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## Third consensus meeting of Indian Menopause Society (2008): A summary

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### THE SCOPE OF THE PROBLEM OF MENOPAUSE IN INDIA

India has a large population, which has already crossed the 1 billion mark with 71 million people over 60 years of age and the number of menopausal women about 43 million. Projected figures in 2026 have estimated the population in India will be 1.4 billion, people over 60 years 173 million, and the menopausal population 103 million. Average age of menopause is 47.5 years in Indian women with an average life expectancy of 71 years.

The varied lifestyles of people in the country, the rural urban divide (72% is rural), the economic imbalance between the poor, middle class, affluent and the multicultural, multiethnic, multireligious composition of the population makes it difficult to formulate generalized recommendations.

### SOCIAL PROBLEMS IN THE INDIAN CONTEXT

The expert committee would like to highlight the problems in the country on the basis of the attitude relevant to menopause in the Indian context. These factors have to be borne in mind by healthcare workers when they are dealing with menopausal women and making recommendations for their health and lifestyle changes. There is a large gender bias against women. Life is steeped in myths and superstition. It is a taboo to discuss reproductive health and sexual problems. Women do not come forward with their complaints.

### MENOPAUSAL SYMPTOMS

Distribution of menopausal symptoms is extremely assorted. Individual variations in India exist just as they do worldwide. Menopausal symptoms have been found to be different in the rural and urban areas. Urogenital symptoms, fatigue and weakness, body aches, and pains are the predominant symptoms in both rural and urban menopausal women. Hot flushes, psychological symptoms, mood swings, and sexual dysfunctions are seen more in urban women.

### OSTEOPENIA AND OSTEOPOROSIS RISKS

Osteopenia and osteoporosis are significant in Indian women. Moreover, 35–40% of women between 40 and 65 years have been detected to suffer from osteopenia whereas 8–30% suffer from osteoporosis from small sample studies. All women over 65 years have been found to have either osteopenia or osteoporosis. This is attributable to low calcium intake in youth and later, lack of exercise in all ages and paradoxically, to lack of exposure to sunlight in women living in urban areas.

## RISKS OF CARDIOVASCULAR DISEASE

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The incidence of cardiovascular disease (CVD) in Indian women has been noted to have significantly risen. The projected deaths from cardiovascular diseases by 2020 are estimated to be 42% of the total deaths. There is an increased prevalence of metabolic syndrome which comprises of insulin resistance, altered glucose tolerance or diabetes, dyslipidemia (low HDL, high LDL, and high triglycerides), hypertension, and central obesity. India has been rightly labeled the diabetic capital of the world today.

## RISK OF STROKE

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There is an increasing burden of stroke in India. The prevalence rate of stroke is 545.1/100,000 persons. The annual incidence rate of stroke is 145.3/100,000 persons with a 30-day case fatality of 41%. The incidence of stroke was found to be similar among slum and nonslum dwellers. There is a higher incidence and case fatality of stroke in women as a result of fast changing lifestyles, hypertension, and diabetes.

## CANCER

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The incidence of cancers in Indian women has been found to be on the rise. Most cancers occur in women between 35 and 64 years. The common cancers in women in India are those of breast (12.1–27.5%), cervix (13.1–35%), ovary (3.5–7.8%), and endometrium (0.7–2.2%) followed by oral cancer. The incidence of different cancers varies between geographical areas.

## ASSOCIATED CHRONIC PROBLEMS

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Other relevant chronic problems increasing morbidity are sarcopenia from lack of exercise, ophthalmic disease that worsens against a backdrop of glaucoma and trachomatis, conjunctivitis, oro-dental issues with the national habit of tobacco and areca nut chewing added to the problems of periodontitis and receding gums on osteoporotic jaws after menopause.

## PREMATURE MENOPAUSE

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Premature menopause in India has been noticed anecdotally to have an increasing incidence and greater prevalence in India. However, this is debated. The investigators, lacking medical perspective, perhaps could have included hysterectomized women and those with pathological secondary amenorrhea. There is a need to confirm by appropriate studies if Indian women in reality do suffer from premature ovarian failure or early menopause.

## SURGICAL MENOPAUSE

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There is an increased burden of surgical menopause in India. A significant number of hysterectomies are performed with bilateral oophorectomies. Perhaps greater recourse is taken to hysterectomy in order to avoid follow-up with other options of conservative management by these women. Gynecologists and surgeons also have a low threshold to perform hysterectomy. More cancers being detected in the community is alarming to women, who, therefore, often demand a hysterectomy.

The following clinical practice points are recommended.

