The Effect of Vitagnus on Treatment of Hot Flash in Menopause

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Abstract: The most common & probably the most undesirable disorders in menopause period, is the hot flash. Since hormone replacement therapy (HRT) for treatment of hot flash has several complications and use of herbal drugs is a new way for treatment of this disorder the aim of this study was to survey the effect of Vitagnus(Vitex Agnus Castus) on treatment of hot flash. In a randomized controlled double blind clinical trial study the efficacy of Vitagus for reducing the hot flash was evaluate as compared to placebo among 46 menopause women who suffered from hot flash. Mean women's age was 51.4 and 52.3years in Vitagnus and plac[2]ebo groups, respectively. Reducing the severity, duration and frequency of hot flash regarding to Cooperman Index, was significant, before and in each stage (15 days & 30 days) after beginning of treatment in two groups ($P < 0.05$), but no significant difference was observed among the groups regarding their effects in every stage of treatment ($P > 0.05$) .We found that the Vitagnus is effective considerably in treatment of hot flash, but its effect is no more than the placebo. So we concluded that, in treatment of hot flash in menopause women more attention must be paid to mental and psychic supports of them.

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Introduction:

Menopause means perpetual cessation of menstruation and one of the stages of women's life that constitutes around 30 years or better to say one third of their life. After menopause, the ovary will stop production of a considerable amount of estrogen and the body will physiologically face the symptoms related to the lack of this hormone. With ascension of life expectancy consequently lengthening the duration of menopause period symptoms & illnesses correlated with lack of estrogen will have greater importance day by day(1).The term " hot flash " is a description of a sudden onset of glow of the head skin neck and the chest that is accompanied by a severe feeling of warmth in the body and is sometimes ended with hydrosis. The duration of hot flash ranges from several seconds to several minutes and rarely lasts to several hours (1).

A vast cross sectional study in America reported that 49 percent of the women who are in the first year of their menopause & 57 percent of those who are pre menopausal period, experience a considerable amount of hot flash and in another study carried out in Sweden (Gutenberg) the maximum prevalence of the symptom among the ages 52 to 54 is about 60 percent and in other studies it has been reported to 75 percent, too. (2)

The vasomotor symptom usually resists to 1 or 2 years after the menopause and may resist to 10 years or even more in others. Besides disturbing the person in the work environment and preventing one of doing daily activities, it's got adverse effects on one's sleep. Severe vasomotor symptoms are actually the result of sudden cessation of estrogen due to the absence of the ovary folicules and not just because of the dearth in the amount of estrogen (3).

Choice treatment of vasomotor symptoms is the replace hormone therapy (HRT). In spite of this a large number of menopause women don't have the ability or tendency to undergo HRT and because of this different therapeutic alternatives for hot flash have been invented such as treatment with Clonidin Bromocriptin oral naloxan Blergal Veraliprid Vitamin E Fluxitin Gabapentin and … (3).

Treatment with systemic estrogen is the most effective way existing for treatment of vasomotor symptoms & sleep disorders correlated with it, but it's got some complications and disadvantages as follows:

Increasing the risk of cardiac attack, stroke, breast cancer and amnesia (Alzheimer disease), it will also increase the probability of trombo embolic disorders by 2 – 3 times.

Other side effects include breast sensitivity, worsening migraine headaches and vaginal bleedings. Contradictions of HRT treatment are: recognized or dubious breast or endometrial tumors, unrecognized & abnormal bleeding of reproductive system, active

trombo embolic disorders and active liver or the bile disease. Relative contradictions related to it are heart disease, migraine headaches, and case history of liver or bile diseases, endometrial cancer or thrombo-embolic events (3).

Considering disadvantages of HRT & contradictions of its use in some menopause women & reluctance of some women to use it most menopause women have got tendency toward trying medicinal herbs nutritional complements and vitamins in order to obviate hot flash and that is due to claims on efficiencies of such methods but it must be confessed that little experiments have been carried out to test their effectiveness and as reported in some studies vasomotor symptoms are excessively sensitive to placebo treatments(4).

