THURSDAY CONCURRENT SESSION #1

S-1. Effects of risk-reducing oophorectomy for hereditary breast and ovarian cancer syndrome: Depression and anxiety findings from the PROSper study
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Objective: Individuals with an identified pathogenic variant in BRCA-1 or -2 (BRCA) are advised to undergo risk-reducing bilateral salpingo-oophorectomy (RRSO) by age 40-45; alternative plans are complex. To mitigate oophorectomy stress, cross-sectional studies, depressive symptoms have been associated with history of oophorectomy. However, mood symptoms and disorders have not been well-examined in patients receiving RRSO following BRCA diagnosis, and limited longitudinal data exists to examine changes before and after RRSO. To address this gap, we sought to determine if RRSO is associated with changes in depressive symptoms and cancer-related anxiety among reproductive-aged individuals with BRCA, compared to those who choose not to undergo surgery. Design: Data were drawn from a longitudinal cohort study of premenopausal women with a BRCA diagnosis who do and do not choose to undergo RRSO within one large, urban healthcare system. Depressive symptoms (Beck Depression Inventory [BDI]) and cancer-related anxiety (Multidimensional Impact of Cancer Risk Assessment [MICRA]) were measured at baseline and every 6 months over a 5-year observed period. Adjusted mean BDI and MICRA scores at each study visit were produced with marginal effects models. Mixed-effects multi-level linear regression models were used to examine associations between RRSO and depressive symptoms and cancer-related anxiety over the five-year observed period. Associations between RRSO and outcomes were assessed in separate models. All models were adjusted for age, race/ethnicity, relationship status, history of depression, history of anxiety, baseline scores (BDI or MICRA), and hormone therapy (time-varying covariate). Results: In this study sample of 99 participants with a BRCA diagnosis followed over 5 years (mean age 40.56 [SE 4.3] at baseline), 42 chose to undergo RRSO during the study period. Comparison of mean change from baseline at each 6-month interval showed significantly higher BDI scores in those with RRSO relative to those without RRSO at 12, 30, and 36 months after baseline, and no significant differences in MICRA at any individual follow-up. Overall, individuals who chose to undergo RRSO had increased depressive symptoms (Beck β 1.16, 95% CI 0.80-2.51) and decreased cancer-related anxiety (MICRA β -0.05, 95% CI -0.09 - -0.004) over the 5-year period relative to those who did not undergo RRSO, adjusted for age, race/ethnicity, partner status, and menopausal hormone therapy use. Conclusion: Among premenopausal individuals with BRCA, undergoing RRSO may be associated with a small increase in depressive symptoms that was not likely to be clinically meaningful. There was also a small overall decrease in cancer-related anxiety. These findings may be beneficial for surgical decision-making in this patient population.

Sources of Funding: This work was supported by the American Cancer Society (VJ).

S-2. Impact of Estrogen Dosing on Cardiovascular Disease Risk Parameters in Women Experiencing Early Menopause due to Bilateral Oophorectomy
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Objective: Women undergoing early menopause due to bilateral oophorectomy experience an abrupt decrease in estrogen and other ovarian hormones, which is associated with an increased risk of cardiovascular disease (CVD). Administration of estrogen therapy (ET) given until the average age of natural menopause performs better with respect to CVD risk reduction. The goal of this study was to compare the effect of standard dose ET versus titrated ET on subclinical atherosclerosis progression, measured as rate of change in carotid artery intima-media thickness (CIMT) over a 5-year period. Methods: We obtained data from a reproductive history questionnaire at baseline on 590 healthy postmenopausal women who participated in the Early vs. Late Intervention Trial with Estradiol (ELITE). Subclinical atherosclerosis progression, measured as rate of change in carotid artery intima-media thickness (CIMT) was determined at baseline and every 6 months over a median trial follow-up of 4.8 years following randomization to hormone therapy (HT) or placebo. We used mixed-effects linear models to assess whether postmenopausal women who had undergone hysterectomy and bilateral oophorectomy had a different CIMT progression rate compared to women with intact ovaries. We assessed whether women undergoing bilateral oophorectomy had significantly higher plasma total triglyceride levels (p=0.003) and lower plasma testosterone levels (p=0.009). The CIMT progression rate in bilateral oophorectomy women was 2.2 μm per year (p=0.04) compared to 1.0 μm per year in postmenopausal women with intact ovaries. The difference was not statistically significant (p=0.08). The CIMT progression rate was significantly greater in postmenopausal women who were more than 50 years old at the time of bilateral oophorectomy (p=0.014) and in postmenopausal women who underwent bilateral oophorectomy more than 15 years prior to randomization (p=0.015) compared with postmenopausal women who had intact uterus and ovaries. Conclusion: Consistent with increased incidence of cardiovascular disease and mortality, hysterectomy with bilateral oophorectomy was associated with increased rate of subclinical atherosclerosis progression relative to natural menopause. The association of subclinical atherosclerosis with bilateral oophorectomy was specifically identified in relation to age and time of oophorectomy in this cohort of healthy postmenopausal women. Further research should continue to examine long-term atherosclerosis outcomes related to oophorectomy.

Sources of Funding: This work was supported by the National Institute on Aging, National Institutes of Health (R01-AG024154 and R01-AG056900).
S-4. Circulating lipid response to an experimental model of menopause that involves induction of sleep fragmentation and hypoestrogenism in women

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Objective: Across the menopause transition, there is a sharp increase in circulating lipids including total cholesterol (TC), high-density lipoprotein-cholesterol (HDL-C), low-density lipoprotein-cholesterol (LDL-C) and triglyceride (TG). While the decline of estrogens (E2) has been implicated in the adverse lipid changes in midlife women, it remains difficult to isolate the effects of the parallel changes in the endocrine milieu, chronological age, and other potential contributing factors such as vasoconstrictor symptoms (VMS) and sleep. As the primary predictor of menopause-related sleep disruption, VMS have been independently associated with dyslipidemia, but menopause-pattern sleep fragmentation (increased awakenings but no change in overall sleep duration) has not been investigated in relation to lipid changes. We therefore investigated whether sleep fragmentation and estradiol (E2) withdrawal via pharmacological E2 suppression contribute independently to adverse changes in circulating lipids using an experimental model of menopause in premenopausal women to remove the confound of age.

Design: We studied 27 premenopausal women (age mean±SD = 28.4±5.6 years; BMI = 25.3±4.2 kg/m²) during two 6-day inpatient stays done in the mid-to-late follicular phase (estrogenized: E2 = 48.7±29.5 pg/mL) and following leuprolide-induced hypoestrogenism (E2 = 7.5±2.9 pg/mL). Each admission involved two nights of unfragmented sleep [8-h time-in-bed (TIB)] followed by three nights of sleep fragmented by auditory stimuli (9-h TIB). Fasting lipids were assessed after 2 days of sleep restriction and after 2 nights of fragmented sleep during both inpatient stays. The effect of sleep fragmentation, E2 state and their interaction was measured using multiple linear models. The within-person changes from the estrogenized to hypo-estrogenized state were compared between unfragmented and fragmented sleep using paired t-tests.

Results: Fasting levels of TC (p=0.001), HDL-C (p=0.01), LDL-C (p=0.05) and TG (p=0.01) were significantly higher when women were hypo-estrogenized compared to the estrogenized state. Combining the data from unfragmented and fragmented sleep, we found that the incremental increase in lipid levels of 7%, 7%, 6% and 13% for TC, HDL-C, LDL-C and TG respectively, during menopause compared to the estrogenized state. Combining the data from unfragmented and fragmented sleep, the within-person change in lipids levels between E2 states did not differ by effect of sleep fragmentation (increased awakenings but no change in overall sleep duration). The effect of sleep fragmentation, E2 state and their interaction was examined.

Conclusion: Four nights of sleep restriction significantly reduced low-dose TG by 18% (p=0.01) and high-dose TG by 12% (p=0.001) (Fig 1). Non-oxidative GIR was also significantly reduced with sleep restriction by 37% at low-dose and 16% at high-dose insulin infusions (p=0.01). No differences in substrate oxidation, REE, or RER were observed. Future studies are needed to uncover how sleep disruption alters metabolism during menopause.

