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Research Article

Comparison of efficacy of soy and estrogen in alleviating post-menopausal vasomotor symptom

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ABSTRACT

Objective: To compare efficacy of soy and estrogen in alleviating post-menopausal vasomotor symptom

Materials & Methods: This comparative study was conducted at Department of Gynecology and Obstetrics, DHQ Hospital, South City Okara from January 2017 to June 2017. Comparison of efficacy between soy and estrogen was done.

Results: The mean age of women in group A was 52.82 ± 6.08 years and in group B was 52.09 ± 6.90 years. The mean hot flushes/day in group A was 2.56 ± 1.19 and in group B was 2.85 ± 1.25. There was 50% post-treatment reduction in hot flushes as compare to number of hot flushes average per day at pre treatment in 57 (93.44%) patients in Group A (Estrogen) while in Group B (Soy), it was seen in 46 (75.41%) patients with p-value of 0.006.

Conclusion: This study concluded that use of estrogen therapy was more effective in alleviating post-menopausal vasomotor symptom compared to soy therapy.

Keywords: Menopause, flushes, estrogen, soy.

INTRODUCTION:

The World Health Organization defines menopause as the permanent cessation of menstruation due to the loss of ovarian follicular activity.[1] Menopause is commonly defined by the state of the uterus and the absence of menstrual flow or "periods", but it can instead be more accurately defined as the permanent cessation of the primary functions of the ovaries. What ceases is the ripening and release of ova and the release of hormones that cause both the build-up of the uterine lining, and the subsequent shedding of the uterine lining (the menses or period). The median age of menopause is 51 years**,** but it may sometimes occur earlier (before the age of 40) for surgical, autoimmune, genetic, iatrogenic and idiopathic reasons.[2]

Menopause occurs due to changes in the levels of female sex hormones, decreases in the circulating levels of estrogen and progesterone, and concomitant increases in the levels of follicle-stimulating hormone and luteinizing hormone. The diagnosis is mainly clinical and retrospective, confirmed after twelve months of amenorrhea. The transition from a potentially reproductive to a

non-reproductive state is normally not sudden or abrupt, occurs over a number of years, and is a consequence of biological aging. For some women, during the transition years the accompanying signs and effects (including lack of energy, hot flashes, and mood changes) can be powerful enough to significantly disrupt their daily activities and sense of well-being. In those cases various different treatments can be tried.[3,4]

The initial years of menopause are often accompanied by vasomotor symptoms such as hot flushes and night sweats. Hot flushes are typically experienced as a feeling of intense heat with sweating and rapid heartbeat, and may typically last from two to thirty minutes for each occurrence. The frequency, severity, and duration of vasomotor symptoms vary according to the population.[5] Menopause related symptoms have a negative effect on the quality of life of postmenopausal women.[6]

Gold standard treatment for postmenopausal symptoms is Hormone Replacement Therapy.[7] Hormone Replacement Therapy is recommended for vasomotor symptoms, treatment of vaginal atrophy and prevention of osteoporosis but it may be associated with various side effects including fluid retention, bloating, breast tenderness or swelling, nausea, leg cramps, headaches, indigestion.[8] HRT may be reasonable for the treatment of menopausal symptoms such as hot flashes.[9] Its use appears to increase the risk of strokes and blood clots.[10] When used for menopausal symptoms it should be used for the shortest time possible and at the lowest dose possible.[10] The response to HRT in each postmenopausal women may not be the same. Genetic polymorphism in estrogen receptors appears to be associated with inter-individual variability in metabolic response to HRT in postmenopausal women.[11]

Estrogen therapy has long been prescribed to treat menopausal symptoms. It has been extensively studied, and it is the most consistently effective therapy for vasomotor symptoms.[12] Estrogen is a steroid hormone which is derived from the androgenic precursors androstenedione and testosterone by means of aromatization. Estrogens affect many different systems, organs, and tissues, including the liver, bone, skin, gastrointestinal tract, breast, uterus, vasculature, and central nervous system. These effects appear to become most prominent during times of estrogen deficiency, such as the menopausal transition.[11]

Soy have been investigated, mainly over the past 10 years, because of their potential effects on the health of postmenopausal women. Even though some clinical studies have demonstrated the efficacy of soy in reducing the frequency and severity of hot flushes. Soy foods have been adopted as a natural alternative to hormone therapies because the soybean contains nutritionally relevant amounts of isoflavones.[13] Isoflavones have been demonstrated to reduce both the severity and the frequency of menopause-related vasomotor symptoms.[14]

Our hospital provides medical care for a wide area of Bahawalpur division. So we had decided to perform this study to assess the treatments for post-menopausal problems in shape of vasomotor symptoms in the patients presenting in gynaecology outpatient department and to study the effect of estrogen and soy therapy for the relief of vasomotor symptoms in our general population. This study would also pave the way for our doctor community to select the right treatment for postmenopausal vasomotor symptoms for our local population.

