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Hormone changes associated with the menopausal transition

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Summary

The Menopausal Transition (MT) is the time in each woman's reproductive life that precedes the final menstrual period (FMP). MT is associated with changes in bleeding pattern and hormone profiles. In recent years, research efforts have characterized changes in reproductive hormones over MT in order to elucidate the process of late reproductive aging and potentially identify predictors of time to menopause. Follicle stimulating hormone (FSH), anti-Mullerian hormone (AMH), inhibin B and estradiol represent the four primary hormone measures of these investigations. Current data show an increase in FSH and decreases in AMH, inhibin B and estradiol over MT (Table 1). AMH appears to be the first marker to change, followed by FSH and inhibin B. Estradiol declines in late MT. To date, there are no validated hormone cutpoints that predict the length of MT or FMP. There are very preliminary data on AMH as a predictor of menopause. Until further evidence identifies clinically useful hormone levels for predicting MT or FMP, diagnosis of MT and FMP should be based on clinical signs and symptoms only.

Introduction

In late reproductive life, menopause occurs after 12 months of amenorrhea and represents the near complete cessation of ovarian hormone secretion. The median age at menopause is 51.4 (1). The menopausal transition refers to the time in each woman's reproductive life that precedes the final menstrual period and is associated with changes in bleeding pattern and hormone profiles. Underlying these changes in bleeding pattern and hormonal profiles is the depletion of ovarian follicles. On average, women spend 4 years in MT, but there is considerable variability in length of MT (1).

Efforts to study these endocrinologic changes help to elucidate the biology of late reproductive aging, specifically ovarian aging. Further, hormone biomarkers that can identify timing of stages of reproductive aging, including predicting the final menstrual period, would have extensive clinical application. The purpose of this report is to review the literature on hormonal changes associated with the menopausal transition MT.

Defining the menopausal transition

Because chronologic age does not always accurately represent reproductive age, there was a need to synthesize a staging system on the process of reproductive aging. In 2001, the Stages of Reproductive Aging Workshop (STRAW) classified female reproductive life into 7 stages using bleeding and hormonal criteria, specifically FSH (2). Creating a staging system for reproductive aging helped to standardize definitions for research. This allowed for

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comparability of data across studies, with the goal of determining and predicting the timing and duration of the MT and the FMP.

Anchored around the FMP, the stages begin after menarche (Early Reproductive Stage). Peak and Late Reproductive Stages follow when menstrual cyclicity becomes regular. Late Reproductive Stage occurs in the setting of regular menstrual cyclicity and elevated FSH. A woman enters the Early Menopausal Transition when her menstrual cycles remain regular but the duration changes by 7 days or more. Finally, the Late Menopausal Transition precedes the FMP and is characterized by at least two skipped menstrual cycles or 60 days of amenorrhea. FMP is identified retrospectively after 12 months of amenorrhea has occurred and is followed by Early and Late Postmenopause. FSH is considered elevated when an early follicular phase sample is 2 standard deviations higher than the mean level for women of peak reproductive age. FSH remains elevated through the MT and Postmenopause (2).

In addition to the STRAW report, there is variability in the bleeding criteria for early and late MT. Through the ReSTAGE Collaboration of several large cohort studies, data suggest that Early MT is most consistent with “persistent” change in menstrual cycle lengths of 7 days or more, while findings supported the STRAW definition of Late MT (3–5).

The nomenclature of the menopausal transition has also included the terms perimenopause, menopausal transition and climacteric. The STRAW consensus workshop recommended using MT in the scientific literature to encompass the menstrual and hormonal changes described above. Perimenopause and climacteric may be used with patients, but encompass a wider time span from STRAW MT to Early Postmenopause.

Hormone biomarkers of reproductive aging

Several hormones in the hypothalamic-pituitary-ovarian axis are markers of ovarian aging, including FSH, estradiol, inhibin B and AMH. FSH is secreted by the anterior pituitary gonadtrophes and is regulated in part through negative feedback by inhibin B and estradiol, hence an “indirect measure” (6). As inhibin B and estradiol vary through each menstrual cycle, FSH levels fluctuate accordingly. With ovarian aging, lower inhibin B also results in decreased negative feedback to the pituitary, resulting in increased FSH secretion and higher early follicular FSH.

Inhibin B and AMH are glycoproteins produced by early ovarian follicles and are hence direct measures of the ovarian follicular pool (6). AMH is primarily secreted by primary, preantral and antral follicles, while inhibin B is primarily secreted by preantral follicles (7). Because the bulk of AMH is produced by gonadotropin-independent follicles, AMH levels remain consistent within and between menstrual cycles (8, 9). As the number of ovarian follicles declines with age, both AMH and early follicular inhibin B levels decrease. Estradiol is produced by granulosa cells of ovarian follicles in response to FSH stimulation. With ovarian aging, estradiol levels fluctuate and finally declines in postmenopause. Significant changes in these reproductive hormones with ovarian aging prompted studies to examine these hormones through the MT. Additional reproductive hormones including luteinizing hormone (LH), inhibin A and progesterone have been analyzed in MT, but to a limited extent. Therefore, the focus of this review is on FSH, estradiol, inhibin B and AMH.