### Lifestyle Changes

For menopause management guidelines, the expert committee strongly recommends and stresses on lifestyle changes as a primary modality of care including adequate exercise, diet-rich in phytoestrogens, calcium, fiber, and low in fat, especially saturated fats. All of these should be initiated in childhood and adolescence and continued lifelong. They have a low or no-cost benefit. In addition, they have benefits on bone health, sarcopenia, CVD, diabetes, and mood.

## Use of Yoga and Meditation

It is also suggested that utilization of yoga and meditation is increased. These are keeping in mind the fact that these recommendations can be universally followed by all Indian women—rich or poor, rural or urban—to improve their global health. Emphasis at all levels of health care should be on inducing an “exercise culture” for women of all ages.

## Use of Hormone Therapy

Menopausal women in the fifth decade of their lives who are symptomatic may continue to be advised oral estrogen–progestin combinations as short-term therapy, which varies from around 2 to 5 years. This should be gradually tapered off to minimize chances of recurrence of symptoms. Most of the other national and international societies recommend that Hormone therapy (HT) is only for symptomatic menopausal women. HT should be in a small dose and for a short duration.

## Pre-HT Assessment

Recommendations for HT use are that all women must have a thorough clinical assessment before starting the therapy. The minimum investigations recommended are the performance of lipid profile and endometrial thickness on transvaginal pelvic ultrasound. Any pre-existing breast cancer should be ruled out by a mammography and/or sonography of the breasts.

## Counseling About Risks of HT

Counseling for HT must include an explanation of the associated risks. HT, particularly conjugated equine estrogens (CEE) and medroxy progesterone acetate (MPA), leads to a small increase in breast cancer incidence, which increases with duration of therapy and age. The relative and absolute risks of pulmonary embolism, stroke, and breast cancer should be explained. The documented additional risks for these are eight cases of each of these per 10,000 women per year, i.e., <1 per 1000 women per year.

Women who are taking only CEE, i.e., estrogen therapy (ET) without the MPA should really not be concerned with these observations as these are not relevant to them. In fact, the estrogen-only arm of the Women's Health Initiative (WHI) trial failed to demonstrate relative harm and was found to be advantageous with regards to breast concerns.

## Contraindications to HT

Absolute contraindications

- 1) Known or suspected pregnancy
- 2) Undiagnosed, abnormal vaginal bleeding
- 3) Endometrial-/gynecological-/hormone-dependent cancers
- 4) Breast cancer
- 5) Severe active liver disease with impaired/abnormal liver function
- 6) Acute vascular thrombosis past or present

Relative contraindications

- 1) Migraine headaches
- 2) Thrombophlebitis
- 3) Strong family history of breast cancer
- 4) Uterine fibroids
- 5) Endometriosis
- 6) Gall bladder disease

## 7) Pancreatitis

### HT for Symptom Control

HT should be used for symptom control. Use HT where appropriate and where symptoms affect quality of life. Start with low dose estrogens. Use local estrogens whenever possible since less rigorous follow-up and monitoring are required particularly for genito-urinary complaints.

### Precautions with use of HT

Precautions with HT use must be taken. Counsel and monitor for side effects and HT-associated risks. It is recommended that all women with a uterus should be prescribed a progestogen along with estrogens for endometrial protection.

### Use of HT in Premature Menopause

Use of HT is recommended long term to patients with premature menopause up until the expected age of menopause, i.e., 50 years as a form of replacement therapy.

### Use of HT in Surgical Menopause

Recommend HT to patients with surgical menopause till age 50. This may be started in the immediate postoperative phase. HT should be weaned off gradually. This again is replacement therapy.

### When to Initiate Therapy

For therapeutic purposes, therapy can be started at any time provided the symptoms warrant treatment and adequate pretherapy assessment has been performed. For prophylaxis, the role of HT, if any, is only in women at high risk for developing osteoporosis. In these women, it should be started after 6–12 months of amenorrhoea when diagnosis of menopause is certain.

HT should be started with the lowest possible dose, i.e., 0.3 mg conjugated equine estrogen as side effects are likely to be more initially and the dose should be increased to 0.625 mg if necessary, depending on symptoms.

### Duration of Therapy

This depends on the indication for use and the therapeutic response of the patient. Patients tend to discontinue HT after acute symptoms are over. However, the hormones should be gradually “weaned off”, or symptoms may recur with abrupt withdrawal. Women may be counseled that risks position of quotes ok are small when HT is taken for <5 years.

Women who are already on HT, i.e., combination of E + P (usually CEE + MPA) whether for less than or more than 5 years should be counseled individually and a personalized decision taken in light of their needs and risk factors. Their physicians and the women themselves should not panic nor be unduly alarmed for the individual risks are small. The women should be reassured that the absolute individual risk-related studies were relatively small. Consideration should be given to switch to micronized progesterone preferably the vaginal or rectal route if acceptable to the woman, to drospirenone, or levonorgestrel containing intrauterine device in relevant circumstances.

