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A cross sectional observation study of postmenopausal symptoms and hormonal management

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Abstract: *Aim:* The aim of this study is to determine the age and symptoms in menopausal women and providing hormonal treatment. *Materials and Methods:* This study was a community based cross sectional, descriptive, observational study conducted among 400 rural women living in and around Vijayapur. Women aged 40 to 55 years who attained natural menopause and cessation of menses for one year were included in the study. The study was carried out from November 2022 to October 2023. Ethical clearance has been taken for this study. The participants were interviewed on one-to-one basis using a self-constructed semi structured questionnaire. *Results:* A total of 400 women belonging to the age group of 40 to 55 years participated in the study. The mean age of the participants was 52.01 ± 2.89 years. The mean age of attaining menopause was 45.67 ± 3.9 years. The least age of attaining menopause was 37years and the maximum age noted was 54 years. Most women (55%) attained menopause in the age group of 45 to 49 years. The incidence of premature menopause was 4.6%. In women with hysterectomy Estrogen alone therapy is beneficial and in women with intact uterus, estrogen progesterone therapy is recommended. *Conclusion:* Almost majority of women are affected by menopausal symptoms and due to sociocultural factors, economic factors adversely affecting the women health. Better to initiate women with hormonal therapy in women with severe symptoms.

Keywords: Menopause, Vasomotor Symptoms, Hormonal Symptoms, Hormonal and Non Hormonal Therapy.

Introduction

Menopause occurs when the ovaries naturally decrease and then stop their production of the hormone estrogen. For almost all individuals, natural menopause occurs between age 45 and 55 years, with an average age of around 51 years. Understanding the use of exogenous hormones for the treatment of menopausal symptoms (ie, menopausal hormone therapy (MHT) [1] is of critical importance to the health of women, especially given that women spend approximately 40% of their lives post-menopause [2].

Postmenopausal symptoms that can be treated with MHT include vasomotor symptoms (VMS) (eg, hot flashes, night sweats), sleep disturbances, sexual dysfunction, and genitourinary tract symptoms (eg, vulvovaginal atrophy, dyspareunia, urinary frequency) [2]. In addition to the treatment of menopausal symptoms, MHT may improve bone health among women after menopause, especially those with osteopenia or elevated risk of fracture [3].

Pharmacotherapy can be hormonal and nonhormonal therapy. Menopause hormone therapy (MHT) consists of a group of preparations with sex hormones administered in cases of low level of estrogen. Estrogen-only therapy is labeled as estrogen replacement therapy (ET, ERT). For combination of estrogens and progestogens, the term is estrogen–progestogen therapy (EPT).

Menopausal hormone therapy: Formulations: MHT is FDA-approved for four indications in menopausal women: VMS, prevention of bone loss, premature hypoestrogenism, and moderate to severe vulvovaginal symptoms.

Estrogens: Estrogen MHT is available in different forms like oral, transdermal and vaginal formulations. Transdermal estrogen

HT can be applied as a gel, patch and spray. For women without a uterus, estrogen alone can be used. Available estrogen formulations include ethinyl estradiol, micronized 17β-estradiol, conjugated equine estrogens (CEE), conjugated estrogens (CE) [Table 1].

Table-1: Various MHT Forms

Formulation	Route	Dose	Frequency
Oral estrogen dosing			
17β-estradiol	0.5-2.0		daily
CEE	0.3-1.25		daily
CE	0.3-1.25		daily
Esterified estrogen	0.3-1.25		daily
Transdermal Estrogen Dosing			
17β-estradiol	Patch	0.025-0.1 mg	Twice weekly or weekly
	Gel	0.25 mg -1.25 mg	daily
	Spray	0.021/90 µL	daily
Low dose, local vaginal estrogen dosing for genitourinary syndrome of menopause			
17β-estradiol	Cream	1 g	Nightly for 2 weeks followed by twice weekly
	Tablet	10 µg	
	Ring*	2 mg	Replace every 90 days
	Insert	4 or 10 µg	Nightly for 2 weeks followed by twice weekly
	Cream	0.5-2 g 0.5 g	Daily for 21 days, stop for 7 days and repeat Use twice weekly
Progestogen dosing			
MP	Oral	100-300	Daily
MPA	Oral	2.5-10	Daily
Norethindrone	Oral	0.35	Daily
NETA	Oral	5	Daily
Megestrol acetate	Oral	20-40	Daily
Levonorgestrel	IUD	52	5 years
Oral estrogen-progestogen dosing			
Continuous/ cyclic	**Estrogen**	**Progestogen**	**Dose[mg]**	**Frequency**
Cyclic	CEE		0.625 + 5	CEE daily; MPA on days 15-28
	17β-estradiol	MP	0.025-0.1 + 200	17β-estradiol daily; MP for 10-14 days/month
Continuous	CEE	MPA	0.625 + 2.5	Daily
			0.625 + 5	Daily
			0.3 + 1.5	Daily
			0.45 + 1.5	Daily
	Ethinyl estradiol	NETA	0.0025 + 0.5	Daily
			0.005 + 1	Daily
	17β-estradiol	NETA	0.5 + 0.1	Daily
			0.1 + 0.5	Daily
	17β-estradiol	MP	1 + 100	Daily
	17β-estradiol	Drospirenone	0.5 + 0.25	Daily

