

RESEARCH ARTICLE

# Effects of phytoestrogen versus conjugated oestrogen on vasomotor symptoms in surgical menopause: a comparative study

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## **ABSTRACT**

**Purpose:** To assess the efficacy, safety, and acceptability of phytoestrogen versus low dose conjugated oestrogen for reducing vasomotor symptoms in women with surgical menopause.

**Method:** 64 nos. of women with surgical menopause having vasomotor symptoms within six weeks of postoperative period were randomly divided in equal two groups. One group was treated with conjugated oestrogen 0.625mg (premarin) daily and another with soya isoflavone (70%) 100 mg (Isoflav CR) daily for 12 weeks. The episode and severity of vasomotor symptoms were self recorded daily. Evaluation was done at interval of 4 weeks till completion of 12 weeks.

**Results:** 29 women in conjugated oestrogen group (n=29) and 26 in phytoestrogen group (n=26) completed 12 weeks treatment cycle. After 12 weeks of treatment hot flashes were reduced significantly in 24(82.75%) women (n=29) with conjugated oestrogen group in comparison to 7 (26.92%) women (n=26) in phytoestrogen group. Night sweats were reduced in 19 (65.51%) women (n=29) in conjugated oestrogen group only. Except some minor side effects like nausea, breast tenderness, headache etc. in conjugated oestrogen group, both the groups were found quite safe and well accepted.

**Conclusion:** Conjugated oestrogen significantly reduced the severity and frequency of vasomotor symptoms in surgical menopause in comparison to phytoestrogen, and both phytoestrogen and conjugated oestrogen were found well tolerated and safe during 12 weeks of study.

**Key words:** Phytoestrogen, menopause, conjugated oestrogen, vasomotor symptoms

**Conflict of interest:** None. **Disclaimer:** Nil.

Menopause, though it is a physiological event that occurs in all women living beyond the age of 60 years. Hysterectomy is associated with an earlier onset of menopause [1]. Hysterectomy with unilateral oophorectomy is associated with an even earlier onset of the menopause [2]. It is now

believed that it can be associated with short term distressing symptoms like vasomotor symptoms and long time life threatening distress like heart diseases and osteoporosis [3].

It appears that 50 years has remained the modal age in each period-classical, medieval and modern.

Received: 12 March 2014/ Accepted: 25 March 2014

Borah BK. Effects of Phytoestrogen versus conjugated oestrogen on vasomotor symptoms in surgical menopause: a comparative study. Journal of Obstetrics & Gynaecology Barpeta, 1 (1), 41-45

The primary difference between age of menopause in classical times and that of today's industrialized nations is that women in ancient times did not usually live beyond fertility to menopause.

But in the modern era, there has been a striking increase in average female life expectancy. Women are now living beyond the time of menopause to old age. So, it is no longer appropriate to dismiss these problems as the inevitable consequences of ageing and only treatment required is sympathy and emotional support.

Worldwide researches now proved that both the long and short term consequences are due to oestrogen deficiency and the benefits of HRT has been shown clearly to outweigh the risk.

Vasomotor symptoms which is a short term consequences of menopause is found with higher incidence and increased severity in surgical menopause [4] and oestrogen supplementation is found effective in relieving these symptoms. Conjugated oestrogen and phytoestrogen both are used for control of vasomotor symptoms.

### **Objectives**

To assess the efficacy, safety and acceptability of phytoestrogen versus conjugated oestrogen for reducing vasomotor symptoms in women with surgical menopause.

### **Method**

A prospective, intention to treat, randomized controlled study was carried out in the department of Obstetrics & Gynaecology, SMCH, Silchar from 1<sup>st</sup> December 2012 to 31<sup>st</sup> January 2013. Total 64 nos. of women with surgical menopause who had undergone total abdominal hysterectomy with bilateral salphingoopherectomy (TAH with BSO) for various indications having complaint of vasomotor symptoms were included in this study.

A detailed history of the cases were taken regarding age, occupation, socio-economic status, indications of TAH with BSO, intra and post operative period, any other associated disorders were recorded. Their presenting complaints were recorded like hot flashes, night sweats, insomnia,

fainting attack, palpitation etc in details including number of attacks, severity, time etc.

Following inclusion and exclusion criteria were considered for selection.

### **Inclusion Criteria**

- Women with surgical menopause only (had undergone TAH with BSO).
- Developed vasomotor symptoms within six weeks of post operative period.
- Hot flashes must be present as a salient symptom.

### **Exclusion Criteria**

- Women having history of breast cancer or breast lump.
- Women having coronary artery disease, venous thrombosis, migraine headache.
- Women with altered liver function test.
- Women having features of pheochromocytoma, thyrotoxicosis and carcinoid syndrome.

Based on inclusion criteria, 64 nos. of women were randomly divided in equal two groups of 32 women in each. One group was treated with conjugated oestrogen 0.625 mg (premarin) daily and another group was treated with isoflavone 70%-100mg daily (isoflav CR) for 12 weeks continuously. Both groups were properly counseled and informed consent was taken from all the women.

All women were provided with a daily chart to record properly regarding attack of vasomotor symptoms like hot flashes, night sweats, insomnia, fainting duration etc. and women were properly instructed to maintain this record daily.

All women were followed at the interval of 4 weeks till completion of treatments. After completion of 12 weeks of continuous treatments, evaluation and analysis were done on the basis of monitoring chart and statement of the women regarding relief of vasomotor symptoms.

