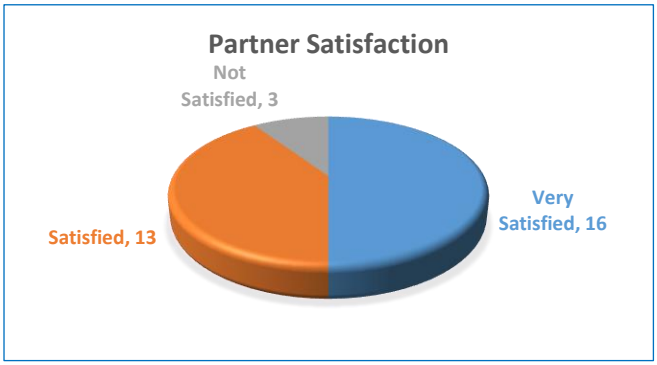
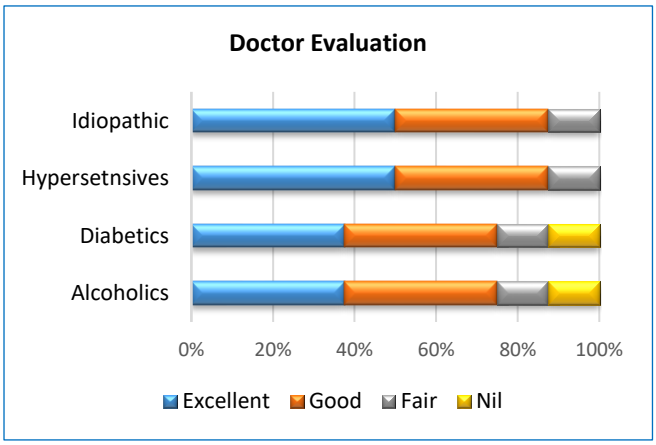
Vigomax Forte TAB	
Very Satisfied	16
Satisfied	13
Not Satisfied	3



E) Doctor's Evaluation

The investigators graded the improvement observed in the patients on a 4-point scale as Excellent, Good, Fair or Nil. The improvement grade noted in all the categories concerned is depicted below.

Vigomax Forte TAB				
	Alcoholics	**Diabetics**	**On Anti-Hypertensives**	**Idiopathic**
Excellent	3	3	4	4
Good	3	3	3	3
Fair	1	1	1	1
Nil	1	1	0	0



F) Patient Dropouts

There were no dropouts from the Vigomax Forte Tablet group although 2 patients from the Placebo group were lost to follow-up within the trial but reported at the end of the study period.

Vigomax Forte Tablet was generally well tolerated. No treatment related serious adverse events (SAE's) were reported during the study or follow-up period. No clinically significant changes in laboratory values, ECG or blood pressure were observed.

DISCUSSION

Erectile dysfunction is probably vastly under reported, as most do not seek treatment for fear of embarrassment, myths about the disorder and cultural beliefs. However, the recent introduction of effective oral treatment sildenafil, has increased the number of patients seeking treatment for this prevalent medical disorder.

As observed from the results, of this study, Vigomax Forte Tablet was effective in restoring sexual function in men with erectile dysfunction of various causes.

Despite its prime importance on erectile function, a limited assessment of the partner relationship was measured.

The improvement of erectile function in this study could be attributed to reported effect of protodioscin, the main ingredient of *Tribulus terrestris* extract.[16]

Protocdioscin has also been reported to increase DHEA (Dehydro Epiandrosterone) level. DHEA is a hormone involved in boosting immune system and increasing the general sense of well-being. DHEA has been shown to improve the functions and integrity of endothelial cell membranes, including those in the corpus cavernosum and blood vessels.[20-21] Adomoelja[22] reported that *Tribulus terrestris* extract treatment increased the level of DHEA in diabetic and non-diabetic subjects with erectile dysfunction.

Protodioscin has also been reported to have a selective effect on hypothalamic hormone production including increasing LH and testosterone secretion without affecting FSH level.

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The increase in testosterone level, as seen in the results, was the most probable mechanism responsible for the improvement of erectile function and libido.[23,24]

Besides *Tribulus terrestris, Withania somnifera, Mucuna pruriens* have been documented in standard Ayurvedic texts to enhance libido.

CONCLUSION

Thus, in this study, Vigomax Forte Tablet enhanced libido as well as erectile function in patient population with varied etiology of erectile dysfunction. Vigomax Forte Tablet was also well tolerated. Based on these data, Vigomax Forte Tablet may have the potential to become a safe & effective treatment option for erectile dysfunction.