Osteoporosis treatment: anti resorptive agents				
Medication	**Class**	**Route**	**Dose (mg)**	**Frequency**
Alendronate	Bisphosphonate	Oral	70	Weekly
			10	Daily
Risedronate		Oral	5	Daily
			35	Weekly
			150	Monthly
Ibandronate		IV	3	Every 3 months
Zolendronic acid		IV	5	Every 12 months
Denosumab	RANK ligand inhibitor	SQ	60	Every 6 months
Osteoporosis treatments: anabolic agents				
Abaloparatide			80mcg	daily
Teriparatide	PTH receptor agonist	SQ	20 mcg	Daily

Indication of progestogen: For women with the uterus intact, estrogen must be administered together with progestogen to reduce the risk of endometrial hyperplasia and cancer. In case of receiving vaginal estrogen therapy due to vaginal atrophy or receiving minimum dose transdermal estrogen therapy to prevent bone disappearance, progestogen may not be administered, but the long-term safety of progestogen administration for more than 1 year remains unclear [4-5] (TABLE 1).

Non-Hormonal Treatments for Vasomotor Symptoms (VMS): For women who are not able to use MHT to treat VMS, there are several alternative pharmacologic and non-pharmacologic therapy options, but the efficacy is generally lower than MHT. Non-pharmacologic therapies include mind-body techniques such as cognitive behavioral therapy, mindfulness-based stress reduction and clinical hypnosis. Other techniques include weight loss, exercise, yoga, acupuncture. There are various non-hormonal pharmacologic treatments for VMS. These include selective serotonin reuptake inhibitors (SSRI), serotonin norepinephrine reuptake inhibitors (SNRI), gaba pentinoids and neurokinin B antagonists [6].

Aims and Objective: Evaluating symptoms in postmenopausal women and providing Hormonal treatment

Material and Methods

This study was a community based cross sectional, descriptive, observational study conducted among 400 rural women living in and around vijayapur. The study was carried out from November 2022 to October 2023. Ethical clearance has been taken for this study. Data were collected from postmenopausal women attending general health camps, women accompanying patients attending gynecology outpatient departments [OPDs]. Data were also collected from house to house surveys. The participants were interviewed on one-to-one basis using a self-constructed semi structured questionnaire. Written informed consent was taken from each participant. The questionnaire prepared in the local language consisted of sociodemographic data, menopausal symptoms, awareness to symptoms and treatment, attitude toward menopause, and treatment availed by symptomatic women.

Examinations required prior to receiving MHT: Prior to initiating MHT include checking the indications and contraindications of MHT, which requires history recording, physical examinations. Because the symptoms of menopause are varied, tests should be conducted for each risk factor based on the basic examination conducted according to the life cycle necessary for women [7-9].

The basic examination, which is a general examination conducted according to the life cycle, should identify lifestyles such as smoking and drinking habits; mental diseases such as depression; and with family history for diseases such as Alzheimer's disease,

osteoporosis, diabetes, endometrial cancer, breast cancer, liver disease, thyroid disease, cardiovascular disease, and venous thromboembolism via history taking. In addition, the basic examination should include a physical examination for height, weight, and blood pressure as well as the pelvis, breast, and thyroid. Blood tests include tests for liver function, kidney function, anemia, and fasting blood sugar as well as lipid examination, followed by mammography, bone mineral density (BMD) test, and Pap smear screening [3]. Furthermore, it is reasonable to regard pelvic ultrasonography as part of the basic examination.

