

## Current Understanding and Practice in Menopause Hormone Therapy: Indian Perspective

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### How to cite this article:

Komal Gaur, Sourabh B Fulmali, Nalini Adele Pinto. Current Understanding and Practice in Menopause Hormone Therapy: Indian Perspective. Indian J Obstet Gynecol. 2019;7(3):413-418.

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**Received on** 13.06.2019; **Accepted on** 11.07.2019

### Abstract

*Background and Objectives:* In spite of increasing awareness, controversies prevail among Obstetrics and Gynaecology healthcare practitioners (HCPs) regarding use of hormone therapy in the management of menopause. This study aimed to assess the current understanding and practices among HCPs in menopause hormonal therapy (MHT) in Tier I and II cities in North and West India.

*Methods:* An MHT certification training course was conducted for HCPs by Pfizer Ltd. in partnership with Indian Menopause Society (IMS), and a subsequent clinic-based cross-sectional interviewer-administered survey was carried out. A section of questions was devoted to obtain feedback on the course. A total of 140 HCPs volunteered to complete the survey and data was reported using descriptive statistics.

*Results:* Eighty nine out of 140 (64%) HCPs believed that hormone therapy should be routinely prescribed to symptomatic menopausal women. The two most common factors influencing initiation of MHT were severity of symptoms (76%) and age at presentation (53%). Conjugated estrogens were the first choice for 44% of HCPs in their prescribing practice and 43% preferred prescribing MHT for 6-12 months. All HCPs reported that the course helped them improve their understanding about menopause and most important learning point was that hormone therapy should be started early. Additionally, 96% of HCPs felt that refresher training in MHT would be beneficial for their practice.

*Conclusions:* Menopause hormonal therapy is gaining acceptance as a preferred treatment in menopause management. However, reservations exist regarding the duration of therapy. Regular training may reinforce confidence of HCPs in prescribing MHT.

**Keywords:** Gynaecologists; Survey; Menopause management.

### Introduction

Menopause forms nearly one-third of a women's life and this is attributable to increasing life expectancy [1]. With an early transition into menopause and continued prevalence of menopausal symptoms like hot flushes, urogenital incontinence and multiple somatic symptoms affecting women in India, [2-4] reservations regarding menopause and managing symptoms continue to exist [5-7]. The transition into menopause can be accompanied by long term complications such as early-onset osteoporosis and vulvo-vaginal atrophy that can impact daily activities if not addressed. With pre- and post-menopausal women requiring increased attention for managing symptoms and risks of illnesses, obstetricians and gynaecologists (OBGYNs) need to advise their patients on the treatment options to improve their quality of life. However, OBGYNs

themselves continue to have reservations about treatment options, particularly with menopause hormonal therapy (MHT), [8,9]. This is partly attributable to the Women's Health Initiative studies [10,11] regarding indications and contraindications to use hormone therapy. We conducted a survey to assess the current understanding and practices of OBGYNs in practicing menopause therapy and any possible change after attending a menopause hormone therapy training program.

## Materials and Methods

A Menopause Hormonal Therapy (MHT) certification course was designed by members of the Indian Menopause Society in partnership with Pfizer Ltd., India. The course involved five modules which discussed the basics of menopause, screening and management of comorbidities, practical prescribing guide, current evidence and clinical case-based discussions spread over a duration of three hours. Twenty obstetric and gynaecologists attended the certification course, who then conducted cascade meetings across nine cities in India. Following nine MHT cascade meetings, a clinic based cross-sectional interviewer administered survey was carried out among 400 obstetricians and gynaecologists (OBGYNs) attendees of the meetings.

Oral informed consent was taken prior to administering the survey. There were total 16 elements in the questionnaire out of which 12 were for assessment of knowledge, attitude and practice change within 6 months after the training. The remaining four questions were to obtain feedback on the conduct of the session. The questionnaire was administered in English language and was conducted in nine cities across northern and western India. The survey was made

available through a survey weblink (active for 10 days).

Data were analyzed and the responses for various questions were calculated as percentages because of its suitability with respect to the nature of the study.

## Results

A total of 140 obstetricians and gynaecologists out of 400 agreed to participate in the survey. Eighty nine out of 140 (64%) HCPs believed that hormone therapy should be routinely prescribed to the patients. The most common complaints that patients presented to their OBGYNs were hot flushes (73%) and vulvovaginal symptoms (burning, dryness, itching; 61%).

While all the HCPs reported that their awareness of MHT increased after the certification course, 76/140 OBGYNs declared that their awareness increased by more than 60% (Table 1). The factors that influenced the HCP's decisions to prescribe hormone therapy following the training session are represented in figure 1; the major factor being severity of symptoms (106/140; 76%). The survey also revealed that 43% of OBGYNs prescribed hormonal therapy for 6-12 months after the training course. The preference of treatment when given four therapy choices, namely, phytoestrogens, estradiol, conjugated estrogens and tibolone, is depicted in figure 2.