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Fig 1. Difference in Insulin Sensitivity with Sleep Restriction

S-6. The association between diabetes type, age of onset, and age at natural menopause: a retrospective cohort study using the Canadian Longitudinal Study on Aging

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Objective: Over the past few decades, the incidence of type 1 diabetes (T1D), type 2 diabetes (T2D) and gestational diabetes (GD) has grown steadily across the globe among all age groups. As a result, more women than ever before are expected to spend a larger proportion of their reproductive years living with a diabetes diagnosis. While most studies have looked at the association between and diabetes cross-sectionally or have studied the risk of developing diabetes post menopause, few studies have examined the inverse - the role of pre-menopausal diabetes and its association with ANM. The aim of the present study was to understand the long-term implications of premenopausal diabetes on women’s reproductive health including their age at natural menopause (ANM). Design: Baseline data from the comprehensive cohort of the Canadian Longitudinal Study on Aging (CLSA) was used for this analysis. Females who reported having a premenopausal diagnosis of T1D, T2D or GD were considered exposed. The main outcome variable was ANM. Kaplan-Meier cumulative survival estimates were used to calculate the median ANM by different diabetes types. Multivariable Cox regression models were used to assess the association between different types of diabetes and ANM while adjusting for various socio-demographic, lifestyle and premenopausal clinical factors. Hazard Ratios (HRs) and 95% confidence intervals were reported.
Interaction between diabetes and hypertension as well as diabetes and BMI were also tested. Finally, a sensitivity analysis was conducted to ensure that those with premature menopause were not skewing the HRs towards early menopause. Results: The sample comprised of 11,436 participants, weighted to represent 1,474,412 Canadian females aged 45-85 years. The median ANM was 52 years. After adjusting for ethnicity, education, smoking, and premenopausal factors including gravidity among other covariates, early age of diagnosis of both T1D (<30 years) and T2D (30-39 years) were associated with later age at natural menopause (T2D: HR 0.39, 95% CI 0.25-0.66). No significant association between GD and ANM was noted. Conclusion: Our results point to accelerated ovarian aging and early menopause among young women living with a diabetes diagnosis. These findings should allow for more focused research geared towards understanding the long-term health implications of diabetes on women’s reproductive health and aging.

Sources of Funding: VM has received the CIHR Canada Graduate Scholarship and Ontario Graduate Scholarship.

THURSDAY CONCURRENT SESSION #2


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Objective: The vaginal mucosa relies on the constant renewal of its epithelium to remain healthy. Epithelial parabasal cells divide and fill up with glycogen as they get pushed towards the vaginal lumen. They end up desquamating and releasing glycogen for the resident lactobacilli to feed on and acidify the medium. The stimulation required for this quiescent mechanism to go on has historically been attributed to estrogens, however, growing clinical evidence supports that androgens may play a role. Aromatase inhibitors (AI) are used in breast cancer survivors to inhibit the synthesis of estrogens. Administering a steroid precursor such as prasterone (DHEA) to patients suffering from vulvovaginal atrophy (VVA) and taking AI will therefore only results in local synthesis of androgens, but no estrogens. We set out to compare the histological changes an atrophic vaginal mucosa goes through with prasterone treatment, with and without exclusion of the estrogenic benefits by AI. Design: A Witner punch was used to collect biopsies both before and after 12 weeks of treatment with 6.5 mg intravaginal prasterone daily (Intrasara®). Upon collection, samples were formalin fixed and paraﬁn embedded for further processing with various stainings. Six menopausal women suffering from VVA and meeting the inclusion criteria were recruited, as well as two breast cancer survivors on AI. High resolution digital pictures of the vestibule were also taken before and after treatment. Results: The degree of epithelial atrophy visible at baseline histology for VVA patients was variable, but all six patients had the histological characteristics of a thick, healthy epithelium by the end of the study. At baseline, both patients on aromatase inhibitors had a very thin, ﬂattened epithelium. Following treatment with prasterone and despite the aromatase inhibitors, the epithelium showed striking histological improvements, regaining thickness, ridges and glycogen synthesis. Elastin staining was mostly limited to a thin subepithelial layer in atrophied vaginal mucosa specimen, whereas it appeared to qualitatively thicken following treatment, with high elastin contents in Reteg pegs. Conclusion: Data presented here are believed to be the first demonstration of profound beneﬁcial effects of androgens on VVA, independently from estrogens. While further studies are warranted to better understand the respective contributions of androgens and estrogens to the beneﬁts observed with prasterone in the treatment of GSM, the data presented here strongly suggests that androgens play a signiﬁcant role in the physiopathology of VVA.

Sources of Funding: This trial was funded by Endoceutics.
S-10. Difference in Venous Thromboembolism Risk between Combination 17β-Estradiol/Progesterone (E2/P4) and Conjugated Equine Estradiol/ Medroxyprogesterone Acetate (CEE/MPA) as Assessed by Us Claims Data

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Objective: In the Women’s Health Initiative study, there was an increased risk of venous thromboembolism (VTE) reported among women treated with CEE/MPA vs placebo. A review of the literature suggests that the use of E2 and P4, in contrast to CEE and MPA, is not associated with an increased risk of VTE and may be associated with a lower risk. The objective of this analysis was to compare VTE risk in menopausal women using two different oral hormone therapy products approved to treat moderate to severe vasomotor symptoms: combination E2/P4 vs CEE/MPA. Design: Retrospective analysis of data from women aged ≥40 years who initiated either 1 mg E2/100 mg P4 or CEE/MPA between October 2018 and June 2021, and who did not have a VTE diagnosis in the prior 6 months, were selected from a large US claims database. Treatment was prescribed by a healthcare professional in a real-world setting and observed through pharmacy dispensing records (retrospective non-interventional study). VTE risk was assessed from the first E2/P4 or CEE/MPA dispensing (index date) until switch to the comparator treatment or end of follow-up (defined as end of any clinical activity observed in the data for a patient or end of data availability). Confounding control was achieved via inverse probability of treatment weighting (IPTW). VTE risk was compared between the E2/P4 and CEE/MPA cohorts using IPT-weighted Kaplan-Meier plots and IPT-weighted regression models. The primary outcome measure was the first diagnosis of VTE observed post-index.

Results: The study included 6,526 women initiated on E2/P4 and 29,535 on CEE/MPA (mean follow-up: 1.2 and 1.4 years post-index, respectively). Pre-IPWT, women initiated on E2/P4 were younger (mean age: 54 vs 56 for CEE/MPA), had less cardiovascular disease (34 vs 44%), less hypercholesterolemia (24 vs 31%), and higher prior utilization of other oral HT (estrogen/estradiol-based: 20 vs 12%; progesterone/ progesterone only: 18 vs 5%); oral contraceptives (5.5% vs 1.7%). All covariates were balanced post-IPTW. The VTE incidence per 10,000 women years was 37 and 53 for E2/P4 and CEE/MPA after IPTW (post-IPTW incidence rate ratio 0.70, 95% confidence interval [CI] 0.53-0.92, P < 0.05). Hazard ratio from the IPTW analyses of time to first VTE was 0.70 (95% CI: 0.53-0.92, P = 0.05) for E2/P4 vs CEE/MPA (see Table). Conclusion: After controlling for confounders, results from these exploratory analyses indicate that the VTE risk may be lower among women initiated on E2/P4 compared to CEE/MPA. Further research is warranted to confirm this finding.


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Objective: Although levels of estradiol (E2), secreted by the ovary, and estrone (E1), secreted by peripheral tissues, are lower in the postmenopause, a number of health outcomes including depressive symptoms, bone health, and cardiovascular health have been shown to associate with endogenous estrogens in the postmenopause, especially estrone, which is less widely studied in relation to brain health. Verbal memory underpins several cognitive domains, including episodic memory, language, and executive function. Although brain aging is characterized by a decline in episodic memory, verbal memory, and executive function, changes in these domains are not uniform across cognitive domains and may vary with age, sex, and health status. Understanding factors associated with better verbal memory in the postmenopause is of particular interest as endogenous estradiol may provide neuroprotective benefits to the brain. Thus, we assessed whether estradiol levels were associated with verbal memory in a large, diverse, and well-characterized cohort of postmenopausal women.