MATERIAL AND METHODS:

This comparative study was conducted at Department of Gynecology and Obstetrics, DHQ Hospital, South City Okara from January 2017 to June 2017.

Postmenopausal women as defined by the natural cessation of menses for 1 year, age 40 to 65 years and women with hot flushes defined as reporting 4 hot flushes average per day were selected.

Women on hormone replacement therapy, Women with a surgically induced menopause (oophorectomy), Women on tamoxifen or

receiving chemotherapy/radiation therapy or planned antineoplastic chemotherapy/radiation therapy, Renal function impairment (serum creatinin greater than the laboratory normal range; orcreatinin clearance <30ml/min), Women taking any dietary supplements for the treatment of hot flashes (ex. soy supplements, vitamin E, flaxseed, red clover extract) within the past 30 days and Inability to complete diary for any reason were excluded from the study.

Randomization was performed by block design. Randomization was 1:1 for Estrogen group or Group A and Soy group or Group B.

Data was collected about the years since menopause and No. of hot flushes average per day before the start of treatment in both groups. Group A was allocated to treatment with estrogen as Premarin 0.3 mg one tablet daily for 12 weeks whereas the Group B was given Soy as tablet Her 50 mg daily for 12 weeks. All the patients were kept blinded about the type of medicine. Medicines was provided to them without strips in plain air-tight glass bottles and a list was made to identify the nature of medicines and was kept hidden from the patients and data recorders.Patients were asked to write down the numbers of hot flushes daily in a diary. Patients were called for follow up after 12 weeks and data was collected of the No. of hot flushes average per day and efficacy. This all data was recorded on a predesigned proforma which contained two parts i.e. part 1st contained the patients bio data while part 2nd contained the study variables.

Data was analyzed with statistical analysis program (SPSS version11.5). Analysis was done to compare proportion of Estrogen group (Group A) and Soy group (Group B). Frequency and percentage was computed for qualitative variables like age groups and efficacy. Mean ± SD was presented for quantitative variables like age, No. of Hot Flushes average per day and years since menopause.Effect modifiers like age and years since menopause were controlled by stratification. Categorical variables were analyzed using the chi-square test for both groups, p $\leq$0.05 was considered statistically significant.

RESULTS:

Age range in this study was from 40 to 65 years with mean age of 52.46 ± 6.49 years.The mean age of women in group A was 52.82 ± 6.08 years and in group B was 52.09 ± 6.90 years. Mean duration of menopause was 11.08 ± 6.28 years. The mean duration of menopause in group A was 11.36 ± 6.22 years and in group B was 10.80 ± 6.38 years.

Treatment was found effective in 57 (93.44%) patients of group A and in 46 (75.41%) patients of group B. Significantly (P = 0.006) higher rate of efficacy of treatment was noted in group A as compared group B. (Table 1)

Patients were divided into 3 age groups, i.e. age group 40-50 years, age group 51-60 years and age group 61-65 years. In age group 40-50 years, treatment was found effective in 21 (91.30%) patients of group A and in 17 (68.0%) patients of group B and the difference was significant with p value 0.047. In age group 51-60 years, efficacy was noted in 29 (93.55%) patients and 24 (80.0%) patients respectively in study group A and B and the difference was insignificant with p value 0.117. In age group 61-65 years, efficacy of treatment was noted in 07 (100.0%) patients of group A and in 05 (83.33%) patients of group B and the difference was insignificant with p value 0.261. (Table 2)

Two groups were made according to Years since menopause i.e. $\leq$ 10 years and >10 years. In $\leq$ 10 years group, treatment was found effective in 26 (89.66%) patients of group A and in 18 (68.0%) patients of group B and the difference was statistically significant with p value 0.05. In >10 years group, efficacy of treatment was noted in 31 (96.88%) patients and 28 (80.0%) patients of group A and B respectively. Difference of efficacy between the both groups was statistically significant with p value 0.03. (Table 3)

Table 1: Comparison of efficacy between both groups

Group	Efficacy		Total	P value
	Yes (%)	No (%)		
A	57 (93.44%)	04 (6.56%)	61	0.006
B	46 (75.41%)	15 (24.59%)	61	

Table 2: Stratification of Efficacy with respect to age groups.

