

EFFICACY AND SAFETY OF ORAL **Best Man** IN MEN WITH SEXUAL DYSFUNCTION (AN OPEN-LABELED, FLEXIBLE-DOSE STUDY)

SUMMARY

OBJECTIVE: To evaluate the efficacy and safety of **Best Man** in an open-labeled pilot study in men with sexual dysfunction of broad-spectrum etiology with more than 3 months duration.

METHOD: 30 men were enrolled in a 3-month prospective, open-labeled, flexible-dose study. Each man received 1 capsule of **Best Man** in the morning every day and, as needed, took 1-2 capsules at night approximately 30 minutes to 3 hours before engaging in sexual activity, without exceeding a total of 3 capsules daily. Efficacy was determined by the responses to question 1 (ability to achieve an erection), question 4 (ability to maintain an erection), question 12 (level of sexual desire) and question 13 (satisfaction with overall sex life) of the 15-item International Index of Erectile Function (IIEF). Other measures of efficacy and safety included the questions about the patient's medical history as well as questions about **Best Man**.

RESULTS: At the end of the study, there was a statistically significant improvement in 4 descriptive evaluations of the 15 IIEF questionnaires. **Best Man** significantly increased the patient's ability to achieve and maintain erections ($p < 0.01$), orgasmic function, ejaculating function, intercourse satisfaction ($p < 0.01$) and overall sexual satisfaction ($p < 0.01$).

CONCLUSIONS: This study suggests that **Best Man** is an effective, well-tolerated alternative treatment for men with sexual dysfunction who prefer a non-drug approach.

BACKGROUND

Sexual dysfunction, often called "Erectile Dysfunction" (ED) or "impotence," is the repeated inability to attain or maintain an erection firm enough for sexual intercourse. The words "sexual dysfunction" and "impotence" may also be used to describe other problems that interfere with sexual intercourse and reproduction, such as a lack of sexual desire and problems with ejaculation or the ability to achieve an orgasm.

Herbal/botanical products used for the improvement of men's sexual dysfunction have had a long history in folk medicine and are becoming increasingly popular in the world as alternatives or adjuncts to pharmacological remedies. As an all-natural botanical supplement designed for men's sexual dysfunction, **Best Man** has been marketed in the United States and many other countries for approximately 3 years. It has earned a very good reputation for its fast and positive effects in men with sexual dysfunction as well as its overall safety. **Best Man** is a combination of botanical extracts using a proprietary, patent-pending technology called "Bio-Enhanced Extraction, (B.E.E.™)", from palm dates, rice bran oil, sweet potato, lychee, pumpkin and ginseng with added essential nutrients for men's function such as L-arginine, vitamin C, vitamin E and zinc. To evaluate its efficacy and safety scientifically, we designed and performed this pilot study. In this report, we are presenting an open-labeled study involving 30 subjects who were given **Best Man** for a period of 12 weeks. The analysis of the data was based on 4 specific questions of the 15-item International Index of Erectile Function (IIEF) completed by these subjects at the beginning of the trial and also at intervals of 4 weeks, 8 weeks and 12 weeks after taking **Best Man** initially.

MATERIALS AND METHOD

Subjects: 30 subjects (all males: ages: 29 to 74) were enrolled to participate in this study.

Selection criteria included:

- 1) Males 18 years and older
- 2) Having at least one of the following conditions: erectile dysfunction, premature ejaculation, dissatisfaction sexually and/or lack of libido (sexual desire).

Exclusion criteria included:

- 1) Currently dealing with uncontrolled, severe medical conditions, such as hypertension (SP >160mmHg and DP >100mgHg) and/or clinical cardiovascular disease (myocardial infarction, angina pectoris, coronary revascularization, stroke, and/or transient ischemic attack).
- 2) A history of clinical cardiovascular disease (myocardial infarction, angina pectoris, coronary revascularization, stroke, and/or transient ischemic attack).
- 3) A history of psychiatric or other medical conditions that may jeopardize compliance
- 4) Currently participating in another clinical trial.

Methods and Procedures:

After the R&D department of Hamida Pharma Inc. approved the protocol of the study, the subjects were recruited from advertisements in the local community. Subjects were screened first with Questionnaire 1 (SEXUAL FUNCTION ASSESSMENT IN MEN AT THE BEGINNING OF THE STUDY OF **Best Man**) (see attachment-1). An informed consent form was obtained from each subject before the beginning of the study, the procedures of the study were explained and a medical history review was completed. All the subjects are patients with sexual dysfunction and 67% of them (20/30) prefer using a natural and/or nutritional alternative approach to improve their sexual health. Many subjects currently suffer from certain diseases that likely could be the causes of ED. 23% (7/30) of the subjects suffer from hypertension and/or were taking medication for hypertension (hydrochlorothiazide and/or triamterene), 13% (4/30) of the subjects with ED suffer from diabetes (1 of them is type I and 3 of them are type II), 10% (3/30) of the subjects contracted ED after prostate surgery and 3% of the subjects (1/30) with ED currently suffer from hyperthyroidism. 20% (6/30) of the subject's conditions may be related to psychological and/or emotional factors and the other causes of ED were unknown or due to aging. In addition to erectile problems, 53% (16/30) of the subjects reported a low or very low sexual desire and only 7% (2/30) of them were moderately satisfied with their overall sex life.