Methods: The STRAND (Study of Transdermal Estradiol and Nerve Growth Factor on Brain Function and Health in Menopause) study is a 52-week, placebo-controlled, double-blind, randomized trial of transdermal estradiol for the treatment of vasomotor symptoms (VMS) associated with menopause. Design: SKYLIGHT 5 was a randomized, placebo-controlled, double-blind, phase 3, 52-week long-term safety study of estradiol 45 mg, estradiol 30 mg or placebo once daily (1:1:1) in women aged 40 and 65 years seeking treatment for VMS associated with menopause. Primary end points were percentage of women with endometrial cancer, and frequency and severity of treatment-emergent adverse events (TEAEs). Endometrial biopsies taken at baseline and week 52 of study treatment were read by 3 independent pathologists who were blinded to participant treatment allocation. Participants enrolled in SKYLIGHT 5 were eligible for inclusion to be included in the primary endometrial biopsy data analysis (Endometrial Health set).

Criteria were consistent with the appropriate FDA Draft Guidance to Industry. To meet the primary end points, the rates of hyperplasia or malignancy were to be ≤ 1% with an upper bound of the one-sided 95% confidence interval 4%. Results: 1830 women were randomized and took a 1 dose of medication (estradiol 45 mg n=609, estradiol 30 mg n=611, placebo n=590). A total of 599 met the criteria for the Endometrial Health set (estradiol 45 mg n=203, estradiol 30 mg n=210, placebo n=186). Endometrial biopsy findings met the prespecified criteria (Table). The incidences of TEAEs and TEAEs leading to discontinuation were similar across groups, and there was a low incidence of serious TEAEs (Table). There was one death in the study (estradiol 30 mg group), which was reported as unrelated to treatment. The most common TEAEs (≥5%) were headache and COVID-19. The frequency of transaminase elevations was low, and these TEAEs were generally isolated, transient, and resolved on treatment or with discontinuation. Conclusion: These data demonstrate the 52-week long-term safety and tolerability of estradiol as studied and support its continued development for the treatment of VMS associated with menopause.

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left inferior frontal gyrus and left middle frontal gyri were positively associated with CVLT-assessed verbal learning, supporting the importance of activation in these areas to verbal learning. During recognition, E2 was negatively associated with activation in the right superior frontal gyrus. E1 was negatively associated with activation in the bilateral superior temporal gyrus, left insula, left precentral gyrus, bilateral postcentral gyrus, and the right superior frontal gyrus during encoding; these regions were not significantly associated with verbal learning. All results corrected p <0.05. Conclusion: Our results suggest that high endogenous levels of E2, but not E1, promote the function of frontal brain areas to support verbal encoding.

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S-13. Efficacy and Safety of Estetrol (E4), a Promising New Treatment for Menopausal Vasomotor Symptoms: Results of Two Phase 3 Randomized, Double-Blind, Placebo-Controlled Trial

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Objective: The brain is the most cholesterol rich organ in the human body. Impaired brain cholesterol metabolism and elevated peripheral cholesterol may contribute to the development of dementia through neurodegenerative and vascular pathology. As the only tissue involved in reverse cholesterol transport from cells, high-density lipoprotein (HDL) may participate in the pathological pathways of dementia. HDL particles (HDL-P) possess numerous features impacting cardiovascular and metabolic health. SWAN previously demonstrated that midlife women may experience HDL dysfunctionality, and that the conventional metric, HDL cholesterol (HDL-C) is a poor measure of HDL function in midlife and older women. Therefore, we aimed to assess the associations of novel HDL metrics (midlife and changes since midlife) with future cognitive performance: The Study of Women’s Health Across the Nation (SWAN) Health and Aging Study.

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Objective: The PCT is sensitive and specific. The positive positivity rate, sensitivity, and specificity of the PCT to detect endometrial proliferation, hyperplasia (with or without atypia), or cancer. The proportion of PCT was pooled using a random-effects model, and the sensitivity and specificity were pooled using a Bayesian hierarchical random summary receiver operating characteristic (HSROC) model and compared across and within specific populations. Specificity calculations excluded studies where with negative PCT tests were not biopsied. Pooled estimates of sensitivity and specificity were used to compute a positive predictive value. Results: After removing duplicates, our search identified 83 articles. Screening of abstracts excluded 46 studies, and that of full text screening an additional 17 articles. Four review articles were identified but were excluded from the meta-analysis portion of the study. The 16 remaining studies that met our inclusion criteria had a total of 21 datasets reporting on 5585 post-menopausal women who underwent the PCT. Seven datasets (n=323) were from a population with risk factors, and 3 datasets (n=45) from a population with atypical adenomous hyperplasia. Positive rate of the PCT was higher in populations with EC than women without EC. The positive predictive value of PCT can be significantly improved by focusing on populations with risk factors, and likely higher prevalence of disease. This supports the use of the PCT together with a risk prediction model.

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midlife total HDL-P was associated with better future immediate recall over time. In addition, greater increase in total HDL-P and HDL-PL since midlife were associated with better cognitive performance. The prospective associations of midlife HDL metrics and their changes since midlife may be targeted in women for maintaining cognitive performance later in life.

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The prospective associations of midlife HDL metrics and their changes since midlife with future cognitive performance were assessed using multivariable-adjusted Cox proportional hazards models, with mortality as the reference point. Covariates included age, education, income, smoking status, systolic blood pressure, insulin resistance, and lipids. Secondary models considered WMHV in specific brain regions (deep, periventricular, frontal, temporal, parietal, occipital) and additional covariates including wake after sleep onset (WASO). Associations with the strongest associations observed for sleep VMS (24-hour VMS, B(SE)=.095 (.045), p=.032; Wake VMS, B(SE)=.078 (.046), p=.092; Sleep VMS, B(SE)=.174 (.060), p=.004). Associations were not accounted for by additional covariates including actigraphy-assessed WASO. When considering the spatial distribution of WMHV, sleep VMS were associated with both deep WMHV and periventricular WMHV, as well as with frontal lobe WMHV. Identification of female-specific midlife markers of poor brain health later in life is critical to identify women who warrant early intervention and prevention. VMS have the potential to serve as female-specific midlife markers of brain health in women.

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S-18. Traumatic experiences and hormone concentrations among midlife women

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Objective: Traumatic experiences are associated with adverse mental and physical health outcomes. However, less is known about how traumatic experiences relate to the hypothalamic pituitary gonadal axis. Psychological trauma has the potential to suppress ovarian function and reduce ovarian estrogen secretion. However, the relationship between trauma and sex hormones among midlife women is not well understood. Further, it is unknown how mitigating factors may impact this association. For example, prior work has found that associations between trauma and health were most pronounced in the context of short sleep. We tested whether traumatic experiences are associated with endogenous sex hormones (estradiol, estrone, follicle stimulating hormone; FSH) in midlife women. We additionally investigated whether these associations vary by sleep duration.

Design: Participants were 260 postmenopausal women free of hormone therapy (79% white, 17% black, 4% other ethnicity; Mean age=59 years). Women completed questionnaires (Brief Trauma Questionnaire, Center for Epidemiological Studies Depression, PTSD Checklist-Civilian Version, demographics), a blood draw, and ambulatory monitoring of sleep (actigraphy) as well as vasomotor symptoms (sternal skin conductance). Estradiol and estrone were assessed via liquid chromatography-mass spectrometry and FSH was assessed via immunoassay. Associations between traumatic events and sex hormones were tested via separate linear regression models. Covariates included age, race/ethnicity, body mass index, and smoking history. Depressive and post-traumatic stress symptoms, physiologic vasomotor symptoms, and time since the final menstrual period were also included in additional models. Sleep duration was evaluated as a moderator of associations between trauma and hormones. Results: Of the 260 women, 165 women (64%) reported a lifetime traumatic event. Women with a trauma history had lower levels of estradiol (ß[SE]=-16.80 [8.04], p<0.04; Figure 1) as well as estrone (ß[SE]=-14.86 [6.01], p=0.01; Figure 1) compared to women without this history in models adjusted for age, race/ethnicity, body mass index, and smoking history. Trauma was not associated with FSH (ß[SE]=0.57 [0.69], p=0.49; multivariable). Findings were not accounted for by depressive or post-traumatic stress symptoms, vasomotor symptoms, or years since the final menstrual period. Sleep duration was a significant moderator of the association between trauma history and estradial, such that the relationship between trauma history and lower estradiol was observed mainly in women sleeping less than 6 hours/night (p=0.01; Figure 1). Conclusion: Among these midlife postmenopausal women, trauma history was associated with lower concentrations of estrone and estradiol. Associations between trauma history and lower estradiol were seen primarily in women with short sleep. This work underscores the importance of considering trauma in relation to endogenous estrogens, which have implications for women’s midlife health.

