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Role of Selective Estrogen Receptor Modulators in Menopause: A Monocentric Hospital Based Qualitative Appraisal

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Abstract

Menopause transition is experienced by 1.5 million women each year and often involves troublesome symptoms including vasomotor symptoms, vaginal dryness, fatigue, and joint pain. Menopausal hormone therapy has been available for over half a century to provide relief from vasomotor symptoms, osteoporosis and symptoms of urogenital atrophy. Recently there has been an interest in a class of compounds known as the selective estrogen receptor modulators (SERMs) that have been found to be effective in treating postmenopausal symptoms. Hence, the present study was aimed to find out the role of SERMs in menopause. This hospital based analytical study was carried out between 1st January 2016 to 31st March 2018 in OBGY Department of A.V.B. Rural Hospital on 332 women of menopausal age group belonging to rural vidarbha region. The data were collected from in-depth interview of unit heads, professors, associate professors, assistant professors, junior residents as well as patients in A.V.B. Rural Hospital, Wardha. Menopausal women were categorised in Group I (6th Decade: 50 - 59 Years), Group II (7th Decade: 60 - 69 Years) and Group III (8th Decade: 70 - 79 Years). The presenting complaints were bone and joint pain(56.01%,26.08%, 19.07% in grade I,II, III), burning micturition (24.17%,23.60%,16.66% in grade I,II, III, hot flashes(67.06%,31.00%,26.37 in grade I,II, III), vaginal dryness (21.02%,38.16%,39.11% in grade I,II, III) and uterine prolapse(11.54%,14.16%,16.66% in grade I,II, III). Drug therapy in the form of symptomatic treatment (OCPs) and surgical treatment was given to the patients. SERMs were not given to any patient due to difficulty in keeping follow up and SERMs associated severe adverse effects. Also these patients belong to rural area and for them it is not possible to bear high cost of this drugs. Further investigations and studies are required to help clarify the relative benefits/risks of novel SERMs in development within specific indications and in patient-specific management in the field of postmenopausal health.

Keywords: *Menopause, vasomotor symptoms, SERMs*

1. Introduction

Menopause is an unspoken and unattended reality of life, the cause of which is still undeciphered completely by man. Menopause is one such midlife stage which might be overcome easily or make a lady miserable depending on her luck.[1] In 1990, about 25 million women worldwide reached menopause; this number is expected to double by the late 2020.[2] The major consequences of menopause are related primarily to estrogen deficiency. It is very difficult to distinguish the consequences of estrogen deficiency from those of aging, as aging and menopause are inextricably linked. The early menopausal symptoms related to the progressive reductions in hormonal secretion and ovarian estrogen deficiency in the literature include hot flashes, sweating, sleep disorders, mental changes and menstrual disorders. Later in the menopause period there also appear urogenital atrophic changes and related sexual dysfunctions, cardiovascular diseases, osteoporosis, and musculoarticular complaints .Systemic estrogen therapy is the most effective treatment available for vasomotor symptoms and the associated sleep disturbance, relief of vaginal dryness, dyspareunia, and urinary symptoms.[3]

Vaginal estrogen therapy appears to reduce urinary symptoms, such as frequency and urgency and has been shown to reduce the likelihood of recurrent urinary tract infections in postmenopausal women.[4] Hormone therapy (HT) is effective in preventing and treating postmenopausal symptoms.[5] Selective estrogen receptor modulators (SERMs) are compounds that act as both estrogen agonists and antagonists, depending on the tissue. SERMs has been approved for both the prevention and treatment of osteoporosis. There are undergoing Clinical trials aimed to differentiate amongst SERMs on selected target tissues for use in postmenopausal women including effects on breast, bone, cardiovascular venous thrombosis risk, endometrium, vagina, vasomotor symptoms, and brain. FDA approved selective estrogen receptor modulators (SERMs) prevent and treat breast cancer, osteoporosis and dyspareunia.[5,6]

Studies suggest that there are safety concerns associated with use of SERMs because of their potential adverse effects that include increased risk of certain visual disturbances, fatal pulmonary embolism, and cancer of both the endometrium and the body of the uterus.[7,8] The present study has been undertaken with an aim to appraise the role of selective estrogen receptor modulators in relieving menopausal symptoms in women taking treatment at AVBRH.

2. Objective

The presented study was carried out to Evaluate Role of Selective Estrogen Receptor Modulators in Menopause at Acharya Vinoba Bhave Rural Hospital, Sawangi (Meghe), Wardha and to appraise different treatment modules prescribed.