The herb vitagnus (vitex agnus castus) is one of phito estrogenic herbs. The fruit of this herb was traditionally used to smoothen the sensual desires and it was even believed that if someone carries a knife whose handle is made of this plant's wood, no sensual thoughts would come to his mind and this is the reason for including the term "castus "with the meaning of sacrosanctity and chastity in the name of this herb (5). Its fruits are like monk's pepper and concerning its special odor, vitagnus is also called chaste berry. The vitagnus fruit is receptacle of essence, glycosides iridous & flavenoids.

The products made of this fruit have therapeutic usages in the following fields : PMS (premenstrual syndrome),hyper menorrhea, hyperprolactinemia, polymenorrhea menstrual disorders, secondary amenorrhea, infertility, uterine fibroma, insufficient milk production decrease in women's sexual desire acne ovarian cysts hormonal obesity, breast pains constipation abdominal cramps (6).

The vitagnus (Chester berry) has a long history of being used in different civilizations from the Greek to the medieval monks. Though using this herb is recommended for hot flash treatment but its efficiency on menopause hasn't yet been proved and is still under further studies. This herb contains irinoids and flavenoids. It's believed that the mechanism of this shrub is to stimulation of dopamine D2 receptors which decrease the amount of prolactin. In vitro this herb also suppressed the opioid receptors. This product has no effect on the amount of LH & FSH. It has also been shown that vitex can retain the amount of progesterone and is used for treatment of menstrual disorders & also infertility with unknown causes in Germany and there has been no report of toxicity in vitex usage in proper doses (1). We decided to survey the effect of Vitagnus on hot flash of menopause women for following reasons:

1. Considering the importance and duration of menopause period in women's life and issues concerned with hot flash
2. Prohibition of routine usage of synthetic hormonal medicine in some women
3. Reluctance of most of women to use of hormone therapy and the tendency towards herbal treatments
4. Particular attention of researchers to herbal medicine with quasi estrogenic properties and without hormone disadvantages

Materials and Methods

This research is a randomized clinical trial, double blind study. Simple sampling was used to select 46 menopause women ranging from 45 to 55 complaining from the hot flash who referred to the gynecology clinics of Ali Ebne Abitaleb hospital affiliated to Zahedan university of medical sciences in southeast of Iran between June 2009 to April 2011 . These qualified women for the experiment tended to be treated after being informed enough about the research, took part in the experiment and were randomly divided into two groups with 23 ones in each group. The women participating in the research had not known intermediary pre-existing illness. Approval was given by the Ethical Committee at Zahedan University of Medical Sciences.

The first group was under treatment with Vitagnus in the form of 20 drops in the morning and 40 drops at night. The medicine used was in the form of oral drops containing 30 ml of vitagnus produced by Pour Sina Corporation and the second group was under treatment with placebo just in the form and dose of the previous group.

The information was gathered through interview and questionnaire including personal characteristics & also the Cooperman questionnaire of hot flash severity was filled by the unit researcher; both before beginning the treatment and 15 & 30 days after treatment period; who was totally unaware of the treatment type of each patient; the questionnaires were archived till the end of study. Demographic information included name & family name, age, menopause duration, frequency and duration of hot flash in 24 hours. Cooperman hot flash questionnaire is a standard questionnaire with high reliability and validity. After that, the information was analyzed with the SPSS software through descriptive & inferential statistical methods. P values less than 0.05 was considered significant. The variance analysis was used in order to compare Cooperman menopause index between two groups in different time intervals. Regarding homogeneity of the variances, Independent T-test was used to compare the duration and frequency of hot flash in two groups.

Results

The findings of the study showed that both groups had no meaningful difference of age, menopause duration, repetitions and length of hot flash in 24 hours and menopause severity index and were almost homogeneous.

According to this study prescription of Vitagnus & placebo will considerably decrease the severity, duration and repetitions of hot flash, due to the fact that comparison of the above variables during treatment i.e. before therapy and also 15 & 30 days after treatment shows meaningful difference between both of the groups. (P value < 0.05)

But no meaningful difference was observed between the effectiveness of vitagnus & placebo on severity, duration and repetitions of hot flash from the statistical view. (P Value > 0.05) (Tables 1-4).