### Follow-Up While on HT

Recommendations regarding follow-up of women on HT are that regular follow-up for all women on HT is mandatory. This should initially be after 1 and 3 months to confirm adequacy of treatment and thereafter annually. Only in special situations, women would require to be monitored more frequently.

## OSTEOPROTECTION

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HT is useful for osteoporosis. Use HT as primary treatment for osteoprotection and osteoporosis correction only in symptomatic women. In otherwise asymptomatic women, a range of other therapies are available for osteoporosis and osteopenia which should be tried.

When HT is started for osteoprotection or osteopenia/osteoporosis, therapy must be started as early as possible after menopause, as rate of bone loss is maximum in the early postmenopausal years. The duration of therapy should be for a minimum of 5 years for benefit to be apparent. Studies indicate that bone mineral density (BMD) declines after discontinuation of estrogen and approaches levels of nonusers. Therefore, another osteoprotective agent should be initiated prior to cessation of HT. However, it must be remembered that HT is not a primary treatment for bone protection.

## CARDIOPROTECTION

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The increase in cardiac events demonstrated in the first year in the WHI trial could have been because the trial was dealing with a mean age group of women who were 63.3 years of age and were really an at-risk population. This observation is similar to the Heart and Estrogen/Progestin Replacement Study (HERS) on women with documented pre-existing coronary heart disease (CHD), where the mean age was 67 years. Younger women should be informed that this data need not necessarily apply to women in their 50s.

The combination of CEE + MPA should not be recommended to women seeking to initiate or continue HT for cardioprotection particularly if they belong to the “at greater risk for developing CHD” group. Instead, alterations in lifestyle measures such as weight reduction, appropriate exercise, and diet, avoidance of excessive alcohol and stress, no smoking, and the use of statins and aspirin should be recommended as first-line measures.

The other benefits of long-term HT on the basis of years of observational data should also be explained in order to give a comprehensive and balanced view. The unique personal health needs, lifestyle, personal, family, and past medical history of each individual has to be considered in the process of decision making.

### Primary Cardioprotection and HT

HT is not recommended for primary cardio-protection, only for symptom relief. HT can have beneficial effects on CHD if started in younger women closer to menopause. Benefits of HT in preventing atherosclerosis occur only when the therapy is started during the early postmenopausal years, known as the “window of opportunity” before advanced atherosclerosis develops. However, no firm recommendations can be made in this regard till further research and evidence become available.

### No Role of HT in Secondary Cardioprotection

HT is not recommended for secondary cardioprotection. In women with known CVD, the use of HT should be discouraged. However, in those symptomatic women who need it, regular guidelines for HT use and appropriate counseling should be followed.

## NEUROPROTECTION

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Large RCTs in older women show decreases in cognitive function with late-life-initiation of HT as seen in the Women's Health Initiative Memory Study (WHIMS). Findings for long-term users of HT among older women who initiated HT early in life are unclear.

There is a lack of studies of estrogen plus progestin in younger women. ET/HT seems to reduce the risk and delay the onset of Alzheimer's disease if initiated early. ET is beneficial in younger postmenopausal women in verbal memory and attention. The concept of a “window of opportunity” for benefits of HT with regards to cerebral function may also exist as it does with cardiovascular effects.

## KEY RECOMMENDATIONS FOR PRESCRIPTION OF HT

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- 1) Individualization of HT, i.e., the dose, type, route, is according to the need of the individual woman.
- 2) Use unopposed estrogen only for women who have undergone hysterectomy.
- 3) Progesterone needs to be added if prescribed for women with an intact uterus.
- 4) The art of prescribing HT is to use the minimum effective dose judiciously on indication, after appropriate counseling.

There are many important issues that need to be considered before deciding on HT.

1. A specific indication for starting HT must be present, and it must be documented.
2. Symptoms which definitely require HT are vasomotor symptoms and symptoms as a result of urogenital atrophy.
3. The main rule for giving HT is to use the “lowest possible dose for shortest possible duration.”
4. For prevention and treatment of osteoporosis, other modalities (bisphosphonates) should be preferred over estrogens.
5. Assessment of risk factors prior to starting HT is an essential prerequisite.
6. Lifestyle modification is an integral component of managing postmenopausal women.

The above summary has been prepared by Dr. Jyothi Unni from “Clinical Practice of Menopausal Medicine – How and Why.” Based on Third National Revised Consensus Guidelines of the Indian Menopause Society”. [www.indianmenopausesociety.org](http://www.indianmenopausesociety.org)

### Footnotes

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