3. Materials & Methods

Type of study: A Hospital Based Observational Study

Locus of study: Acharya Vinoba Bhave Rural Hospital, J.N.M.C., Sawangi (M), Wardha, Maharashtra.

Study population: Females with menopausal symptoms coming to Obstetrics and Gynaecology O.P.D of A.V.B.R.H, Sawangi (Meghe), Wardha.

Sample size: 332

Duration of study: 1st January 2016 to 31th march 2018

Inclusion criteria

- Menopausal women willing to participate in the study.
- **Age group:** 50 to 79 years

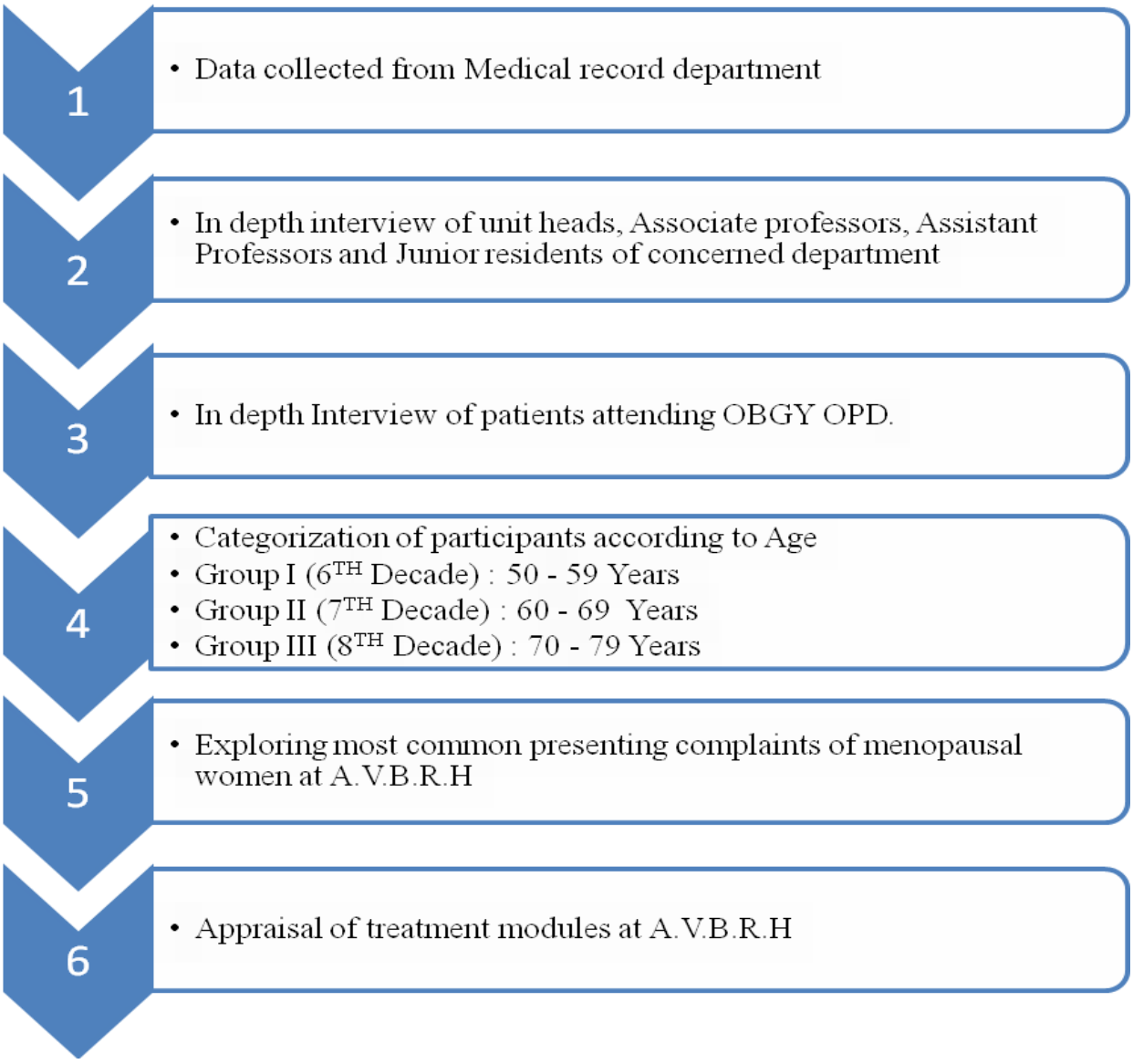
Exclusion criteria

- Menopausal women not willing to participate in the study.