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Objective: Nationally, 70% of Latinas report vasomotor symptoms (VMS), or hot flashes and night sweats, during the menopause transition. Latinas experience a greater prevalence and longer duration of VMS than non-Latina White women. Although it is well known that depressive symptoms, sleep disturbances, and cardiovascular disease (CVD) risk are associated with VMS, Latinas remain underrepresented in menopause research. The objective of this study was to identify sociocultural, behavioral, and CVD risk factors related to VMS in midlife Latinas. Design: This is a cross-sectional analysis using baseline data from 44 participants enrolled in Menopausia, Salud, Corazon, an experimental study designed to reduce cardiovascular disease (CVD) risk in Latinas during the menopause transition. Eligible participants are Latinas aged 40–60 years living in North Carolina, who are postmenopausal or early postmenopausal, and free of CVD. Bilingual (English, Spanish) research assistants and community health workers recruited women from community settings including businesses, churches, clinics, health fairs, and community-based organizations. Cortisol was extracted from hair samples (1-3 cm in length) using Salimetrics kit 1-3002 and run in duplicates, with results reported as the average of the duplicates (pg/mg). Psychosocial factors (e.g., financial strain, perceived stress, everyday discrimination, resiliency) and menopause symptoms were collected using interviewer-administered questionnaires. Cardiometabolic factors included weight, waist circumference, body mass index, blood pressure, and lipid profile were assessed during an in-person clinical exam. Separate bivariate linear regression analyses were conducted to assess factors associated with hair cortisol. Tests were two-sided, α=0.05. Results: Women were on average age 47.7 ± 4.8 years, 48% had a high school education or higher, 52% were Spanish-speaking only, and 57% reported as the average of the duplicates (pg/mg). Psychosocial factors (e.g., financial strain, perceived stress, everyday discrimination, resiliency) and menopause symptoms were collected using interviewer-administered questionnaires. Cardiometabolic factors included weight, waist circumference, body mass index, blood pressure, and lipid profile were assessed during an in-person clinical exam. Separate bivariate linear regression analyses were conducted to assess factors associated with hair cortisol. Tests were two-sided, α=0.05. Results: Women were on average age 47.7 ± 4.8 years, 48% had a high school education or higher, 52% were Spanish-speaking only, and 57% reported...
S-21. Persistent gap in menopause care 20 years after the WHI in France: a population-based study of menopause-related symptoms and their management

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Objective: To assess the current management of menopause in France with regard to menopause-related and genitourinary symptoms, with a focus on menopause hormone therapy (MHT) use.

Design: The ELISA Study is a population-based survey of 5,004 French representative women aged 50 to 65 years. From July to August 2020, the participating women answered an online computer assisted web interview on menopause, genitourinary symptoms and their management, and women’s self-rated status of MHT.

Results: Among the 5,004 selected women, 4,041 of whose postmenopausal status was confirmed were included in the final analyses. Of the untreated 3,685 women, 87% reported at least 1 menopausal symptom, with a significantly higher percentage of symptomatic women in the 50-54 age group (92%, p<0.05) than in the other two age groups (55-59 years: 89% and 60-64 years: 82%). 68% of the surveyed women experienced average over 2.5 symptoms of the genitourinary syndrome of menopause (GSM). Using a visual analogue scale (VAS) from 0 (no impact) to 10 (high impact) to evaluate the impact of menopausal/GSM symptoms on their quality of life, mean VAS score was 5.9 (SD: 2.2), with 25% of the women aged 55-59 years rating their quality of life between 8 and 10. 61% of the surveyed women reported being regularly followed by a health care professional. 44% of women reported never having discussed their menopausal/GSM symptoms with a health care provider. The main reasons were because menopause is “a normal part of women’s lives”, because it was not “necessary to do so”, or their symptoms were “not serious enough.” Only 242 women (6%) were current MHT users, of whom 49% were using estrogen-alone therapy and 71% were using transdermal estrogen. Fear of hormones (35%) and MHT side effects (25%) were the main reasons given for not using MHT. 62% of the women reported that the decision not to take MHT was supported by their physician’s opinion.

Conclusion: This large population-based survey confirmed not only the high prevalence of menopause-related and GSM symptoms in postmenopausal women in France, but also the very low percentage of MHT users in France. Twenty years after the publication of the initial Women’s Health Initiative (WHI) results, management of postmenopausal women is still characterized by unmet needs in menopausal care. Therefore, there is a strong need to educate the public and health care providers about menopause-related problems and possible solutions, including MHT through dedicated educational programs.

Sources of Funding: Theramex France SAS

FRIDAY CONCURRENT SESSION #2

S-22. A pilot trial of a virtually-delivered group mindfulness intervention for midlife and older women with low libido

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Objective: Low libido is common among women and is associated with significant distress. Mindfulness meditation is effective for low libido in women, but existing interventions are not tailored by age. We conducted a pilot randomized controlled trial of a virtually delivered, mindfulness-based group intervention for midlife and older women with low libido compared to an active control group. We assessed feasibility, acceptability, and explored preliminary outcomes of sexual dysfunction and distress.

Design: Women aged 45 and older who had bothersome low libido were randomized to the intervention or an educational control group. Women in both groups met weekly six times for 90 minutes over videoconference with either a physician and a mindfulness instructor (intervention) or a physician alone (control). Women in the intervention group received mindfulness meditation training and sexual psychoeducation. Women in the control group received general menopause health education without a focus on sexuality. We assessed satisfaction and likelihood of recommending the group to another woman with low libido at group conclusion on 5-point Likert scales (primary outcomes). We assessed sexual function [Female Sexual Function Index (FSFI)] and sexual distress [Female Sexual Distress Scale-Revised (FSDS-R)] at baseline and at 1 and 6 months (exploratory outcomes). Lower scores on the FSFI and FSDS-R denote better sexual function and lower sexual distress. We used chi squared tests to examine differences in primary outcomes between groups. We fitted linear regression models to compare changes in FSFI and FSDS-R from baseline to 12 weeks for each group.

Results: Of 81 women screened, 61 were randomized, 41 attended at least one session, and 37 had follow-up data available (N=15 intervention, N=22 control). Mean age was 57 (range 47-76), and 19% were pre- or perimenopausal, 54% were post-menopausal, and 26% had hysterectomy or oophorectomy. Satisfaction was high in both groups. In the mindfulness group, 13% were extremely satisfied, 60% very, 20% moderately, 7% a little, and 0% not at all (education group: 5%, 41%, 41%, 9%, 5%, ch2=2.82, p=0.244). Women in the mindfulness group were more likely to recommend it to another woman with low libido. In the mindfulness group, 67% would definitely or probably recommend, 33% maybe, and 0% a little or not at all (education group: 41%, 27%, 36%, chi2=6.98, p=0.031). Women randomized to mindfulness had greater improvements in sexual function (mean FSFI change: -4.0 intervention v. -1.5 control, p<0.001) and sexual distress (mean FSDS-R change: -7.4 intervention v. -3.2 control, p=0.001) compared to women in the education group.

Conclusion: A virtually-delivered, mindfulness-based group intervention for midlife and older women with low libido is feasible and acceptable and results in greater improvements in sexual function and sexual distress compared to active control.

Sources of Funding: NIH’s National Institute on Aging (K23AG052628) and National Heart Lung and Blood Institute (K24HL123565).

S-23. Sexual functioning of peri- and postmenopausal women Veterans may differ by sexual orientation

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Objective: Sexual function is a dynamic process that reflects an interaction of vascular, neurological, hormonal, and psychosocial factors. An estimated 25-85% of postmenopausal women report challenges with sexual function. Evidence suggests that sexual minority women (SMW; a term encompassing a range of sexual orientations for women with same-sex attractions and/or partners) may have increased risk of adverse mental and physical health outcomes in and after the menopause transition, including more severe menopause symptoms. However, research also suggests that SMW may demonstrate unique pathways of resilience during the menopause transition. Overall, little is known about SMW’s experiences of menopause. To address this gap, we examined whether indices of sexual functioning differed between SMW and heterosexual women in a sample of peri- and postmenopausal women Veterans. We further explored associations of sexual functioning with psychosocial factors among women by self-identified sexual orientation.

