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Dasgupta's Recent Advances in Obstetrics and Gynaecology

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Menopause Hormone Therapy

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INTRODUCTION

Menopause a word derived from Greek literature means "cessation of the monthly period." However, the symptoms accompanying this cessation, affect the quality of life (QOL), so menopause is now defined as a hormone deficiency state rather than as a phase of normal maturation.

Menopause hormone therapy (MHT) is a treatment used to relieve symptoms of menopause like hot flushes, night sweats, mood swings, vaginal dryness, decreased sexual drive, etc. Many of these symptoms pass in few years, but they can be very unpleasant and MHT can offer relief for grueling symptoms of menopause.

Menopause transition is a good opportunity to institute the healthy lifestyles which are as follows:

- Balanced diet
- Meditation, massage, weight-bearing exercise
- Pursuing hobbies, deep breathing exercises
- Supplements: Calcium, vitamin B complex, vitamin A, D, C, and E
- Phytoestrogens: Binds to E2 receptors, and as a natural selective estrogen receptor modulators (SERM)
- Food-containing phytoestrogens, carrot, beet root, pumpkins, potato, red beans, peas, garlic, eggs.

Apart from lifestyle modification, some women do require supplements of hormones to alleviate symptoms of menopause. They should be carefully selected after ruling out contraindications. Counseling must be done regarding dosage and route of medication, need to follow-up, possible side effects, and complications.

INDICATIONS OF MENOPAUSE HORMONE THERAPY

Menopause hormone therapy can be instated in following situations:

- To relieve vasomotor symptoms like hot flushes and mood swings.
- Menopause hormone therapy is considered to be the most potent and effective therapy for estrogen-deficient urogenital symptoms (genitourinary syndrome of menopause)
- To improve the quality of life
- Preventing osteoporosis in postmenopausal women.

WHEN TO START?

Detailed discussion of therapeutic options must be done with the client and her partner. The healthcare provider must understand the needs of the client and counseling should be offered.

- Women experiencing a spontaneous ovarian failure before the age of 45 and particularly before the age of 40 (before the age of natural menopause) are at higher risk of cardiovascular diseases or osteoporosis. Hormone therapy given until the normal age of menopause under medical supervision will provide benefit to these women. Surgical menopause following hysterectomy with bilateral salpingo-oophorectomy (BSO).
- Premature cessation of ovarian function due to chemotherapy/radiotherapy given for cancers.
- Women more than 60 years having symptoms.
- Nulliparous women who have high risk of osteoporosis and bone fractures.

CONTRAINDICATIONS OF HORMONE THERAPY

- Active endometrial and gynaecological hormone-dependent cancers
- Undiagnosed abnormal vaginal bleeding
- Severe active liver disease
- Estrogen dependent venous thrombosis
- Active breast cancer and estrogen and progesterone receptor positive cancers
- Inherent increased risk of thromboembolism.

Relative Contraindications

- Migraine and headaches
- Endometriosis
- Family history of breast cancer
- Gallbladder disease
- Superficial thrombophlebitis
- Uterine fibroids.

DIFFERENT DRUGS ARE USED FOR MHT

- Estrogens
- Progesterones

- Combined estrogens and progesterones
- Androgens
- Tibolone
- SERMs.

Estrogens

Oral Preparations

- *Conjugated equine estrogens (CEEs)* are formulated from mare urine extracts. These estrogens are a concoction of estrone (50%) and a series of equine estrogen that possesses very long half-lives, and even during the week when the women are not taking this drug, this preparation provides continued effectiveness. It is available in doses from 0.3 mg to 2.5 mg. They are effective for both prevention of osteoporosis and for vasomotor symptoms.
- *Micronized estradiol:* It is orally active form that is available in doses of 0.5–2 mg per pill. It is initially absorbed and then is converted into estrone in GI mucosa and liver.
- *Ethinyl estradiol:* It is very potent and orally active estrogen. It was developed to be used in oral contraceptives. It causes an elevation in the production of HDL-C, lipase, thyroxine-binding globulin (TBG), corticosteroid-binding globulin (CBG), sex-hormone binding globulin (SHBG), ceruloplasmin, and ferritin as well as various clotting factors. So, in susceptible woman, there is risk of thromboembolism disorders. It is not used for MHT.

Transdermal Estrogens

These novel preparations have a mixture of estradiol with a resin and that forms the adhesive material on the occlusive membrane. The drug absorption process depends on the estradiol concentration in the adhesive as well as the surface area of the patch. Estradiol is a fat solvent which the skin absorbs immediately and from there it enters into the circulation.