Age (years)	Group A (n=61)		Group B (n=61)		p-value
	Efficacy		Efficacy		
	Yes	No	Yes	No	
40-50	21 (91.30%)	02 (8.70%)	17 (68.0%)	08 (32.0%)	**0.047**
51-60	29 (93.55%)	02 (6.45%)	24 (80.0%)	06 (20.0%)	**0.117**
61-65	07 (100.0%)	00 (0.0%)	05 (83.33%)	01 (16.67%)	**0.261**

Table 3: Stratification of Efficacy with respect to years since menopause

Years since menopause	Group A (n=61)		Group B (n=61)		p-value
	Efficacy		Efficacy		
	Yes	No	Yes	No	
≤ 10	26 (89.66%)	03 (10.34%)	18 (68.0%)	08 (32.0%)	**0.05**
>10	31 (96.88%)	01 (3.12%)	28 (80.0%)	07 (20.0%)	**0.03**

DISCUSSION:

Menopause is the natural process of women's life which includes inability to conceive and stoppage of menstruation". Age of 51 years is the average of menopause.[15]The symptoms preceding menopause are irregular menstruation and after menopause are hot flushes, dry skin and vaginal dryness. Some women also experience emotional and physical symptoms. The attitude and knowledge about menopause may differ from one female to another and these differences are because of female age, parity, education and hormonal status as well as their cultural, economical and geographical status.[16]

This randomized controlled study has compared the efficacy of soy and estrogen in alleviating post-menopausal vasomotor symptom. Mean age of patients in our study was 52.46 ± 6.49years.The mean age of women in group A (estrogen) was 52.82 ± 6.08 years and in group B (soy) was 52.09 ± 6.90 years. Majority of the patients 61 (50.0%) were between 51 to 60 years of age. These results were very much comparable with study of Fawad Aet al[7] who had found a mean age of 53 years with majority of patients between 50 to 60 years of age. Vitolins MZ et al[17] in his study had also found the mean age of 55 years in menopause women which is also much comparable to our study. Similarly, Nahas EAP et al[18] in his study has also found the mean age of 55 years.

In our study, there was 50% post-treatment reduction in hot flushes as compare to number of hot flushes average per day at pre treatment in 57 (93.44%) patients in Group A (Estrogen) while in Group B (Soy), it was seen in 46 (75.41%) patients. So, Efficacy was 93.44% in group A (Estrogen) and 75.41% in group B (Soy) with p-value of 0.006. In a recent systematic review shows that estrogen therapy can expect a 75% reduction in the frequency of hot flushes and an 87% reduction in their severity.[19]Fawad A and Danish N reported 80% women with hot flushes got complete relief when treated with estrogen therapy.[20]Vitolins MZ and his associates have reported that when Estrogen and Soy treatments are compared for the postmenopausal vasomotor

symptoms, the numbers of hot flushes experienced by the women were 2.9% for Estrogen therapy and 18.4% for Soy therapy.[17]In a recently done randomized controlled trial by Borah BK[21], it was found that hot flashes werereduced significantly in82.75% women inoestrogen group in comparison to26.92% women only in soy group.Estrogen alone markedly improves the frequency and severity of VMS as demonstrated by many randomized trials.[132] Estrogens, which are available in oral, transdermal, vaginal ring and topical forms, are effective in up to 90% of women with VMS.[22]

According to Utian W H, Lederman et al[23],vasomotor symptoms in surgical menopause canbe reduced upto 80% with oestrogen. In Canada, 99 women aged 45–60 y and menopausal for 1–8 y were enrolled in a 16-wk study of quality of life and hot flash frequency and severity.[24] They received 1 muffin daily containing soy, wheat, or flaxseed flour. Soy muffins contained 25 g of soy flour, supplying 42 mg of isoflavones daily. Among the 87 women who completed the trial, there was no significant difference in the frequency and severity of hot flashes between treatment groups.

CONCLUSION:

This study concluded that efficacy of estrogen therapy (93.44%) was more in alleviating post-menopausal vasomotor symptom compared to soy therapy (75.41%). So, we recommend that estrogen therapy should be used as primary treatment in women for relief of post-menopausal vasomotor symptomin order to reduce their morbidity.

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