Design: We analyzed cross-sectional survey data from middle-aged and older (45-64 years old) women Veterans who receive Veteran’s Health Administration (VHA) health care. There is a higher percentage of SMW among women Veterans relative to the general population. Self-reported sexual orientation was used to categorize women as heterosexual vs. SMW, which included lesbian, bisexual, and pansexual women. Participants completed the Day-to-Day Impact of Vaginal Aging Questionnaire (DIVA) Sexual Functioning 5-item subscale, and self-reported genitourinary symptoms related to sexual function (vaginal irritation, vaginal dryness, pain during sexual activity, or less sexual activity in the past 2 weeks). Depression, anxiety, and trauma symptoms were assessed with the Patient Health Questionnaire 9-item (PHQ-9), General Anxiety Disorder 7-item (GAD-7) and PTSD Check List (PCL). We used independent sample t-tests (continuous variables) and chi-square tests (categorical variables) to examine differences in sexual function and genitourinary symptoms by sexual orientation. We further investigated these relationships using logistic and linear regression models adjusting for age, education, race, and body mass index. We used Pearson’s correlation to explore associations with psychosocial factors that may contribute to sexual functioning among each sexual orientation identity.

Results: In the analytic sample of 198 women, 52 (26%) self-identified as SMW. A greater proportion of SMW (65%) reported engagement with any type of sexual activity (e.g., solo or partnered) in the past month than heterosexual women (40%), X2 (2, N=198) = 10.6, p<0.01, which remained significant after controlling for covariates (OR 1.21, 95% CI: 1.32-8.55). In fully adjusted models, SMW reported better sexual functioning as indicated by lower DIVA scores (B=-0.59, p=0.02) and were less likely to report vaginal dryness (B=-1.15, p=0.02), but did not significantly differ from heterosexual women in reporting vaginal irritation. Exploratory correlational analyses revealed that experience of military sexual assault was associated with lower sexual function (r = 0.19, p=0.03) in heterosexual women, but not SMW. Greater depression (r=0.05, p=0.001) and anxiety (r=-0.26, p<0.01) and trauma-related (r=-0.24, p=0.03) symptoms were related to poorer sexual functioning in heterosexual women, but not SMW. Conclusion: Midlife and older SMW Veterans were more likely to be sexually active and reported better sexual functioning and less pain during sexual activity, compared to their heterosexual peers. SMW were also less likely to report some vaginal symptoms. Although untested, past work has posited that SMW with same-sex partners may have more favorable sexual function outcomes during the menopause transition due to greater variation in sexual behaviors, compared to heterosexual women who are more likely to engage in
S-24. Association Between Vasomotor Symptom Frequency and Weight Gain in the Study of Women’s Health Across the Nation (SWAN)

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Objective: The primary objective of this analysis was to quantify the extent to which changes in VMS frequency are associated with subsequent weight gain in midlife women. This analysis also aimed to assess possible mediation of weight gain by sleep problems and potential moderation by menopause stage, and to examine the extent to which cumulative exposure to VMS is associated with long-term weight gain. Design: Longitudinal data from the multi-site Study of Women’s Health Across the Nation (SWAN), a large, multi-ethnic cohort of women in midlife (n=3302, age 42–52 years at baseline), were analyzed retrospectively. SWAN data were collected at annual assessments at baseline and at up to 10 follow-up visits from 1995 through 2008. The current sample included participants with a visit (t) who had 2 lagged visits (t–1 and t–2). Self-reported VMS frequency (number of days in past 2 weeks with hot flushes and night sweats: 0, 1–5, 6–9, 10–13, and 14 days; high frequency categorized as ≥26 days) and BMI (0.29 ppt; 0.08 kg/m2; P <.01), and waist circumference (0.30 ppt; 0.03 cm; P =.04) compared with visits in which VMS frequency did not change. Onset of high VMS frequency (≥6 days in the past 2 weeks) from visit t–2 to visit t–1 was significantly associated with relative increases in weight measures at visit t–1 to t. Associations between cumulative exposure to VMS (10 consecutive visits with ≥6 days or with any days of VMS in past 2 weeks) and overall changes in weight were also examined by linear regression. Associations between changes in VMS frequency and changes in weight measures were calculated overall and by menopause stage. Proportional and absolute changes in weight measures were calculated over visits. Mediation of VMS weight gain associations by sleep problems and moderation by menopause stage were explored. Results: The main analytic sample included data from 2361 participants (12,030 visits; at baseline, mean age 51.1 [SD: 3.7], 45.5% late perimenopausal or postmenopausal, 47.5% White). Increases in VMS frequency from visit t–2 to visit t–1 were associated with significant increases in waist circumference and weight (β = 0.74 for pre-menopausal women and 0.78 for peri-menopausal women, suggesting that the model for predicting poor sleep has good discrimination in both groups. There was not a statistically significant association between migraine history and sleep duration ≤7 hours vs >7 hours) in either pre- or peri-menopausal women. Conclusion: This cross-sectional study confirms an association between a history of migraine and poor sleep in pre- and perimenopausal women. However, in contrast to the relationship in perimenopausal women, the relationship appears to be explained by other factors known to influence VMS frequency such as BMI, age, and the presence of hot flashes in perimenopausal women. Clinicians caring for women should query patients with migraine about sleep, irrespective of menopause status. Management strategies to address poor sleep in migraineurs may differ depending on menopause stage.

Sources of Funding: None

S-26. Experience of Menopause in the Workplace: Data from the Mayo Clinic Registry of Midlife Women

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Objective: Previous research, conducted mainly outside the U.S., has shown that menopause symptoms may adversely impact a woman’s performance, motivation, and relationships in the workplace, ultimately reducing her overall engagement at work. Given that midlife women constitute a significant proportion of the global workforce, the potential economic impact of menopause symptoms in the workplace and the lost work productivity are staggering. The current study’s aim was to evaluate the impact of menopause symptoms in the workplace among women receiving primary care at a U.S. tertiary care center. Design: This was a cross-sectional study conducted among women in the Mayo Clinic Registry of Midlife Women (Hormones and Experiences of Aging, HERA). Women aged 45-60 years, who receive primary care at four Mayo Clinic locations (Florida, AZ, Jacksonville, Rochester, MN), were included. A cross-sectional analysis from the Study of Women’s Health Across the Nation (SWAN), a large, multi-ethnic cohort of women in midlife (n=3302, age 42–52 years at baseline), were analyzed retrospectively. SWAN data were collected at annual assessments at baseline and up to 10 follow-up visits from 1995 through 2008. The current sample included participants with a visit (t) who had 2 lagged visits (t–1 and t–2). Self-reported VMS frequency (number of days in past 2 weeks with hot flushes and night sweats: 0, 1–5, 6–9, 10–13, and 14 days; high frequency categorized as ≥26 days) and BMI (0.29 ppt; 0.08 kg/m2; P <.01), and waist circumference (0.30 ppt; 0.03 cm; P =.04) compared with visits in which VMS frequency did not change. Onset of high VMS frequency (≥6 days in the past 2 weeks) from visit t–2 to visit t–1 was significantly associated with relative increases in weight measures at visit t–1 to t. Associations between cumulative exposure to VMS (10 consecutive visits with ≥6 days or with any days of VMS in past 2 weeks) and overall changes in weight were also examined by linear regression. Associations between changes in VMS frequency and changes in weight measures were calculated overall and by menopause stage. Proportional and absolute changes in weight measures were calculated over visits. Mediation of VMS weight gain associations by sleep problems and moderation by menopause stage were explored. Results: The main analytic sample included data from 2361 participants (12,030 visits; at baseline, mean age 51.1 [SD: 3.7], 45.5% late perimenopausal or postmenopausal, 47.5% White). Increases in VMS frequency from visit t–2 to visit t–1 were associated with significant increases in waist circumference and weight (β = 0.74 for pre-menopausal women and 0.78 for peri-menopausal women, suggesting that the model for predicting poor sleep has good discrimination in both groups. There was not a statistically significant association between migraine history and sleep duration ≤7 hours vs >7 hours) in either pre- or peri-menopausal women. Conclusion: This cross-sectional study confirms an association between a history of migraine and poor sleep in pre- and perimenopausal women. However, in contrast to the relationship in perimenopausal women, the relationship appears to be explained by other factors known to influence VMS frequency such as BMI, age, and the presence of hot flashes in perimenopausal women. Clinicians caring for women should query patients with migraine about sleep, irrespective of menopause status. Management strategies to address poor sleep in migraineurs may differ depending on menopause stage.