Benefit: It is beneficial in obese woman who are suffering from climacteric symptoms. Risk of venous thromboembolism is not seen.

Estradiol Spray

It has a unique metered dose transdermal spray technology ensuring slow and steady estrogen levels needed for low and flexible doses of estrogen.

Vaginal Preparation

These contain CEE or micronized estradiol. To treat vaginal atrophy as well as dryness, these preparations are utilized to deliver minimal local doses of estrogens to the vagina.

Summary of estrogens is described in Table 1.

TABLE 1: Summary of estrogens.

Molecule	*Strength*	*Route*	*Advantage*
Conjugated equine estrogen	0.625 mg	Oral	Potential for improving the cardiovascular risk profile, helpful in vasomotor symptoms (VMS) and prevention of osteoporosis
Estradiol valerate	1.0 mg	Oral	Fast absorption, helpful in vasomotor symptoms
Ethinyl estradiol	0.02 mg	Oral	Very potent orally active estrogen, helpful in VMS
Conjugated estrogen not derived from mares	0.3 mg	Oral	Helpful in VMS
Conjugated equine estrogen	0.625 mg/g	Vaginal	Useful in genitourinary syndrome of menopause (VVA), decreased risk of venous thromboembolism
Estradiol	25 μg	Vaginal tab	Useful in genitourinary syndrome of menopause (VVA), Reduces UTI, decreased risk of venous thromboembolism
Estradiol	25, 50, 100 μg	Transdermal	First pass metabolism is avoided, first line of choice in obese woman, potential for improving the cardiovascular risk profile, helpful in vasomotor symptoms and prevention of osteoporosis
Dot estradiol patch	0.025, 0.0375 mg	Transdermal	First pass metabolism is avoided, potential for improving the cardiovascular risk profile, helpful in vasomotor symptoms and prevention of osteoporosis
Estradiol	0.375 mg	Dermal spray	First pass metabolism is avoided, potential for improving the cardiovascular risk profile, helpful in vasomotor symptoms and prevention of osteoporosis

Progesterone

These are integral part of MHT in a woman with an intact uterus. They are added in the second half of cycle for minimum of 12 days or a month to reduce the risk of endometrial hyperplasia and carcinoma which occur due to continuous estrogenic stimulation of endometrium. Progesterone without androgenic activity is preferred.

The different preparation used are:

Synthetic

- Medroxyprogesterone acetate (MPA)
- Norethisterone acetate.

Side effects:

- Derangements in lipid profile and coagulation profile.
- Less side effects than synthetic.

- Not androgenic therefore no negative effect on lipid profile.
- The risk of breast cancer will not increase.

Newer Progesterone (Fourth Generation)

They have been designated to have no androgenic or estrogenic actions and are similar to physiological hormone progesterone.

Drospirenone is derived from spironolactone. It is antimineralocorticoid steroid with partial anti-androgenic effect so it has no negative effect on the lipid profile. It has positive effects on weight and blood pressure.

Side effects of progesterone: Weight gain, bloating, irregular bleeding, acne, breast tenderness, headache, fatigue, anxiety, and depression.

Hysterectomised woman do not require progesterone and should be prescribed estrogen alone as the risk of breast cancer is increased by the addition of progesterone. However, in woman who have undergone hysterectomy for endometriosis, if residual disease is suspected, addition of a progesterone may be considered.

Summary of progesterones is described in Table 2.

Combined Therapy

The clinical goal of combined regimen is to provide uterine protection, maintain estrogen benefits and minimize side effects.

TABLE 2: Summary of progestogens.

Drug	*Route Min 12 days/ month*	*Sequential*	*Continuous*	*Advantages*
MPA	Oral	5 mg daily	2.5 mg daily	Reduced incidence of breakthrough bleeding
Norethisterone	Oral	1mg daily	0.3 mg daily	Reduced incidence of breakthrough bleeding
Drosperinone	Oral	—	2 mg daily	Reduced incidence of breakthrough bleeding
Natural progesterone	Oral	300 mg daily	200 mg daily	Reduced incidence of breakthrough bleeding, decreased risk of breast cancer
Natural progesterone	Vaginal tab	200 mg daily	100 mg daily	Minimal systemic absorptions with high local concentration of progesterone in the endometrium
Natural progesterone	Vaginal gel	45 mg	45 mg	Minimal systemic absorptions with high local concentration of progesterone in the endometrium
Levonorgestrel-releasing intrauterine system	Intrauterine	—	20 μg daily	Strong antiproliferative effect on the endometrium

Combined HT

Perimenopausal women should be given cyclic MHT rather than continuous MHT (Table 3).