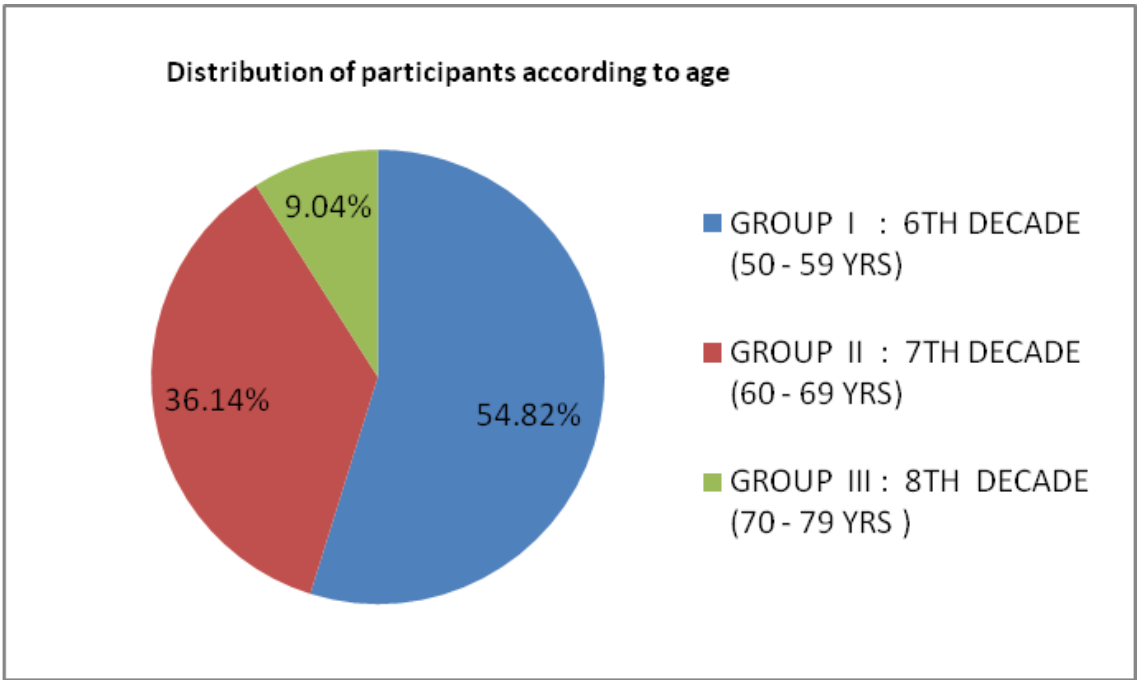
Software used in analysis:
SPSS 22.0 version and GraphPad Prism 6.0 version

Ethical clearance
The study was approved by the Institutional Ethical Committee.

Study design:



4. Observation & results



Graph 1: Distribution of participants according to age

At AVBRH women with menopause presents with various spectrum of complaints. Observations of that data is shown below in table 1.

Table 1: Spectrum of presenting complaints in menopausal women

SPECTRUM OF PRESENTING COMPLAINTS	GROUP I 6TH DECADE	GROUP II 7TH DECADE	GROUP III 8TH DECADE	χ2	p-value
Bone & Joint Pain	26.01%	34.08%	56.07%	11.789	0.003
Burning micturition	24.17%	23.80%	16.66%	1.223	0.54
Hot Flushes	37.06%	19.02%	7.37%	19.68	0.0001
Uterine prolapse	11.54%	14.16%	16.66%	0.624	0.734
Miscellaneous(Pain in abdomen, Weakness)	28.69%	47.50%	26.67%	11..736	0.003

Various treatment modules used in menopausal women at AVBRH are tabulated below in table 2. Conservative treatment in the form of hormone replacement therapy given to most of patients was oral contraceptive pills. Patient drainage at AVBRH mostly belongs to poor rural population in vidarbha region. SERM were not given to patients by doctors due unaffordable high cost of drugs, non compliance, gross side effects and poor follow up. Symptomatic drug therapy includes various drugs like analgesics, antibiotics, antifungals, urinary alkalisers, topical estrogen creams, anti depressants etc.