In addition, 96% of HCPs felt that refresher training in MHT would be beneficial for their practice (Table 1). The three most common messages recalled by the participants from the training were 1) Hormone therapy should be started early, 2) Counselling is essential prior to starting therapy and 3) Hormone therapy is safe to use for long term.

**Table 1:** Consolidated Data of Survey Results

Improvement in awareness after MHT certification course					
Range (%)	0-20	20-40	40-60	60-80	80-100
No. of responses	11	23	30	50	26

Patients treated with menopause hormone therapy post training			
No. of patients treated	0-5	5-10	>10
No. of responses	60	53	26

Duration of prescribing hormone therapy post MHT certification course				
Duration (months)	<3	3-6	6-12	>12
No. of responses	20	47	60	12

Most common complaints of menopausal patients encountered<sup>a</sup>

Symptom	Hot flushes	Vulvo-vaginal symptoms <sup>b</sup>	Emotional disturbances <sup>c</sup>	Loss of libido
No. of responses	102	85	75	41

Factors influencing decisions to prescribe hormone therapy<sup>a</sup>

Factors	Severity of symptoms	Age at presentation	Co-morbid conditions	Acceptance level of patient	Others <sup>d</sup>
No. of responses	106	74	56	50	5

Choice of treatment for menopause hormone therapy

Priority	1	2	3	4
Treatment	Conjugated estrogens	Phytoestrogens	Estradiol	Tibolone

Benefit of conducting a training of MHT

Polar	Yes	No	No response
No. of responses	134	4	2

Frequency of refresher training in MHT awareness and practice

Frequency	Annually	Half-yearly	Quarterly	No response
No. of responses	67	58	12	3

Note: <sup>a</sup>Total number of responses are more than 140 as many participants chose more than one option; <sup>b</sup>Includes burning, dryness, itching; <sup>c</sup>Includes mood-swings, anxiety, depression; <sup>d</sup>Includes affordability, patient readiness for follow-up, attitude towards therapy, all factors listed.

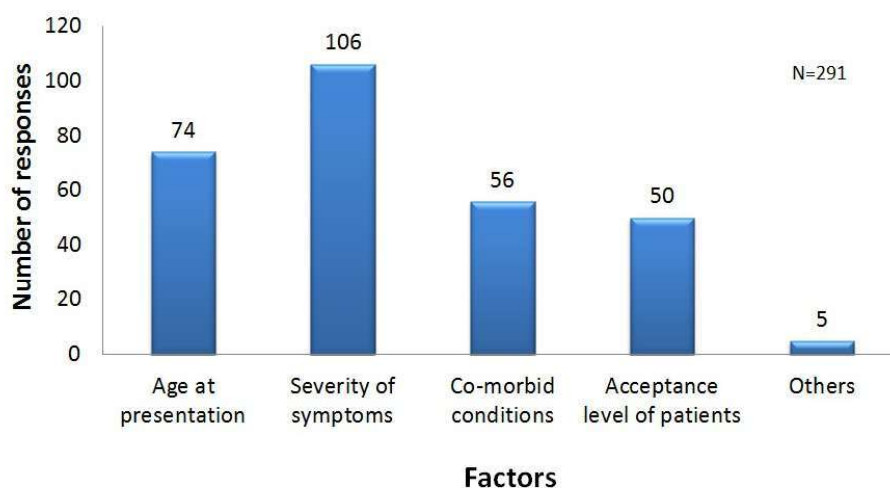


Fig. 1: Factors Influencing the Decision of HCPs to Prescribe Hormone Therapy

**Note:** The number of responses indicated total more than 140 (i.e. number of HCPs) as many respondents in the survey selected more than one factor influencing their decision. "Other" factors include affordability, patient readiness for follow-up, attitude towards therapy and all factors listed.

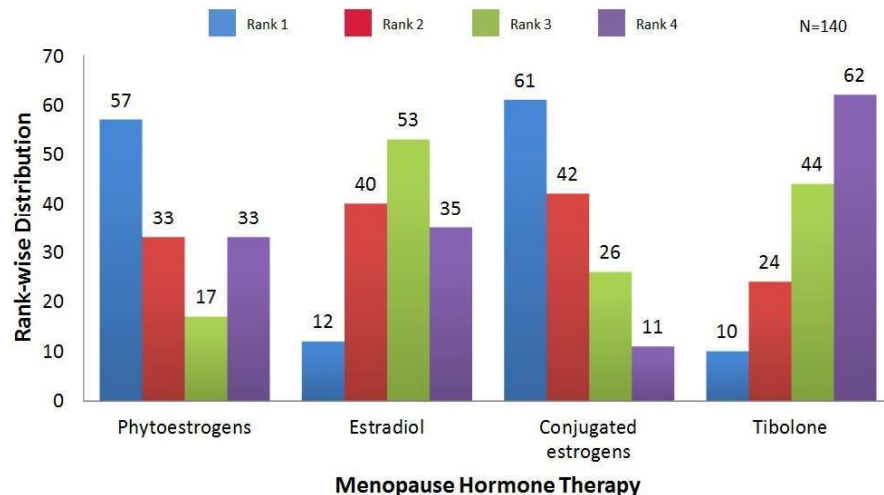


Fig. 2: Choice of Treatment for Menopause Therapy after Certification Course

**Note:** Respondants ranked their order of preference of each of the four therapies (Phytoestrogens, Estradiol, Conjugated estrogens and Tibolone); 1 being the most preferred therapy while 4 being the least preferred therapy when given the choice of using any one particular therapy for menopause management