At the beginning of the study, each subject was given open-labeled **Best Man** product and instructions on how to take **Best Man** as well as certain recommendations on their lifestyle. Each subject took 1 capsule in the morning daily for 12 weeks and, as needed, took 1-2 capsules approximately 30 minutes to 3 hours before engaging in sexual activities.

Each subject finished and submitted Questionnaire 2 (SEXUAL FUNCTION ASSESSMENT IN MEN AFTER THE ACTUAL TRIAL OF **Best Man**) (see attachment-2) separately at the end of 4 week, 8 week and 12 week intervals after taking **Best Man** initially.

RESULTS

The compliance of this study and the acceptance of **Best Man** were satisfactory. 28 subjects completed the 12-week trial period. 2 subjects dropped out in the first 4 weeks. 24 subjects took **Best Man** every morning for 12 weeks without interruption and also took 1-2 capsules before each sexual activity. 4 subjects (4/28) took **Best Man** inconsecutively; 2 of them took **Best Man** only before engaging in sexual activities and the other 2 subjects took **Best Man** before engaging in sexual activities, but they also took 1 capsule in the morning intermittently. 29 subjects (29/30) reported no side effects during the 12 week study and only 1 subject reported **Best Man** had given him “too much energy and resulted in some slight insomnia if **Best Man** was taken too close to bedtime (<1 hour)”. The effects of **Best Man** in men’s ability to achieve an erection, the maintenance of an erection, sexual desire and overall satisfaction of sex life were evaluated statistically and the results are shown on Table 1 to Table 4. The orgasmic function and ejaculating function were also evaluated and the results showed some improvements after taking **Best Man**. 3 subjects (3/6) with premature ejaculation reported an improvement after taking **Best Man** N.

Table 1. Ability to achieve an erection during sexual activities

Scores\Time	Before		After	
	Baseline (n=30)	In 4 weeks (n=28)	In 8 weeks (n=28)	In 12 weeks (n=28)
0: No sexual activity	5	0	0	1
1. Almost never or never	5	2	2	1
2. A few times	14	7	6	3
3. Sometimes	3	9	4	5
4. Most time	3	8	12	13
5. Almost always or always	0	2	4	5
Mean scores ± S.E.	1.93±0.21	3.04±0.20*	3.36±0.23*	3.54±0.23*

*P<0.01 (Significant difference compared with baseline)

Table 1 shows the changes in the ability to achieve an erection during sexual activities reported by 28 subjects. At the beginning of the study, 5 subjects reported no sexual activities for more than 3 months, 5 subjects reported “a few times” and only 10% of the subjects (3/30) could achieve an erection most times during sexual activity. At the end of 12 weeks, 64% of subjects (18/28) could achieve an erection most times during sexual activity. The mean score increased from 1.93 at the beginning of the study to 3.04, 3.36 and 3.54 at the end of the 4, 8 and 12 week periods. Compared with the baseline value, the increase of the mean scores at the end of the 4, 8 and 12-week periods are highly significant (p<0.01).

Table 2. Maintenance of an erection during sexual activities

Scores\Time	Before		After	
	Baseline (n=30)	In 4 weeks (n=28)	In 8 weeks (n=28)	In 12 weeks (n=28)
0: Did not attempt intercourse	6	1	0	0
1. Extremely difficult	10	3	2	2
2. Very difficult	8	6	4	3

3. Difficult	3	4	3	2
4. Slightly difficult	2	11	14	15
5. Not difficult	1	3	5	6
Mean scores \pm S.E.	1.60 \pm 0.24	3.07 \pm 0.26*	3.57 \pm 0.22*	3.67 \pm 0.22*

*P<0.01 (Significant difference compared with baseline)

Table 2 shows the change in the maintenance of an erection during sexual intercourse by 28 subjects. 6 subjects reported that they “did not attempt intercourse”, 10 subjects reported that it was “extremely difficult” to maintain an erection, 8 reported that it was “very difficult” to maintain an erection and 3 reported that it was “difficult” to maintain an erection at the beginning of the study. At the end of 12 weeks, 2 subjects reported “extremely difficult”, 3 reported “very difficult” and 2 reported “difficult”. The mean scores increased from 1.60 at the beginning of the study to 3.07, 3.57 and 3.67 at the end of 4, 8 and 12 week periods. Compared with the baseline value, the changes at the end of 4, 8 and 12-week periods were significant (p<0.01).