Indications of MHT:

- Climacteric syndrome
  - Vasomotor problems
  - Psychic problems
- Estrogen-deficiency syndrome
  - Organic – urogenital atrophy
  - Metabolic – osteoporosis
  - Primary prevention of the ischemic cardiac disease; with early start only
- Expected effects of long-term administration of estrogens – contrary to the risks of the long-term use
  - Prevention of Alzheimer's disease and Parkinson's disease and strengthening their treatment
  - Prevention of senile macular degeneration and geriatric blindness
  - Prevention of geriatric tooth loss and oral health
  - Prevention of colorectal cancer
  - MHT, menopause hormone therapy.

Contraindications of MHT:

- Breast carcinoma – current, in personal anamnesis, suspected
  - Invasive breast carcinoma, premalignant changes of breast (atypical ductal hyperplasia, lobular neoplasia) and a ductal carcinoma *in situ* (intraductal carcinoma)
- Estrogen-dependent malignant carcinoma – known or suspected
  - E.g. unfounded bleeding from genitals as a sign of endometrial carcinoma
- Untreated estrogen-dependent carcinomas
  - Endometrial carcinoma, breast carcinoma, endometrial stromal sarcoma
- Active hepatopathy
- Anamnestic or current idiopathic thromboembolic disease
  - Pulmonary embolism, phlebothrombosis
- Active or recent arterial thromboembolism
  - E.g. coronary thrombosis, angina pectoris
- Known intolerance to a certain constituent of the preparation

Results

A total of 400 women belonging to the age group of 40 to 55 years participated in the study. The mean age of the participants was 52.01 ± 2.89 years. The mean age of attaining menopause was 45.67 ± 3.9 years. The least age of attaining menopause was 37years and the maximum age noted was 54 years. Most women (55%) attained menopause in the age group of 45 to 49 years. The incidence of premature menopause was 4.6% (Table 2).

Table-2: Demographic data of participants

Characteristic	Frequency	Percentage
Age [years]		
40-44	16	4
45-49	108	27
50-55	276	69
Age of menopause [years]		
<40	23	5.75
40-44	116	29
45-49	255	63.75
50-55	86	21.5

Most common symptom is psychosomatic [72%] out of which Muscle and joint pain accounts for 64%, followed by fatigue 65%, Vasomotor symptoms [41.5%] of which hot flushes 40% and night sweats 36.2%. Among urinary symptoms, urge incontinence accounts for 16.5%, Stress incontinence 10.75%, urinary frequency in 28.25%, dysuria in 18.75%, Recurrent UTI in 8.25%. Dyspareunia in 17%, Genital prolapse in 2.5%, Post menopausal bleeding in 2%.

Among 166 women with vasomotor symptoms, 80 women had moderate to severe VMS which were given treatment of Estrogen

alone therapy. Estrogen Progestogen therapy given for 68 women. Low dose vaginal estrogen therapy is used to treat Genito urinary symptoms of menopause like Dyspareunia, Vaginal dryness. Among 122 women, 76 women had severe genito urinary symptoms. Rest women with mild symptoms had given Reassurance (Table 3 & 4).

Table-3: Frequency of menopausal symptoms

Symptom	Frequency	Percentage
Psychosomatic	288	72
Muscle and joint pain	256	64
Fatigue	260	65
Insomnia	116	29
Poor memory	78	19.5
Irritability	124	31
Lack of concentration	68	17
Low mood	35	8.7
Vasomotor	166	41.5
Hot flushes	160	40
Headache	76	19
Palpitations	14	3
Night sweats	145	36.2
Stress Incontinence	43	10.75
Urge incontinence	66	16.5
Sexual symptoms	167	41.75
Vaginal dryness/ Itching	54	13.5
Loss of libido	118	29.5
Genital prolapse	10	2.5
Post menopausal bleeding	8	2
Recurrent UTI	33	8.25
Frequency	113	28.25
Dysuria	75	18.75
Dyspareunia	68	17