Table 2: Showing percentage distribution of treatment modules

Treatment modules	Group I	Group II	Group III
Conservative treatment	64.17%	21.01%	12.33%
Surgical treatment	3.29%	1.66%	3.3%

5. Discussion

The intensity and frequency of menopausal symptoms vary from woman to woman. If symptoms are problematic, or a woman is at high risk of developing osteoporosis or heart disease, medical treatment may be recommended. Ultimately, the decision to have treatment is a very personal one and should be made by the woman only after receiving a full explanation from her doctor of the benefits and counter benefits of the various treatment options.

In the present study the most common symptoms in Group I 6th Decade were hot flushes 37.06%, weakness in 28.69%, bone & joint pains in 26.01%, burning micturation 24.17%. Group II 7th Decade were bone & joint pains in 34.08%, hot flushes 19.02%, weakness in 47.50%, burning micturation 23.80%. Group III 7th Decade were bone & joint pains in 56.07%, weakness in 26.67%, burning micturation 16.66%, hot flushes 7.37%,

Malla VG et al. did a study to evaluate most common menopausal complaint in Indian women and found that fatigue (62%), followed by hot flashes (56%), cold sweats (52%), and backache (51%) as most common symptoms. It has always been believed that vasomotor symptoms dominate the menopausal symptomatology in Western women and musculoskeletal symptoms along with sleeplessness predominate in Asian women.[9]

Bairy L et al. Did a study on 352 meopausal patients and found that the Most frequent menopausal symptoms were aching in muscle and joints, feeling tired, poor memory, lower backache and difficulty in sleeping. The vasomotor and sexual domains were less

frequently complained when compared to physical and psychological domains.[10]

In the present study Conservative treatment in the form of hormone replacement therapy given to most of patients was oral contraceptive pills. Patient drainage at AVBRH mostly belongs to poor rural population in vidarbha region. Because of low cost of oc pills, easy availability, reduction in bone loss & dysmenorrhea and protection against iron deficiency anemia, oc pills are the ideal treatment option at AVBRH. SERM were not prescribed to patients by doctors due unaffordable high cost of drugs, non compliance, gross side effects and poor follow up. Symptomatic drug therapy includes various drugs like analgesics, antibiotics, antifungals, urinary alkalisers, topical estrogen creams, anti depressants etc.

Van Winter et al. concluded in their study on menopausal women that use of low-dose oral contraceptive pills in women over 35 years of age provides protection against unwanted pregnancy, maintains a stable hormonal environment and decreases abnormal menstrual bleeding. Other non contraceptive health benefits of oral contraceptives include a reduction in bone loss and protection against iron deficiency anemia, dysmenorrhea, benign breast disease, endometrial cancer and epithelial ovarian cancer.[11]

Combined hormonal contraceptives appear to have a positive effect on bone health18 and may be helpful for perimenopausal symptoms, including hot flushes and night sweats. Women experiencing vasomotor symptoms during the hormone-free break can be advised to use the pill or ring continuously for three months or longer.[12]

Combined oestrogen/progestogen contraceptive pills (COCPs) may be used continuously until the expected time of the menopause.[13] With the most recent versions of SERMs, they have become suitable for treatment of osteoporosis in postmenopausal women. Although SERMs are effective for preventing vertebral fractures and maintaining BMD, they have certain limitations in preventing non-vertebral fractures. SERMs also have extra-skeletal effects as well as related side effects, and thus require caution in their use. The effects for those over age 70 have also been proven to a certain degree. In terms of patient compliance, SERM use was better adhere to than for BP. Overall, the long-term safety of SERM are acceptable; however, after eight years of usage, side effects are more likely to be observed. Based on these characteristics, SERMs are currently expected to be a good choice for treating osteoporosis in postmenopausal women.[14]

6. Conclusion

The intensity and frequency of menopausal symptoms vary from woman to woman. The decision to have treatment is a very personal one and should be made by the woman only after receiving a full explanation from her doctor of the benefits and counter benefits of the various treatment options. Patient drainage at AVBRH mostly belongs to poor rural population in vidarbha region with limited health education. Conservative treatment in the form of oral contraceptive pills remains the main line of treatment for most of women with menopausal symptoms. Selective estrogen receptor modulators (SERMs) were not prescribed to patients by doctors due to unaffordable high cost of drugs, non compliance, gross side effects and poor follow up. Further investigations and studies are required to help clarify the relative benefits/risks of novel SERMs in development within specific indications and in patient-specific management in the field of postmenopausal health.

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