Table1. The results of intragroup, reciprocal & intergroup effects of Cooperman menopause index

Intergroup Cooperman menopause index is meaningful i.e. in both vitagnus & placebo groups the index has gradually decreased by lapse of time. There has also been a meaningful difference between two groups considering the reduction of Cooperman menopause index and Vitagnus has been more effective in bringing on this reduction.

Table 2. Effects of intragroup, reciprocal & intergroup outcomes of hot flash frequency

Analyzing variance by way of repetition was used to compare hot flash occurrences as for group therapy and time intervals. The results showed that the difference is meaningful inside the groups; namely the times of hot flash occurrences decrease by lapse of time but the reciprocal effect and inter group effect weren't' observed i.e. though repetitions of hot flash do decrease by lapse of time but this reduction isn't meaningful between two groups.

Table 3. The results of reciprocal, intra & inter group effects of hot flash duration

Variance analysis by method of repetition was used to compare duration of hot flash attacks with respect to group therapy & time intervals under study. The results showed the existence of meaningful difference in duration of hot flash but no reciprocal or intragroup effect was seen .

Table 4. Comparison of hot flash severity between two groups during different treatment phases

Wilcoxon rank-sum test was used to compare hot flash severity in each of therapy groups separately in time intervals & the results showed that there was a meaningful difference in all time intervals in the vitagnus group But in the placebo group this remarkable difference is between the time before therapy beginning & 15 days after treatment finish and before therapy beginning &30 days after treatment finish, but there's no meaningful difference between 15 & 30 days after treatment end.

Considering repetitions of hot flash, there was a reduction by pass of time in each group but this reduction was not meaningful between two groups of vitagnus & placebo.

From the stand point of hot flash duration, there was a meaningful difference inside the groups but again there was co meaningful intergroup difference.

Of hot flash severity, in the vitagnus group 69.6% of women had severe hot flash & in the placebo group it was about 78.3%. 15 days after the end of therapy period, 4.3 percent of women of both groups had got severe hot flash & 30 days after the therapy no severe hot flash was observed. The intensity of hot flash in the vitagnus group has got a meaningful difference before & after treatment and is so in the placebo group but the severity of hot flash in different times has got no meaningful statistical difference in two groups .

Finally it could be said that in the vitagnus group all phases of different time intervals were different in the severity of hot flash, so Vitagnus is effective in reduction of hot flash. In the placebo group the difference is between beginning of therapy and 15 days after the end of treatment period and before therapy beginning and 30 days after treatment, but no difference can be seen between 15 & 30 days after the therapy, to wit, placebo has been effective in hot flash treatment, too but its effect after 15 days past therapy is just as its effect on 30th day after the therapy.

According to this study both vitagnus & placebo were effective on reduction of hot flash severity, duration and repetitions, but had no meaningful difference in degree of their effect.

Discussion & Conclusions:

In accord with this study both vitagnus & placebo effectively reduce the severity duration and repetitions of hot flash & there 's a meaningful difference of the above variables in both groups just before the therapy and 15 & 30 days after it but no meaningful difference can be seen between vitagnus & placebo effects.

Research upon therapeutic effects of vitagnus herb has been started since summer 2000 and different results have been reported. In a research conducted by Abbaspour titled " The effect of Vitagnus on frequency and severity of hot flash in menopause teachers of Sari City " total recuperation of hot flash after the 8th week in the Vitagnus & placebo groups has been reported 80% and 12.5% respectively.(7) The difference between findings of this study with ours can lie in the longer therapy period of 8 weeks in their study compared to 30 days of ours demographic & climate differences in two

regions or probably greater sample size in their research.

In the Penotti research that corresponds to our study with Vitagnus application reduction of about 40% in hot flash symptoms has been reported that's equal to the placebo effect .(8)

But according to Lorraine research Vitagnus has no effect on treatment of hot flash (9) which is converse to our findings.