Disadvantages: Progesterone reverses the coronary benefits of estrogen therapy by affecting the HDL/LDL ratio. Based on various studies, it is strongly suggested that the progestogen component of the MHT leads to an increase in breast cancer.

Androgen Replacement Therapy

As per the recommendation of international menopause society, the administration of individualized MHT (including androgenic preparations) leads to improvement of sexuality and the overall quality of life. To meet the treatment goal, androgen co-therapy should be administered at the lowest dose for the shortest period of time. Surgical menopause—androgen replacement should be reserved for those women who are with severe androgen insufficiency (adrenal failure, bilateral oophorectomy).

Beneficial Effects

- Increase in the libido
- Mood sense of well being
- Decrease in the breast tenderness
- BMD increments in the spine.

Side Effects

Long-term use of androgens may lead to hirsutism and acne.

Testosterone

The declined sexual desire that leads the affected women to confront hypoactive sexual desire disorder (HSDD) is the primary indication for testosterone. It is available in oral as well as transdermal preparations.

Dehydroepiandrosterone

The use of dehydroepiandrosterone (DHEA) daily and topically, is propitious in the treatment of genitourinary syndrome of menopause (vulvovagnial atrophy)

TABLE 3: Combined hormonal therapy.

Regimen	*Estrogen*	*Progesterone*
Cyclic	Days 1–25	Last 10–14 days of ET cycle
Cyclic—combined	Days 1–25	Days 1–25
Continuous combined	Daily	Daily
Intermittent combined	Daily	Repeated cycles of 3 days on (pulsed progestogen; 3 days off continuous—pulsed)

and dyspareunia due to safety profile in woman with contraindications to MHT. 6 weeks DHEA (25–50 mg per day oral) has given result of good increase in recognizable physical and psychological well being in case of depressed surgically menopausal women, e.g. bilateral oophorectomy/adrenal failure.

Tibolone

It is a 19 nonsteroid synthetic compound developed specifically to be used for HRT which has selective estrogen and progestational properties with weak androgenic activity. It suppresses menopausal symptoms and lowers raised gonadotropin levels.

Advantages

- No endometrial stimulation is seen. Progesterone is not required.
- It is good for vasomotor and urogenital symptoms.
- There is no increase in the risk of breast cancer.
- Urogenital atrophy, psychomotor symptoms, libido, and osteoporosis are improved like other forms of HRT. Dose is 2.5 mg daily orally. It is found to increase the BMD in lumbar spine and hip.

Duration of Therapy

Optimal results are obtained after 3 months. The drugs should not be started within 1 year of natural menopause (chances of irregular bleeding). However, after surgery it may be started immediately.

Contraindications: CVS, cerebrovascular liver, and kidney disease.

Selective Estrogen Receptor Modulators

They cause estrogenic agonism in bones but estrogens antagonism in uterus and breast. These are indicated particularly for prevention of osteoporosis. There is an increase in SERMs use, which is although not precisely a form of HRT, e.g. raloxifene, bazedoxifene, ospemifene.

- Raloxifene is approved for the treatment of osteoporosis in postmenopausal women the dose of 60 mg/day.
- In women who are with a uterus, the combination of SERM (Bazedoxifene 20 mg/day) and CEE (0.45 mg/day) which is also known as tissue selective estrogen complex, is shown to prevent bone loss associated with menopause and is a *progesterone-free alternative* for MHT.
- Thickness of endometrium is reduced by bazedoxifene.
- For the oral treatment of genitourinary syndrome of menopause/vulvovaginal atrophy, ospemifene has been approved. Endometrial safety has also been demonstrated.

MONITORING OF WOMEN OF MHT

Since the menopause, the MHT safety depends largely up on age and time. The women who are healthy and younger than 60 years of age have rare risk of

breast cancer with combined EPT. Modern progesterones and SERMs optimize metabolic and breast effects. The formulation, dose, and the administration route for MHT should be determined individually and reevaluated periodically.