### **Result and Observation:**

During this period of study, a total of 64 women with surgical menopause were enrolled on basis of inclusion criteria. Out of them 9 women could not be followed. 29 women in conjugated

oestrogen group and 26 women in phytoestrogen group, total 55 nos. had completed 12 weeks treatment cycle.

Table 1 shows the demographic profile. Amongst the women completed 12 weeks treatment cycle most of the women belong to perimenopausal age group of which 26 (47.27%) belong to (46-50) years of age.

Age in years	No of women
35-40	6
41-45	11
46-50	26
51-55	9
56-60	3

Indications of TAH with BSO are mentioned in table 2. Out of 55 women completed treatment in this study, DUB (n=19, 34.54%) and multiple uterine fibroid (n=22, 40%) in perimenopausal age group was found as the major indication.

Indications	No. of women	%
Multiple uterine fibroids in perimenopausal age group	22	40
DUB in perimenopausal age group	19	34.54
Ca ovary	8	14.54
Multiple uterine fibroids with B/L ovarian cyst	2	3.63
DUB with bilateral ovarian cyst	2	3.63
Uterine fibroids with family H/O ovarian malignancy	2	3.63

As hot flash was taken as a salient criteria for the study group, 100% (n=55) of women were having complaint of hot flashes. Table 3 shows comparative evaluation of women suffering from vasomotor symptoms in both groups prior to treatment.

**Table 3. Comparative evaluation of no. of women suffering from vasomotor symptoms in both groups prior to treatment**

Vasomotor symptoms	Conjugated oestrogen group (n=29)	Phytoestrogen group (n=26)
	Nos. (%)	Nos. (%)
Hot flashes	29 (100%)	26 (100%)
Night sweats	23 (79.3%)	14 (53.84%)
Insomnia	10 (34.48%)	11 (42.3%)
Palpitation	7 (24.13%)	9 (34.61%)
Headache	7 (24.13%)	7 (26.92%)
Fainting attack	3 (5.45%)	Nil (0%)

Table 4 shows the evaluation of women getting relief from vasomotor symptoms in both groups after 12 weeks of completed treatment. Hot flashes were reduced significantly in 24(82.75%) women in conjugated oestrogen group in comparison to 7(26.92%) women only in phytoestrogen group. That is also not by the number of episodes, only by severity.

were found quite safe and well accepted by all women enrolled in this study.

Night sweats are reduced in 15 (65.21%) women in conjugated oestrogen group only. In both groups no significant effects were found on insomnia, palpitation, headache, fainting attack etc.

**Discussion**

This study represents our observation over a period of 1 year 3 months. Women with surgical menopause having vasomotor symptoms require special management for improvement of their quality of life.

Table 5 shows comparative evaluation of side effects in both groups. Except some minor side effects like nausea, breast tenderness, leg cramps etc. in conjugated oestrogen group, both the groups

Several studies suggest that for appropriately selected women with surgical menopause can be treated with HRT with conjugated oestrogen for relieving vasomotor symptoms and found quite

**Table 4. Comparative evaluation of no. of women getting relief from vasomotor symptoms after completing 12 weeks treatment**

Vasomotor symptoms	Conjugated oestrogen group	Phytoestrogen group
	Nos. (%)	Nos. (%)
Hot flashes	24 (82.75%)	7 (26.92%)
Night sweats	15 (65.21%)	1 (7.14%)
Insomnia	1 (10%)	Nil (0%)
Palpitation	Nil (0%)	Nil (0%)
Headache	Nil (0%)	Nil (0%)
Fainting attack	Nil (0%)	Nil (0%)

**Table 5: Comparative evaluation of side effects**

	Conjugated oestrogen group	Phytoestrogen group
	Nos. (%)	Nos. (%)
Nausea	5 (17.24%)	1 (3.84%)
Breast tenderness	2 (6.89%)	Nil (0%)
Leg cramps	2 (6.89%)	Nil (0%)
Limb pain	Nil (0%)	Nil (0%)
Fluid retention	Nil (0%)	Nil (0%)
Vaginal discharge	Nil (0%)	Nil (0%)
Eye irritation	Nil (0%)	Nil (0%)

safe and effective [5,6,7]. According to Hickey et al, hot flashes can be reduced upto 87% [8,9,10, 11,12]

and night sweats can be reduced upto 65% by using conjugated oestrogen which is comparable to our study.

On the other hand, hot flashes were reduced only (26.92%) in phytoestrogen group of the study. This study can be compared to some our study like Albertazzi P et al [13], Washburn S et al [14].

According to Utian W H, Lederman et al [15], vasomotor symptoms in surgical menopause can be reduced upto 80% with conjugated oestrogen which can be compared to our study with 82.75% success rate to control hot flashes.

According to Gregory Burke and colleagues [16], North Carolina, phytoestrogen reduces the severity of hot flashes, not the number of attack which is comparable to our study also.

In 1999, Nagata C, Shimizu H et al [17], shows that phytoestrogen alleviates vasomotor symp-

toms especially hot flashes in surgical menopause that does not correspond to our study.

**Conclusion**

With proper selection and proper observation, vasomotor symptoms in surgical menopause can be treated with hormone replacement therapy specially with conjugated oestrogen. Conjugated oestrogen significantly reduces the severity and frequency of vasomotor symptoms in surgical menopause in comparison to phytoestrogen. Both phytoestrogen and conjugated oestrogen were found well tolerated and safe during this 12 weeks of study.

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