In accordance with a research done by Chapin in year 2000, usage of Vitagnus does considerably reduce menopausal symptoms.(10)

In another study carried out to investigate the impact of Vitagnus & passi-pay (passionflower) on menopausal hot flash, the severity of hot flash was compared among three groups of Vitagnus, passi-pay and placebo and it was concluded that the effect on hot flash in the vitagnus & passi pay had no meaningful difference but it was meaningful in comparison to the placebo (11) and so the findings of this research doesn't correspond to the outcome of our study.

Multiple researches have shown that there is a tangible response to placebo in menopause women and so it might be said that the reason for inefficiency of placebo in some studies may be due to the samples being informed about the placebo. (The research not being double blinded)

In a random study in England, there was no difference between implanted estrogen & placebo of reducing the amount of hot flash in menopaused women. (12)In his article titled "eleven herbs specifically for women "Jamison points out that Vitagnus is valuable in treatment of symptoms associated with lack of estrogen. (13)

Dibachi with the aim of determining effect of Vitagnus on menopausal complications surveyed upon 180 women of menopausal ages & concluded that Vitagnus effectively on treatment of hot flash is the average of 21.92 % .(14)

Regarding the importance of corporal & psychic, physiological changes of menopause that today constitutes around one third of women's life, & under findings of this research it can be inferred that paying attention to psychic factors and dependency of our women society on medicinal treatments, the placebo can play an effective role in treatment of hot flash so as to reduce the severity, duration and repetitions of hot flash considerably & be useful just as much as Vitagnus.

Of course, regarding the different results of various researches carried out inside & outside the country it's recommended to perform a research with greater sample size and longer duration of time so as to state more confidently about vitagnus efficiency / inefficiency on treatment of hot flash. Since according to the findings of this study there's no meaningful difference among severity duration & repetitions of hot flash in both groups under therapy with vitagnus & placebo after & before the therapy besides confirming & emphasizing the use of this valuable herb in treatment of hot flash especially with wider studies the underscore of this survey is upon support therapy of menopause women because the remarkable effect of placebo on obviation of the patients' symptoms shows the impressibility of their physical symptoms of psychic & mental supports & also our responsibility to guide the patients' entourage to take an inclusive care of the menopause women .

Ethical considerations

Personal information of the patients will remained private and considering the affectivity and harmlessness of Vitagnus in various studies and lack of a standard-routine treatment of hot flash, the research has got no moral and ethical issues.

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Table 1. The results of intergroup, reciprocal & intergroup effects of Cooperman menopause index

P value	D.F	F	P value
Intragroup effect of Cooperman menopause index	2	168.02	0.0001
Reciprocal effect of Cooperman menopause index	2	0.065	0.937
Intergroup effect of Cooperman menopause index	1	9.15	0.004

Table 2. Effects of intergroup, reciprocal & intergroup outcomes of hot flash frequency

Resource	D.F	F	P value
Intragroup effect of hot flash repetitions	2	18.816	0.0001
Reciprocal effect of hot flash repetitions	2	0.604	0.549
Intergroup effect of hot flash repetitions	1	1.43	0.313

Table 3. The results of reciprocal, intra & inter group effects of hot flash duration

Resource	D.F	F	P value
The intragroup effects of hot flash attacks' duration	2	127.54	0.0001
Reciprocal effects of hot flash attacks' duration	2	0.277	0.759
Inter group effect of hot flash attack's duration	1	0.067	0.796

Table 4. Comparison of hot flash severity between two groups during different treatment phases

Group	Therapy Phase	Rank Sum	Mean Rank	Z	P value
Vitagnus	Before & 15 days after therapy	231	11	-4.08	0.0001
	Before & 30 days after therapy	253	11.5	-4.2	0.0001
	15 & 30 days after therapy	15	3	-2.2	0.025
Placebo	Before & 15 days after therapy	231	11	-4.16	0.0001
	Before & 30 days after therapy	253	11.5	-4.2	0.0001
	15 & 30 days after therapy	6	2	-1.7	0.08

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