In early menopause, the margin of opportunity is now being confirmed when the cardiovascular harm or distress is avoided and the benefits can be achieved by recent randomized trials such as Danish Osteoporosis Prevention Study (DOPS) and Kronos Early Estrogen Prevention Study (KEEPS) and the Early versus Late Intervention Trial with Estradiol (ELITE).

Younger women were studied by *DOPS* at the onset of menopause. These women received standard doses of estradiol and norethisterone or no treatment, for 10 years and had 16 years of follow-up. Significant reduction in mortality and hospitalization for MI as well as congestive heart failure were there.

No difference was shown by the KEEPS, between transdermal estradiol 0.05 mg, CEE 0.45 mg, and placebo in context of intermediate endpoints: carotid artery intima-media thickness and coronary calcium. No atherosclerosis was found in these young healthy women and there is a possibility that over 4 years, there was inadequate progression to detect the differences between the groups.

The effects of oral estradiol 1 mg and placebo were studied by the ELITE trial, in two groups of women, one below 6 years from menopause and the other above10 years from menopause. Over time, a reduction in carotid artery intima-media thickness was shown in the younger women, along with no change in the older population. This confirmed that to influence the progression of coronary disease, the timing of estrogen treatment is essential.

Women's Health Initiative Study, 2003

The planning and launching of the Women's Health Initiative (WHI) was done in the 1990s, when there was considerable evidence that disease in postmenopausal women might be prevented by estrogen with or without a progestin. The WHI Hormone Therapy Trials included 27,347 women of ages 50–79 who were followed during the active treatment (5.6 years in the *estrogen-plus-progestin* trial, 7.2 years in the *estrogen-alone* trial) and for an extended period of time with no treatment, for a total follow-up of 13 years.

Comparison is done between rates of coronary heart disease, stroke, breast cancer, colorectal cancer, endometrial cancer, blood clots in the lungs, hip fracture, and death among women assigned to the hormones as well as women assigned to placebo study pills. To measure the balance of harm and benefit, these illnesses and death were also combined in a global index . Other important outcomes were also studied.

Dissimilarities and similarities in the effects of *estrogen-plus-progestin* and es*trogen-alone* were shown in the study:

- *Heart disease:* During the first year, *estrogen-plus-progestin* increased coronary heart disease risk by 80%, but over the entire treatment period it increased only by 18%; this risk did not differ by age. During this time, there was no increase in coronary heart disease risk by estrogen-alone, but

there was a decreased risk among women who were in their 50s and this became significant over the total 13-year follow-up period.

- *Breast cancer:* Over the entire treatment period, there was a progressive increase in breast cancer risk to 24% by the e*strogen-plus-progestin*. The cancers were diagnosed at a more advanced stage. This risk remained elevated over the total follow-up time of 13 years. *Estrogen-alone* leads to reduction of breast cancer risk, an effect that became statistically significant over the 13 years of total follow-up time.
- *Stroke and blood clots*: The stroke risk increased by about one-third during the treatment period, by both *estrogen-plus-progestin* and *estrogen-alone*. The risk of blood clots in the legs or lung is also increased by these regimens, although this effect was greater for *estrogen-plus-progestin* than for *estrogen-alone*. After women stopped treatment, the increased risks of stroke and blood clots were not seen and it did not differ by age group.
- *Hip fracture*: During the treatment period, both *estrogen-plus-progestin* and *estrogen-alone* decreased the hip fracture risk by 33%. This risk slowly increased after stopping, but was still lower in women who had taken *estrogen-plus-progestin* and similar in women who had taken *estrogen-alone*.
- *Colorectal cancer*: Colorectal cancer risk was decreased by e*strogen-plus-progestin*, with cancers diagnosed at a more advanced stage; and differences by age were not seen. No overall effect on colorectal cancer risk was seen by e*strogen-alone*, but there was an increase in risk in the older women than younger women. No hormone effects were there in either of the trial after stopping.
- *Overall illness and death (Global index)*: During the treatment period, *estrogen-plus-progestin* increased the global index of combined illness and the death by 12%. *Estrogen-alone* had no overall effect on the illness and death, although there was a reduction in the risk for women in their 50s and increase for women in their 70s. No hormone effects were there in either trial after stopping.
- *Other results*: In women aged 65 years and over, there was an increase by hormone use in probable dementia. Memory was not affected in women aged between 50 years and 54 years. During both the trials, gallbladder disease and urinary incontinence was elevated by 50–60%, and diabetes was reduced by 14–19%. In women aged between 50 years and 54 years, night sweats and hot flashes were reduced in both the trials.