## Discussion

The findings of this study in terms of the most common symptoms observed in menopausal women were vasomotor symptoms such as hot flushes (73%), and urogenital symptoms (61%). This observation is similar to other studies [12, 13], thereby warranting the need for HCPs to initiate menopause hormonal therapy for effective resolution of symptoms [14]. In terms of menopausal symptomatology, Western women are known to have vasomotor symptoms which often dominate over other menopausal symptoms, as compared to Asian women where musculoskeletal symptoms predominate [15]. However, diversities in terms of ethnic, cultural and socioeconomic circumstances have seen fluctuations of hot flushes symptom among Asian women ranging from 9.8 to 38.5% [16]. Our study reveals data in line with frequent menopause symptoms of women from the Western population; in the context of sample size the data may also align with similar studies among Asian women.

Our study further revealed that 91% HCPs preferred prescribing hormonal therapy for <1 year. Determining a suitable duration for MHT is crucial and needs to be individualized to a patient based on a wide range of factors. The NAMS 2017 Hormone Therapy Position Statement states that the therapy duration may be an important factor for increased breast cancer risk, particularly in longer

durations of use [17]. While the relief of vasomotor symptoms can be observed in patients with extended use, their recurrence is approximately 50% when MHT is discontinued, independent of age and duration of use [17]. A study by Yeganeh *et al.* (2017) reported members of a menopause society were more likely to offer combined and oestrogen-only MHT for 6-10 years than 1-5 years for women over 50 years [18]. Although mixed views exist regarding the duration of MHT, assessment of the need for this intervention needs to be done on a routine basis to balance risks and benefits of MHT for each individual patient.

Reservations regarding the prescribing of MHT continue to exist among Indian HCPs. The study showed that although 64% of OBGYNs believed that MHT should form a major part of menopause management, only 19% prescribed this therapy to more than 10 patients. A possible reason for this discrepancy could be the controversies raised by the Women's Health Initiative (WHI) HT trials over increase in risks of breast cancer, no decreased cardiovascular risks, and no overall benefit to HT users [10,19]. A survey conducted by the American College of Obstetricians and Gynaecologists among practicing OBGYNs further revealed scepticism of the WHI results among HCPs [20]. The Indian study by Meherishi *et al.* (2010) also highlighted the WHI controversies as a reason for the reservations among OBGYNs with respect to prescribing MHT to patients [13].

One of the major limitations of this study is the relatively small sample size with respect to the number of OBGYN HCPs in the country, and therefore the survey may not reflect a true perception of these HCPs. However, since responses were obtained from Tier I and II Indian cities where HCPs are more receptive about prescribing menopause hormone therapy, our data can give a relative idea of the attitude and practice of MHT within these cities. Another drawback of the study is the failure in obtaining a pre-survey of the HCPs attending the meetings to assess their knowledge about MHT. Therefore, a follow-up survey will provide a substantial view on whether there is a stable change in the menopause practices of HCPs across the country.

This study substantiates literature in terms of the commonly observed menopausal symptoms in the West and India. Although the study data slightly differs from the Pan Asian Menopause (PAM) study observations reflecting the most common menopausal symptoms being body and joint aches and pains, a wide variation in vasomotor symptoms is also reflected among Asian women [21].

Menopause hormonal therapy is an option that Indian gynaecologists may consider after thorough assessment of their patients symptoms. Although scepticism regarding the use of MHT exists, it is on the path of gaining acceptance as a preferred treatment in menopause management. The decision to opt for hormone therapy may be taken if the benefits outweigh the risks of MHT for each individual patient. However, reservations may still continue to exist regarding the duration of hormone therapy. Regular training may reinforce the confidence of HCPs in prescribing MHT for a longer duration.

### *Key Messages*

Menopause management in India is slowly gaining importance due to increasing number of women in the associated age group. Clinicians are hesitant to prescribe hormone therapy despite evidence favouring MHT. Frequent training and refresher courses may abreast clinicians with recent guidelines and recommendations highlighting the benefits of menopause hormone therapy.

### *Conflicting Interest:*

Dr K. Gaur is a full-time employee of Pfizer India Ltd. at the time of publication. Dr Sourabh Fulmali was a full-time employee of Pfizer India Ltd. at the time of manuscript preparation and submission.

N.A. Pinto was working as a Consultant with Pfizer India Ltd. at the time of manuscript submission. The submitted manuscript is only for academic purpose. None of the authors intend to unduly influence or promote any product through this publication.

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