Sources of Funding: None
A Decade of MsFLASH Findings – Time to Get the Word Out

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OBJECTIVE: The MsFLASH trials contributed substantially to our understanding of menopausal symptom treatment. It is important that clinicians counseling women about menopause are familiar with these findings to make choices in areas of care and treatment.

Materials and methods: The MsFLASH trials included 2,260 individuals aged 45-52 in the service and provided symptom measurement using the Menopause Rating Scale over a 12-month period. Of these, 55% self-reported as perimenopausal, 12% as postmenopausal, 7% as premenopausal, 3% as ‘induced’ and 22% as ‘not sure’. 23% reported taking HRT. 17% had taken time off work due to menopausal symptoms. To assess menopausal symptoms over time, 895 participants completed the Menopause Rating Scale (MRS) both at baseline and after 90 days. The users of the service also completed the Net Promoter Score (NPS) at day 90 to measure service satisfaction.

Results: The MRS is a validated psychometric tool to evaluate severity of menopausal symptoms in relation to health-related quality of life. MRS enables comparison of symptom severity over time and helps in measuring service quality. The NPS is a customer loyalty measurement tool based on an individual’s relative likelihood of referring other clients who have likely referred the service to others on a scale of 1-10. A score between 100 to 100 is obtained. A score above 30 is good, above 20 favourable and above 80, world results. At baseline, 69% of users reported severe MRS scores (-6.44 95% CI[-5.08, -7.79], p < 0.001), induced (-5.06, 95% CI[-2.41,-7.72], p < 0.001) or post-menopausal (-6.44 95% CI[-5.08, -7.79], p < 0.001), induced (-5.06, 95% CI[-2.41,-7.72], p < 0.001) or not sure (-4.46 95% CI[-3.35, -5.57], p < 0.001), in comparison to premenopausal users (-5.2, 95% CI[-4.5, -5.8], p = 0.02). Of the users with severe MRS scores at baseline, 99% of users reported no mild or moderate symptoms after using Pep. Additionally, the more users that were engaged with the app, the larger the reduction in MRS symptoms reported (R2 = 0.03, β = 0.35, 95% CI[0.283, 0.418], p < 0.001). After 90 days there was a 23.65% reduction in MRS score (-4.46 95% CI[-3.99, -3.39], p < 0.001), with individual comparisons showing greater reductions for users who were beginning peri- (4.46 95% CI[-3.78, -5.41], p < 0.001) or post-menopausal (6.44 95% CI[-5.08, -7.79], p < 0.001), induced (-5.06, 95% CI[-2.41,-7.72], p < 0.001) or not sure (-4.46 95% CI[-3.35, -5.57], p < 0.001), in comparison to premenopausal users (-5.2, 95% CI[-4.5, -5.8], p = 0.02). Of the users with severe MRS scores at baseline, 99% of users reported no mild or moderate symptoms after using Pep. Additionally, the more users that were engaged with the app, the larger the reduction in MRS symptoms reported (R2 = 0.03, β = 0.35, 95% CI[0.283, 0.418], p < 0.001). NPS was 77, indicating excellent customer experience. Conclusion: The majority of women reported severe menopausal symptoms upon joining the service, often resulting in needing to take time off work. The intervention was associated with a very high level of satisfaction amongst participants and a significant reduction in the severity of symptoms after 90 days. The level of app engagement was also associated with the reduction in symptom severity. The results indicated the need for a nurse-led, digitally-accessed menopause programme is a promising new avenue to managing menopausal symptoms.

Sources of funding: None

P-2. Pelvic Floor Disorders Amongst Midlife and Older Female Veterans

Khadija Alshowaikh, MD, Nsozi Anamene, RN, Juana Hutchinson-Colas, MD, Gloria Bachmann, MD, OB/GYN, Rutgers Robert Wood Johnson Medical School New Brunswick, New Brunswick, NJ

OBJECTIVE: Women are the fastest-growing group in the Veteran population. Since women may experience more acute care, such as pelvic organ prolapse, lower urinary tract symptoms, and fecal incontinence during active duty, such as decreased access to care and bathrooms, postponed intervention may increase the risk of pelvic floor disorders and decreases quality of care. The service may have unique risk factors for pelvic floor disorders directly related to their military service. Pelvic floor disorders (PFD), including urinary incontinence, pelvic organ prolapse, lower urinary tract symptoms, and fecal incontinence may have an adverse impact on the quality of life and are associated with significant mental health comorbidities as women advance through the midlife years and beyond. The Department of Defense recognizes a knowledge gap regarding women’s health requirements and has advocated for more research on health issues that affect female service members. We aim to focus on the urogynecological health needs of women Veterans and the unique management issues faced by clinicians.

Design: A Literature review via Pubmed/Medline and Google Scholar was conducted. Keywords included “pelvic floor disorder,” “urinary incontinence,” “pelvic organ prolapse,” “lower urinary tract symptoms,” “fecal incontinence,” “aging,” and “veteran women.”

Results: Limited data note that urinary conditions are the most common diagnoses amongst women Veterans, especially those aged 65 years and older. Approximately 50% of Veteran women exhibit some loss of pelvic support leading to pelvic organ prolapse and are twice as likely as men to develop a bladder or pelvic floor syndrome. Military-specific factors associated with increased PFD include strenuous exercise during basic and paratrooper training, psychological stress, and harmful urinary habits during active duty, such as decreased access to care and bathrooms, postponed intervention and fluid restriction. Longitudinal and clinical studies demonstrate that amongst military women, c-section rate is low, and many environmental hazards that present new and unique health risks. Female veterans’ may have unique risk factors for pelvic floor disorders directly related to their military service. Pelvic floor disorders (PFD), including urinary incontinence, pelvic organ prolapse, lower urinary tract symptoms, and fecal incontinence may have an adverse impact on the quality of life and are associated with significant mental health comorbidities as women advance through the midlife years and beyond. The Department of Defense recognizes a knowledge gap regarding women’s health requirements and has advocated for more research on health issues that affect female service members. We aim to focus on the urogynecological health needs of women Veterans and the unique management issues faced by clinicians.
Premenopausal women with ultrasound-confirmed UF and MBL potentially perimenopausal women and the overall pooled population: age (47.4 [1.7] years) at baseline, UF volume <80 mL and at least a 50% reduction from baseline MBL volume over the last 35 days of treatment, measured by the alkaline hematin method. Key secondary efficacy endpoints: 1) amenorrhea rate; 2) mean percent reduction in MBL volume; 3) reduction in distress from bleeding, passing of blood clots, and tightness/pressure in the pelvic area, as measured by the Bleeding and Pelvic Discomfort (BPD) scale; 4) proportion of women with moderate-to-severe pain at baseline (Numerical Rating Score [NRS] ≥ 4) achieving minimal-to-no fibroid-associated pain; 5) proportion of women with anemia (hemoglobin <10.5 g/dL) at baseline who achieved an increase in hemoglobin levels of >2 g/dL; 6) percent change in largest UF volume; and 7) percent change in uterine volume. Analyses comparing the Rel-CT group vs placebo group were performed on the modified intent-to-treat population using pooled data from LIBERTY 1 and 2. Proportions were compared using Cochran–Mantel–Haenszel tests, and changes or percent changes in continuous variables were compared using a generalized linear model with treatment, visit, baseline MBL and treatment by visit interaction included as fixed effects.

**Results:** Potentially perimenopausal women included 282/768 (36.7%) women from LIBERTY 1 and 2 (95 randomized to Rel-CT; 94 to placebo). Mean [standard deviation] baseline characteristics were similar (except for age) between potentially perimenopausal women and the overall pooled population: age (47.4 [1.7] years vs 42.5 [5.2] years, respectively), body mass index (31.1 [6.4] vs 31.2 [7.1] kg/m²), MBL volume (228.6 [146.4] vs 243.0 [182.2] mL). Efficacy results are reported in Table 1. Adverse events for potentially perimenopausal women were consistent with those for the overall population. **Conclusion:** In potentially perimenopausal women from the LIBERTY studies, Rel-CT demonstrated a significant reduction of MBL volume; achievement of amenorrhea; improvements in hemoglobin levels; UF-associated pain and quality of life; and reductions in UF volume vs placebo, and was generally well-tolerated through 24 weeks. Results were consistent with the overall study population.