Table 3. Sexual desire

Scores\Time	Before		After	
	Baseline (n=30)	In 4 weeks (n=28)	In 8 weeks (n=28)	In 12 weeks (n=28)
1. Very low or none at all	4	0	0	0
2. Low	12	3	2	2
3. Moderate	11	12	10	8
4. High	2	10	12	14
5. Very high	1	3	4	4
Mean scores \pm S.E.	2.47 \pm 0.17	3.46 \pm 0.16*	3.64 \pm 0.16*	3.71 \pm 0.15*

*P<0.01 (Significant difference compared with baseline)

Table 3 shows the changes in the sexual desire reported by 28 subjects. 4 subjects reported “very low” and 12 subjects reported “low” sexual desire at the beginning of the study. At the end of the 12-week study, only 2 subjects reported “low “ sexual desire. 26 subjects reported “moderate”, “high” or “very high” sexual desire. The mean score increased from 2.47 at the beginning of the study to 3.71 at the end of the 12-week period. The increase of scores at the end of the 4, 8 and 12 week periods were statistically significant compared with the baseline value (p<0.01).

Table 4. Overall satisfaction of sex life

Scores\Time	Before		After	
	Baseline (n=30)	In 4 weeks (n=28)	In 8 weeks (n=28)	In 12 weeks (n=28)
1. Very dissatisfied	9	3	1	1
2. Moderately dissatisfied	12	7	5	2
3. Equally satisfied & dissatisfied	7	6	5	4

4. Moderately satisfied	2	9	12	16
5. Very satisfied	0	3	5	5
Mean scores \pm S.E.	2.07 \pm 0.17	3.07 \pm 0.23*	3.54 \pm 0.21*	3.79 \pm 0.18*

*P<0.01 (Significant difference compared with baseline)

Table 4 shows the changes in the overall satisfaction of the subject's sex life. Only 2 subjects reported that they were "moderately satisfied" with their overall sex life at the beginning of the study. At the end of the 12-week period, 21 subjects reported "moderately satisfied" or "very satisfied". The mean score was 2.07 at the beginning and at the end of the 4, 8 and 12-week periods, reached 3.07, 3.54 and 3.79. The increase of the mean scores was significant compared with the baseline value. (p<0.01)

DISCUSSION

The compliance of this open-labeled study and the acceptance of **Best Man** were satisfactory. 28 subjects completed this study. 2 subjects dropped out in the first 4 weeks. One of the subjects had a long business trip overseas during the study period and the other subject dropped out of the study without a specific explanation. No significant side effects were reported, except one subject reported that **Best Man** had given him too much energy and resulted in some minor insomnia if it was taken too close to bedtime (<1 hour). This observation was not found from the other subjects, but interestingly, 83.3% of the subjects reported an "increased energy level". In order to find out the reason and the possible range of the influence of insomnia and other possible side effects, further studies may be necessary.

Sexual dysfunction, especially Erectile Dysfunction (ED), is a common problem with a prevalence of approximately 50% in men aged 40 to 70. There are several etiologies for ED including vasculogenic, neurogenic, hormonal and/or psychogenic factors and also one-fourth of ED can be drug related. The commonly prescribed oral medicines act in different mechanisms. For example, Apomorphine works as a centrally acting agent and Sildenafil acts by inhibiting cyclic GMP-specific phosphodiesterase Type V. The mechanism of **Best Man** may be different from either medicine. **Best Man** is a combination of botanical extracts that may play an important role in naturally increasing the level of testosterone that can be effective transdermally. Abundant clinical literature has shown that testosterone levels directly and indirectly influence the fundamental components of male and female sexual function, including genital development, sex drive, ejaculation, penile and vaginal sensitivity and erectile function in males. **Best Man** might have another important role by increasing the level of NO (Nitric oxide), which helps increase sexual function in both normal males and males with compromised libido. Many researchers believe that NO can correct up to 90% of all penile dysfunction, for it allows an increased amount of blood supply to the penis that is essential for an erection. **Best Man** also works as a powerful anti-oxidant that helps reduce oxidative stress, promote prostate health and also increase the level of NO. The real mechanism of action of **Best Man** is not completely clear; further studies may be needed.

CONCLUSION

This open-labeled study evaluated the effects of **Best Man** on men's sexual function including an ability to achieve an erection, maintenance of an erection, sexual desire and the overall satisfaction of sex life. All the statistical results compared with the baseline value were significant (p<0.01). **Best Man** showed positive effects not only on forgoing aspects, but also on the orgasmic function and ejaculating function. No significant side effects were found. This study

suggested that **Best Man** is an effective, well-tolerated, alternative treatment for men with sexual dysfunction of varied etiologies and manifestations.

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