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REFERENCES

1. NIH Consensus Development Panel on Impotence: Impotence. JAMA 270: 83-90, 1993.
2. Montague DK, Barada JH, Belker AM, *et al:* Clinical guidelines panel on erectile dysfunction: summary report on the treatment of organic erectile dysfunction. J Urol 156:2007-2011, 1996.
3. Feldman H.A., Goldstein I. and Hatzichristou D.G. *et al.* Impotence and its medical and psychosexual correlates: results of the Massachusetts Male Aging Study. / *Urol* 1994,151:54-61.
4. Lim P.H. and Ng F.C. Erectile dysfunction in Singapore men: presentation, diagnosis, treatment and results. *Ann Acad Med Singapore* 1992, 21:248-253.
5. Wagner G. and Saenz de Tejada I. Update on male erectile dysfunction. *BMJ* 1998, 316:678-682.
6. Morales A., Heaton J.P. and Johnston B. *et al.* Oral and topical treatment of erectile dysfunction: present and future. *Urol Clin North Am* 1995, 22:879-886.
7. Reid K., Surridge D.H. and Morales A. *et al.* Double-blind trial of yohimbine in treatment of psychogenic impotence. *Lancet* 1987, 2:421-423.
8. Meinhardt W., Schmitz P.I. and Kropman R.F. *et al.* Trazodone, a double blind trial for treatment of erectile dysfunction. *Int J Impot Res* 1997, 9:163-165.
9. Montorsi F., Strambi L.F. and Guazzoni G. *et al.* Effect of yohimbine-trazodone on psychogenic impotence: a randomized, double blind, placebo-controlled study. *Urology* 1994, 44:732-736.
10. Boolell M., Allen M.J. and Ballard S.A. *et al.* Sildenafil: an orally active type 5 cyclic GMP-specific phosphodiesterase inhibitor for the treatment of penile erectile dysfunction. *Int J Impot Res* 1996, 8:47-52.
11. Goldstein I., Lue T. and Padma-Nathan H. *et al.* Oral sildenafil in the treatment of erectile dysfunction. TV *Engl J Med* 1998, 338:1397-1404.
12. Boolell M., Gepi-Attee S. and Gingell J.C. *et al.* Sildenafil, a novel effective oral therapy for male erectile dysfunction. *Br J Urol* 1996, 78:257-261.
13. Morales A., Gingell C. and Collins H. *et al.* Clinical safety of oral sildenafil citrate (Viagra) in the treatment of erectile dysfunction. *Int J Impot Res* 1998, 10:69-74.
14. FDA resources page. Food and Drug Administration web site. Available at http://www.fda.gov/cder/consumerinfo/viagra/default.htm. Accessed December 1998.
15. Pfizer, Viagra (sildenafil citrate) Package Insert. Revised November 1998.
16. Adimoelja A Phytochemicals and the breakthrough of traditional herbs in the management of sexual dysfunctions. *IntJAndrol* 2000; 23 Suppl 2:82-4
17. IIMS Therapeutic Focus (1994).
18. Moeloek, N., Adimoelja, A., Tanojo, T., and Pangkahila, W. (1994) Trials of Tribulus terrestris (Libilov) on oligozoospermia. In Proceedings of the Vlth National Congress and Illrd International Symposium on New Perspectives of Andrology on Human Reproduction in Manado, Indonesia.
19. Viktorov, I.V., Kaloyanov, A., Lilov, L., and Zlatanova, V. (1982) Clinical Investigation on Tribestan in Male with Disorders in the Sexual Function. MBI 1981.
20. Gaby, A.R. (1993) DHEA: The Hormone That "Does It All". Holistic Medicine, Spring Ed.: 19-23.
21. Chemick, R. (1996) DHEA Breakthrough. Bellatine Books, New York: 29-95.

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22. Adimoelja, A. (1997) Treatment of sexual dysfunction in diabetes mellitus subjects using orally administered protodioscin and injection of vasoactive compounds. In Seminar of Erectile Dysfunction of Diabetes in Bandung, Indonesia.

23. Viktorov, I.V., Kaloyanov, A., Lilov, L., and Zlatanova, V. (1982) Clinical Investigation on Tribestan in Male with Disorders in the Sexual Function. MBI 1981.

24. Carani, C, Granata, A.R.M., Fustini, M., and Marrama, P. (1996) *Prolactine and Testosterone: Their Roles in Male Sexual Functions. J. Andrology* 19: 48-54

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