Longitudinal data on the MT

Several large prospective cohort studies have contributed the bulk of data on late reproductive aging and MT, including TREMIN Study (5), Melbourne Women’s Midlife Health Project (MWMHP) (10), Seattle Midlife Women’s Health Study (SMWHS) (11),

Massachusetts Women's Health Study (MWHS) (12), Michigan Bone Health and Metabolism Study (MBHMS) (13), Study of Women's Health Across the Nation (SWAN) (14) and the Penn Ovarian Aging Study (Penn) (15). These studies have not only helped to define and evaluate STRAW criteria, but also provide significant data on reproductive hormones in MT. Because the variation in hormone measures may be large between women (16), the repeated measures from individual women obtained by these studies resulted in improved power to detect meaningful changes during the MT. This review will focus primarily on data from these large cohorts.

Analysis of hormonal data in women of late reproductive age

One theme among studies examining reproductive hormones through late ovarian aging is the challenge of analyzing these data. First, there is the need to account for multiple, correlated measures in each subject. Studies that reduce these data and treat each observation independently may generated erroneous data (17). Second, changes in hormones through the MT are non-linear. That is, the rate at which hormones such as FSH increases over time is not constant in an individual woman or between two women. Therefore, multiple statistical modeling efforts have been undertaken to produce estimates of change over time (18).

FSH

In 2001, early follicular phase FSH was the only endocrine measure incorporated into the STRAW staging system, in part due to its widespread availability and lower cost. FSH levels rise progressively during the MT (15), an observation that is attributed to declining inhibin B (16). Relative to the FMP, the largest increases in FSH occurred during the 18–24 months on either side of the FMP in the MWMHP and MBHMS cohorts (13, 16). Moreover, the change in FSH depends more strongly on timing of the FMP and less strongly on chronologic age. These analyses did not determine the FSH profile by MT stages. Nor could an FSH cutpoint that is predictive of time to FMP be established (16).

The ReSTAGE collaboration between SWAN and the MWMHP examined 1) if FSH was a marker of the late MT, and 2) if FSH added to the ability of bleeding pattern alone to predict time to FMP (19). Higher follicular phase FSH was associated with a higher risk of late MT and time to FMP. Using FSH cutpoints of <10, 10–19.9, 20–39.9 and 40 IU/L, subjects with FSH of 40 IU/L or greater had the highest odds ratio (OR) for bleeding pattern consistent with the late MT. The authors suggested that FSH of 40 IU/L or greater could be incorporated as a marker for late MT (19). However, no diagnostic test characteristics (sensitivity, specificity, positive predictive value, negative predictive value) using this cutpoint of 40 were presented. Without determining such test characteristics, it is not known if this or an alternate cutpoint would optimize diagnostic accuracy. In addition, FSH was less predictive of time to FMP than bleeding criteria. From these data, the clinical utility of measuring FSH in the late MT is not clear.

The Daily Hormone Study of SWAN collected daily urine specimens to examine hormonal risk factors for entry into the early MT (20). In data from 804 participants, short menstrual cycles < 21 days were associated with lower daily production of FSH and anovulation, while longer cycles >35 days were associated with higher daily production of FSH and anovulation. These findings suggest that abnormal menstrual bleeding patterns in the MT have a hormonal bias. However, FSH was not significantly associated with bleeding duration and flow. Therefore, the authors did not recommend hormonal evaluation in the setting of bothersome bleeding patterns.

AMH

AMH has been a hormone of interest in investigations on MT because it is directly secreted by the ovary, in particular by granulosa cells surrounding ovarian follicles. As ovarian follicle number declines with age, so do AMH levels (21). Also, these investigations are a natural extension of data on AMH as a biomarker of decreased ovarian reserve and in vitro fertilization outcomes (22). AMH peaks at puberty and declines thereafter, including over the MT (23, 24). AMH declines even earlier than FSH rises in the Late Reproductive Stage. In women in Peak and Late Reproductive Stages, AMH is lower in those who enter early MT in the next few years than those who remained in Reproductive Stages (25). Comparing AMH levels in MT to Reproductive Stages, AMH is significantly lower in MT (26). By late MT and Postmenopause, most subjects have AMH levels below the detection threshold of the assay. Some cross-sectional data suggest that AMH, when compared to FSH, inhibin B and estradiol, is the first indicator of MT (27).

Longitudinal studies have examined if AMH is a possible biomarker of MT and predictor of FMP. In a prospective cohort study of 50 premenopausal women with 6 annual measures of AMH before their FMP, log-transformed AMH declined in a linear fashion between 10 and 5 years prior to FMP. The strong association between the rate of decline and the time point 5 years prior to FMP suggested potential predictive ability. However, from the 5 years mark to FMP, AMH becomes virtually undetectable (limit of detection 0.05 ng/mL) (3). As a consequence, no further rates of decline in AMH can be described in the 5 years before FMP. This study demonstrates one of the primary limitations in using current commercial AMH assays for predicting time in MT and time to FMP – the limit of detectability.