### Table 1. Efficacy Results for Potentially Perimenopausal Women and the Overall Study Population

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Rel-CT (N=225)</th>
<th>Placebo (N=265)</th>
<th>p</th>
<th>Difference [95% CI]</th>
<th>Proportion of women who achieved ≥80% reduction in MBL volume ≥80% reduction in MBL volume (N=206)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proportion of women with ≥80% and ≥25% reduction in MBL volume, n (%)</td>
<td>48 (22.3)</td>
<td>16 (6.0)</td>
<td>&lt;0.0001</td>
<td>32 (15.0)</td>
<td>10 (4.0)</td>
</tr>
<tr>
<td>Women who achieved amenorrhea at the last 3 days of treatment, n (%)</td>
<td>68 (30.2)</td>
<td>12 (4.6)</td>
<td>&lt;0.0001</td>
<td>46 (21.9)</td>
<td>8 (3.0)</td>
</tr>
<tr>
<td>Women with a NRS score ≥4 during the 35 days prior to randomization who achieved a NRS score ≤2 for UF-associated pain on the last 3 days of treatment, n (%)</td>
<td>24 (10.7)</td>
<td>2 (0.8)</td>
<td>&lt;0.0001</td>
<td>16 (7.6)</td>
<td>2 (0.8)</td>
</tr>
<tr>
<td>Women with a NRS score ≥4 during the 35 days prior to randomization who achieved an increase in hemoglobin levels of ≥2 g/dL, from baseline at Week 24, LS mean (SE)</td>
<td>4 (1.39)</td>
<td>4 (1.39)</td>
<td>0.99</td>
<td>0.0117 (0.1167)</td>
<td>0.1000 (0.1000)</td>
</tr>
<tr>
<td>Percent change from baseline to Week 24 in primary, UF volume, LS mean (SE)</td>
<td>-7.2 (7.81)</td>
<td>-11.4 (-1.24)</td>
<td>&lt;0.0001</td>
<td>-6.7 (6.16)</td>
<td>-15.4 (2.28)</td>
</tr>
</tbody>
</table>

**P-4. The Psychosocial Impact of Body Image in Peri- and Post-menopausal Women**

Harriet Asheroom, Lucy Guan, MPH, Juana Hutchinson-Colas, MD, Gloria Bachmann, MD, Rutgers Robert Wood Johnson Medical School New Brunswick, New Brunswick, NJ

**Objective:** Body changes during the peri- and post-menopausal period may positively or negatively influence a woman’s self-body image. Symptoms and signs can include flushing, vaginal dryness, breast changes, sexual dysfunction, wrinkles, and weight gain. Psychosocial symptoms include mood changes or age-related anxiety. A negative attitude towards menopausal changes can manifest in a negative body image, which can enhance body dissatisfaction, low self-esteem, and sexual dysfunction. This review explores the relationship between menopausal symptoms and body esteem. **Design:** A literature review using PubMed to find peer reviewed journal articles examining the relationship between body image and peri- or post-menopausal symptoms. **Results:** One study found a correlation between a higher mean BMI and negative body image in post-menopausal women of multiple racial/ethnic groups. Women who gained weight or had multiple weight fluctuations reported higher levels of a negative body image. Another study assessed the relationship between the severity of post-menopausal symptoms and body image, additionally affected by socio-demographic factors. Significant positive correlations were found between body image and the education level of the wife (p < 0.001, r = 0.20), education level of the husband, (p < 0.001, r = 0.26), and adequacy of monthly household income (p < 0.001, r = 0.32). Overall, increasing severity of menopausal symptoms correlated with decreasing body image. However, women with higher monthly incomes appeared to have less risk of a negative body image. A qualitative study reported that a negative body image related to physical symptoms such as weight gain and having breasts that had an age-related appearance. Women who reported having received higher sexual satisfaction noted the importance of having a supportive partner to boost their self-acceptance and self-confidence. Other studies showed an elevated severity of menopause symptoms was correlated to a greater prevalence of eating and body shape disorders. Data from other studies noted that menopausal attitudes were negatively related to body surveillance (p < 0.05) and positively related to body esteem (p < 0.05). Body surveillance was defined as women viewing their own bodies as an outside observer, with cultural context influencing how they interpret changes in their bodies. Appearance-related aging anxiety was positively related to body surveillance (p < 0.05), but unrelated to body esteem. Another study found supporting evidence that women dissatisfied with their body image, compared to cultural standards, had greater negative attitudes toward menopause. Many women tied menopause anxiety about the aging process, considering old age to be unattractive and linked to feeling invisible in society. However, this study also found women who felt more freedom and confidence during this period of their life despite the physical changes to their bodies. They reported that accepting menopause as a natural and inevitable process while caring less about cultural standards of beauty contributed to their positive attitude.

**Conclusion:** These data suggest that severity of menopause symptoms may be influenced by insecurity regarding body image. However, several studies included in this review have limited generalizability since all participants were from similar geographic regions. Cultural constructs of femininity and body attractiveness may influence a woman’s body image in different ways. These studies also found multifaceted responses, suggesting some women may view menopause as a new and exciting period of their life, highlighting the importance of studying diverse samples while evaluating the psychosocial impact of menopause. Given the connection between menopause and appearance, it would be beneficial for health care providers to incorporate “body-positive” counseling to women experiencing menopause. These interventions should not only focus on weight loss but should encompass broader health behavior transformations, helping women accept the physical and psychological changes that occur during menopause. Appearance-related aging anxiety was positively related to body surveillance, suggesting that women dissatisfied with their body image, compared to cultural standards, had greater negative attitudes toward menopause. Many women tied menopause anxiety about the aging process, considering old age to be unattractive and linked to feeling invisible in society. However, this study also found women who felt more freedom and confidence during this period of their life despite the physical changes to their bodies. They reported that accepting menopause as a natural and inevitable process while caring less about cultural standards of beauty contributed to their positive attitude.

### Sources of Funding:

None.

### P-5. Culture: An Influence on the Menopausal experience.

Ephane D. Barthels, Eseh Vijayakumar, Gloria Bachmann, MD, Juana Hutchinson-Colas, MD, Robert Wood Johnson Women’s Health Institute, Rutgers The State University of New Jersey, New Brunswick, NJ

**Objective:** Menopause, which marks the end of a woman’s natural fertility is a transition that all women experience. However, a woman’s culture, values, and even individual attitudes can influence how she views, experiences, and manages this period of her life. Menopause is not widely spoken about or understood in several cultures and can be seen as a taboo topic, where this event is seen as a positive and a natural change. These data suggest that severity of menopause symptoms may be influenced by insecurity regarding body image. However, several studies included in this review have limited generalizability since all participants were from similar geographic regions. Cultural constructs of femininity and body attractiveness may influence a woman’s body image in different ways. These studies also found multifaceted responses, suggesting some women may view menopause as a new and exciting period of their life, highlighting the importance of studying diverse samples while evaluating the psychosocial impact of menopause. Given the connection between menopause and appearance, it would be beneficial for health care providers to incorporate “body-positive” counseling to women experiencing menopause. These interventions should not only focus on weight loss but should encompass broader health behavior transformations, helping women accept the physical and psychological changes that occur during menopause. Appearance-related aging anxiety was positively related to body surveillance, suggesting that women dissatisfied with their body image, compared to cultural standards, had greater negative attitudes toward menopause. Many women tied menopause anxiety about the aging process, considering old age to be unattractive and linked to feeling invisible in society. However, this study also found women who felt more freedom and confidence during this period of their life despite the physical changes to their bodies. They reported that accepting menopause as a natural and inevitable process while caring less about cultural standards of beauty contributed to their positive attitude. The implications of cultural determinants on the menopause experience was explored.