Table-4: Hormonal Therapy

Formulation	Indication	Contraindication	No of women with major symptoms relieved with treatment	Percentage
Estrogen-alone therapy [women with hysterectomy]	-Management of moderate to severe Vasomotor symptoms -Prevention of osteoporosis in women not able to tolerate basic medications	*Absolute:* unexplained vaginal bleeding, history of VTE, known blood clotting disorder, untreated Hypertension, history of endometrial, breast, or other estrogen-dependent cancer, liver disorder, hypersensitivity to HT, history of CHD, stroke *Relative:* High Triglycerides , elevated risk of breast cancer	80	20
Estrogen-progestogen therapy (women with an intact uterus)	Management of moderate to severe Vasomotor symptoms	*Absolute:* unexplained vaginal bleeding, history of VTE, known blood clotting disorder, untreated Hypertension, history of endometrial, breast, or other estrogen-dependent cancer, liver disorder, hypersensitivity to HT, history of CHD, stroke *Relative:* High Triglycerides, elevated risk of breast cancer	68	17
Low-Dose Vaginal Estrogen Therapy	-Treatment of genitourinary symptoms of menopause like dyspareunia, vaginal dryness	Unexplained vaginal bleeding, known breast cancer, endometrial cancer or other estrogen-dependent cancer	76	19

Discussion

The mean age of attaining menopause in our study subjects was 45.67± 3.9 years. The mean age of menopause in rural areas of India as observed in other studies ranged from 44.06 ± 3.06 to 48.26 ± 4.86 years [10-11]. With increasing life expectancy and comparatively lower mean age at menopause, we can expect Indian women to have a longer postmenopausal period and its consequences than their counterparts worldwide.

In this present study, Psychosomatic symptoms seen in 72%.Among psychomotor symptoms most common is Muscle and joint pains in 64%.Similar to our study, Kumar et al [12] reported 78% women had psychosomatic symptoms. In our study Fatiguibility accounts for 65%. The frequency of fatiguability in Indian rural postmenopausal women ranged from 40.1 to 89.1% [13-15]. Similar range of frequency was noted in Indian urban women (40.4 - 74.3%). About 67.1 to 80% of Asian and African postmenopausal women described excessive physical and mental exhaustion. Borker et al [15] found depression and irritability to be the commonest complaint (90.7%).

Insomnia 29%, In our study Poor memory in 19.5%. A study by Dasgupta and Ray [16] a higher percentage of women complained of decreased concentration (68.2%) and poor memory (81.7%). In the present study Irritability accounts for 31%.Borker et al found depression and irritability to be the commonest complaint (90.7%). In the present study, low mood was found in 8.7% women, which was comparable with other studies (24.7– 44%). Lack of concentration in this study is 17%. A study by Dasgupta and Ray [16] a higher percentage of women complained of decreased concentration (68.2%) and poor memory (81.7%).

In this study vasomotor symptoms accounts for 40%. Aaron et al, [17] Dutta et al [11], and Leena and Varghese found hot flushes and night sweats to be the commonest symptoms in their studies. The frequency of hot flushes was 41.5% in the present study and 15.6 to 78.2% in other studies on rural women. The frequency of night sweats was 44.2% in the present study and ranged from 38 to 62.7% of rural women in other studies [18]. The frequency of hot flushes and night sweats in Indian urban postmenopausal women ranged from 38.2 to 80.9%. Aaron et al [17] Dutta et al [11] and Leena and Varghese found hot flushes and night sweats to be the commonest symptoms in their studies. The frequency of hot flushes was 51.2% in the present study and 15.6 to 78.2% in other studies on rural women. The frequency of night sweats was 36.2% in the present study and ranged from 38 to 62.7% of rural women in other studies. The frequency of hot flushes and night sweats in Indian urban postmenopausal women ranged from 38.2 to 80.9%. Stress incontinence in this study is 10.75%.The frequency of stress incontinence observed in other studies was 21.9 to 38.8% [19].

Urge incontinence in this study is 16.5%. Other studies have reported urgency and increased frequency of micturition in 4 to 18% and 5.8 to 17% women respectively [20].

Sexual symptoms in this study 41.75%. The incidence of sexual symptoms was 6.4 to 47.2% in other studies [21]. In the current study Loss of libido 29.5%.In other studies, the frequency of loss of libido observed was highly variable (6–94.3%)

In this study Genital prolapse in 2.5% and Post menopausal bleeding in 2%. The incidence of postmenopausal bleeding (14.4–29.8%) and genital prolapse (20.6–23.7%) in other studies was comparatively higher than in the present study.

Conclusions

The present study shows that the average age of menopause in our region was comparable with that of other Indian women. Majority of women had one or more symptoms, the commonest being psychosomatic. There is clear evidence for the effectiveness of MHT for the treatment of VMS of menopause, and benefits may exceed risks of CHD, stroke, and VTE, especially among women who are less than 10 years since menopause, less than 60 years old, and without significant cardiometabolic comorbidities or contraindications to MHT

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