These findings provide the strongest evidence base available to guide individualized counseling and personal decisions about hormone therapy. Estrogen-alone in women who have had a hysterectomy, particularly younger women, has a very different and more favorable risk-benefit profile than oestrogen-plus-progestin in women with an intact uterus.

Taking all of the study effects into consideration, hormone therapy is not recommended for prevention of chronic disease, but it remains a reasonable option for managing short-term menopausal symptoms in younger women.

FDA APPROVED INDICATIONS OF MHT

- *Vasomotor symptoms (VMS):* In women without contraindications, hormone therapy is recommended as a first-line therapy for VMS.
- *Prevention of bone loss:* In postmenopausal women with age less than 60 years and showing an increased risk of osteoporosis and fractures, MHT may be considered as primary therapy.
- Hypo-estrogenism is caused by hypogonadism premature ovarian insufficiency (POI), or premature surgical menopause without contraindications. MHT is recommended until the intermediaryage of menopause.
- *Genitourinary* syndrome of menopause (GSM)/vulvovaginal atrophy: As a first-line therapy, low dose vaginal estrogens are recommended.

The 2017 hormone therapy position statement of the North American Menopause Society (NAMS):

The most effective treatment for VMS and the GSM is hormone therapy and it has been shown to prevent bone loss as well as fracture. Depending upon the type, dose, usage duration, administration route, initiation timing and whether a progestogen is used or not, the risk of HT differs.

There should be individualization of the treatment for identification of the most relevant HT type, dose, formulation, administration route, and usage duration, using best available evidence to maximize the benefits and minimize the risk, with periodic reevaluation of the benefits and the risk of HT continuation and discontinuation.

For women who are younger than 60 years or who fall within 10 years of menopause onset with no contraindication, as well as those who are at an elevated risk for bone fracture or bone loss: in all these women, the benefit–risk ratio is found to be the most assuring for treatment of tedious VMS.

The woman who initiate more than 10 or 20 years from menopause onset or are aged 60 years or older, the benefit–risk ratio is found to be less favorable for them. This is because of the greater absolute risks of coronary heart disease, stroke, venous thromboembolism, and dementia.

For documented indications such as bone loss or persistent VMS, longer duration of therapy should be there, with shared decision making and periodic reevaluation.

When bothersome GSM symptoms are not relieved with over the counter therapies and there are no indications for the use of systemic HT, low dose vaginal estrogen therapy is recommended.

CONCLUSION

Although many potential side effects are there along with risk involved in taking MHT that may be reduced by tailoring the therapy to individual patients, emerging data suggest that the side effects are decreased by:

- Usage of lower doses of MHT
- Minimization or elimination of systemic progestogens (by utilizing intrauterine progestogen delivery systems)
- Usage of non-oral routes in some women
- Initiation of MHT in symptomatic women from near menopause.

Young woman with premature menopause clearly deserve MHT. Hysterectomized woman should receive estrogen alone, while those with intact uterus be given estrogen and progesterone.

Perimenopausal woman should be given cyclic MHT rather than continuous MHT.

MHT affords no protection in organs such as CVS disease, cognitive disorder.

Combined MHT increases the risk of breast cancer, gallstones and migraine.

Transdermal route is better than oral route.

Systemic reviews of MHT exhibit two main side effects, which are:

- Irregular uterine bleeding (which is normal during the first few months of cyclic MHT)
- Tenderness of the breast when excessive estrogen is used.

Long-term therapy is suitable for woman with prolonged symptoms, who are aware of the possible risk and personal circumstances.

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Dasgupta's
Recent Advances in
Obstetrics and Gynaecology

The Recent Advances in Obstetrics and Gynaecology is scheduled to be the first volume in an ongoing series, which seeks to address a much felt lacuna in postgraduate teaching. Aimed primarily at postgraduate students and residents, this book is a collection of focused articles from much sought after teachers and authors who bring decades of experience and expertise in their respective fields.

Typically, students only receive a short period of study leave prior to the examinations during which, precious time is lost scouring for resources and locating updated guidelines, research papers and evidence on topics of thematic interest. Hence, the authors address this paucity with this textbook series, which aims to unite senior, respected and stalwart postgraduate teachers from all over India who have been mentors and guides to generations of students. Each chapter focuses on traditional concepts as well as the most modern updated evidence on the issues at hand.

The book will be a useful compendium for postgraduate students and readers who wish to keep themselves updated with the latest evidence.

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