A second prospective cohort study of 147 women examined cutpoints in AMH to predict menopause within the next 6 years. In regularly menstruating women between 40 and 50 at baseline, baseline AMH greater than 0.39 ng/mL has an 80% positive predictive value (PPV) for not entering menopause in the next 6 years (28). Stated in another way, a woman who is between 40 and 50 with regular menstrual cycles and an AMH greater than 0.39 ng/ml would have 80% likelihood that she will not become menopausal in the next 6 years. Although the study design did not allow for analyzing time to menopause, if validated, AMH would be the first biomarker that can predict ovarian function in late reproductive age. With more data, choosing cutpoints to increase the PPV would also have more clinical utility.

Inhibin B

In several cohorts, inhibin B is one of the hormone measures of early MT (15, 29, 30). In the Penn study, inhibin B was significantly lower and FSH was significantly higher even with a subtle change in menstrual cycle length: one observed change in cycle length of 7 days (30). In the approach to FMP, longitudinal data exhibit a similar pattern to AMH. Log-transformed inhibin B declined in a curvilinear fashion until a time point 5 years before the FMP, when most inhibin B levels also become undetectable (3). Comparing AMH and inhibin B, AMH is more likely an informative marker than inhibin B with respect to time to FMP and age at FMP (3). Cross-sectional data grouping hormone levels by STRAW stage also suggest that inhibin B was largely undetectable in late MT (24).

There is some data suggesting that measuring inhibin B levels through the FMP is possible in the setting of good immunoassays. Data from the MWMHP showed a large proportion, but not all measurements of inhibin B to be undetectable in the year prior to FMP. At two year prior to FMP, 41% of inhibin B are undetectable, and at one year prior to FMP, 71 % are undetectable (16, 29). The discrepancy between these findings and the ones above may be a result of different assays. The MBHMS cohort used a commercial assay, while the

Melbourne group used inhibin B ELISA from a research lab, which could have improved sensitivity.

Estradiol

During MT, estradiol levels initially fluctuate with FSH levels, and these fluctuations may result in higher levels than during the Reproductive Stages (31–33). Estradiol levels are generally maintained well after other hormone measures of ovarian aging demonstrate senescence. The rate of decline of estradiol occurs late in MT, particularly in the 1–2 years prior to FMP (16, 34). When grouped by STRAW stages, longitudinal measures of estradiol are not significantly different from Reproductive Stage levels until Postmenopause (15). Daily urine studies also support that average estrogen secretion can be higher initially with short cycle intervals, but begins to decline in late MT (20). Notably, peak estrogen secretion in a given menstrual cycle does not decline until post-menopause (35). Overall, significant inter- and intra-individual variability in serum estradiol are observed in the MT and no cutpoint to predict timing of MT or FMP has been identified.

Covariates that impact reproductive hormones in the MT

Several covariates are considered in studies on reproductive hormones and MT, including age, body size, smoking status, race and ethnicity. Many of these characteristics are associated with both reproductive hormones and bleeding patterns/menopause. For example, increased age is associated with hormonal changes that reflect reproductive senescence (16). Increased age is also associated with increased likelihood of entering MT and ultimately FMP. As such, age is a potential confounder of any association between reproductive hormones and MT.

In addition to age, increase in body mass index (BMI) is associated with lower AMH, estradiol and FSH levels in late reproductive age (16, 26, 36). Smoking is associated with earlier FMP as well as lower estradiol and higher FSH (15, 37). Through SWAN and Penn, hormonal levels in MT appear to vary by race and ethnicity. Chinese and Japanese women had lower estradiol compared with Caucasians, while African-American and Hispanic women had comparable estradiol levels as Caucasians. African-American women had higher FSH concentrations than Caucasians (37, 38). In Penn data, African-American women had lower estradiol levels than Caucasians, but the effect was mediated in part by BMI (15). In sum, these observations suggest that confounding and/or potential interactions with these covariates should be explored statistically in studies on reproductive hormones and late reproductive aging.

Clinical testing

Currently, FSH, AMH, inhibin B and estradiol have been demonstrated to exhibit significant change through the MT, but do not reliably predict length of MT or the FMP. Therefore, the diagnosis of MT is recommended to be based on signs and symptoms and not on hormone testing (39).

Conclusion

MT is associated with changes in bleeding pattern and hormone profiles. Current data show an increase in FSH and decreases in AMH, inhibin B and estradiol over MT. AMH appears to be the first marker to change, followed by FSH and inhibin B. Estradiol declines in late MT. To date, there are no validated hormone cutpoints that predict the length of MT or FMP. There are very preliminary data on AMH as a predictor of menopause. Until further

evidence identifies clinically useful hormone levels for predicting MT or FMP, diagnosis of MT and FMP should be based on clinical signs and symptoms only.

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Table 1

Summary of hormones of reproductive aging by STRAW criteria

	Peak Reproductive	Late Reproductive	Early MT	Late MT		Postmenopause
FSH	Normal	↑	↑	↑	**FMP**	↑
AMH	Normal/↓	↓	↓	Undetectable		Undetectable
Inhibin B	Normal	↓	↓	Undetectable		Undetectable
Estradiol	Normal	Normal	Normal	↓		↓