**Design:** A literature review via PubMed/Medline and Google Scholar was conducted. Keywords included “cultural aspects of menopause,” “menopause and culture,” “menopausal experience influence on emotions,” and “and “reporting of menopause symptoms and culture.” Results: The available data suggest that culture can influence the menopause experience. In several cultures, such as the Mayan culture, women view menopause as a positive experience that brings about the end of menstruation, the end of contraception use, and sexual freedom. Menopause also
signifies the end of strict gender roles for women in Islamic cultures. In Indigenous cultures, women who undergo menopause tend to have an increased role in both the family and the religion as they are often seen as wise women. These women have an elevated social status in their communities, leading to a positive menopausal experience. Among European and North American White women, however, menopause is usually associated with aging. In addition to culture, lifestyle choices that include nutrition and exercise may positively impact the menopause experience as well. For example, Japanese women tend to have fewer vasomotor symptoms than Western women probably due to a higher consumption of soy and phytoestrogens. Among all women, data support the fact that exercise may also reduce menopausal symptoms such as depression and improve vasomotor symptoms. Conclusion: In several non-Western cultures, menstruation leads to increased participation in religion or family life for many women. As such, as they go through menopause, these women tend to embrace the freedom that comes with the menopausal transition. This view can be revisited as a rebirth, a time when they can do things they may have been restricted to before. A positive menopause experience also may lead to lower symptom reporting. The commonality between the cultures and a positive experience appears to be an increased societal status for the woman. However, the menopausal experience is not homogeneous; therefore, more research is needed to determine how culture affects menopause.

Sources of Funding: None

P-6. Women's Experience with Menopause: A Second National Survey
Devon Bernsley, BA, Alyssa Dweck, MS, MD, James Komorowski, MS. Bonafide Health, LLC, Harrison, NY
Objective: In 2021, an inaugural menopause survey of over 1,000 women (40-65 yrs) was published. This survey focused on women’s awareness, confidants, and treatments associated with menopause. A second, similar survey emphasizing perimenopausal or menopausal symptoms was performed and sent as an online survey focusing on five stages: 1) Overall Knowledge of Perimenopause/Menopause, 2) Experience with Menopause, 3) Sex During Menopause, 4) Male Knowledge & Experience, and 5) Aging as a Woman. Results: 2,005 women responded to the national survey. Overall Knowledge of Perimenopause/Menopause. Regarding perimenopausal awareness: 30% were not aware what perimenopause is, 27% were not aware of the common signs or symptoms, 34% were not aware when perimenopause typically starts, and 39% were not aware of treatment options for menopause symptoms. Women want to know the following about perimenopause: 71% want to learn how to manage symptoms, 69% the signs and symptoms to look out for, 64% what is “normal” and what should be escalated to a healthcare provider, 59% when symptoms can start, 47% how to talk to people without being embarrassed, and 41% how to ask others for support. Experience with Menopause. When asked what would help them feel more supported in aging: 54% responded mental health support, 45% open conversations with loved ones, and 34% open conversations in the media. Sex During Menopause. The following were symptoms that make intimacy during menopause less enjoyable: 43% reported low libido, 33% less confidence, and 29% painful intercourse. In 71% of these cases, women reported that their partner is understanding about their symptoms during intercourse. With menopause, 25% of women reported the inability to orgasm, and 22% reported weaker orgasms. Male Knowledge & Experience. When asked about their beliefs, 76% of women stated their partner understands from romantic partners, 68% from male friends, and 70% from male family members. Also, 65% reported that their partner understands their symptoms of menopause well, and 28% said they understand extremely well. When asked what would make them feel more supported by men, 41% answered more menopausal education, 38% general discussions about women’s health, 28% research done by men in their lives, and 25% answered men opening up discussions. Of these women, 77% talk openly with men in their life about menopause and 47% speak very openly. Women found that talking openly about menopause leads to positive outcomes: 50% found it educates men, 45% reported it helps men be more supportive, 40% reported feeling relieved, 34% felt less alone, and 30% reported that it builds empathy in men. Aging as a Woman. When asked how they feel about aging: 44% don’t feel old, 36% feel anxious, 27% feel sad, and 20% feel content. Women were twice as likely to feel anxious about aging versus happy (36% vs. 16%). When asked about embracing aging, women responding: 27% were very confident, 43% were somewhat confident, and 30% were not confident. Of these women, 60% felt that more pro-aging content is needed. Regarding the negative stereotypes of aging: 44% feel the negative media portrayal age affects menopause is addressed in the media, 34% would feel more supported as they age if more conversations were represented in the media, and 32% think there is stereotyping and prejudice shown towards older women compared to previous years. Conclusion: A major finding of this national survey is that women desire more information and knowledge of perimenopause/menopause. Education on the symptoms of menopause, the timing of symptoms, and how to support women with menopause-related symptoms appears vital to important to women. With 73% of respondents feeling less very confident about aging, reducing stigma and increasing awareness is a priority overall, this broad, national survey conveys the drastic need for increased education and social awareness as it relates to menopause so that women feel more supported.

Sources of Funding: This study was funded by JDS Therapeutics, LLC, the parent company of Bonafide Health, LLC.
Objective: To provide an overview of the study design and wealth of data and biological specimens available from the Study of Women’s Health Across the Nation (SWAN) cohort study. An expansive collection of SWAN biospecimens and datasets are available to investigators and trainees. These resources can be used for pilot studies, research projects, and manuscripts. Understanding the existing resources and the process required to access them provides a broad group of researchers the opportunity to advance academic research.

Sources of Funding: The Study of Women’s Health Across the Nation (SWAN) has grant support from the National Institutes of Health (NIH), DIHS, through the National Institute on Aging (NIA), the National Institute of Nursing Research (NINR) and the National Institute of Minority Health and Health Disparities (NIMHD). Grants U10 NR004061; U10AG012505, U10AG012535, U10AG012539, U10AG012546, U10AG012553, U10AG012554, U10AG012495, and U19AG063720. The content of this abstract is solely the responsibility of the authors and does not necessarily represent the official views of the NIA, NINR, ORWH or the NIH.

Objective: Sexual desire and responses may change due to natural menopause and could potentially negatively impact a once-healthy sexual relationship between a heterosexual couple. The objective of this study was to describe the lived experience perceived changes in sexual desire and responses from a menopausal female or a male partner of a menopausal female. The approach used to reveal the true essence of a participant’s lived experience of perceived changes in sexual desire and responses which highlighted perceptions, feelings, and personal reactions. The theoretical framework used for this study was Meleis’ (2010) transformational theory of nursing defined as “a passage from one fairly stable state to another fairly stable state” (Chick & Meleis, 1986). In transitions theory, a clinician considers inhibitors and facilitators of successful transitions along with factors that facilitate successful transitions while considering, the recipient’s personal meaning and attitude. In-depth interviews were used for data collection and research took place at a specialty clinic in southeast Texas, and via ZOOM because of the COVID-19 pandemic. Results: Participant’s ages ranged from 43 years to 68 years. 95% were married. 75% had 20 or more years the same partner. 75% were African American, 5% Asian, 10% Caucasian, and 10% Hispanic. 75% had been diagnosed with menopause through grade 12, 25% of elevated college, 20% had a 4-year degree, and 40% had beyond a 4-year degree. Results are presented as developed themes. Theme 1: An uncomfortable experience with decreased desire. 84% of females experienced a decreased or non-existent sexual desire because of pain due to menopause. 100% of males described the same experience. Theme 2: Conflicting messages of desire. 75% of females gave a conflicting message saying she had no sexual desire yet voiced she enjoyed sex. All males were consistent with their responses. Theme 3: Physical and mental metamorphosis. 83% of females experienced thinking she should have the desired avenged vaginal sex, but her body had responded as such. 25% of males perceived a strong erection but in essence he lacked rigidity. Theme 4: A sense of duty 92% of females felt obligated to perform her “wifely duty”. 87.5% of males did not feel obligated. Theme 5: The discrepancies in sexuality. 87.5% of females described the differences between their own desires and males with sex resulted in decreased sexual desire because of preparation needed beforehand. Females because of having to apply a vaginal lubricant and males because of the need to use erectile dysfunction medication. Theme 6: A natural part of aging. 31% of females described age affects her physical appearance and perceived this influenced her mate partner’s desire. 62.5% of males said age correlated with other life-abilities affecting sexual desire, but not because of his partner’s menopausal state. Theme 7: Love conquers all. 81% of females stressed her decrease in sexual desire was not reflective of her love for her partner. 75% of males emphasized changes in his partner’s sexual desire or response did not negatively affect his love for his partner. Conclusion: This phenomenological inquiry subsidized a gap in the literature by creating new data that provided insight into lived experiences of perceived changes in sexual desire and responses during the menopause transition or after menopause from the perspective of both females and males which is scarcely acknowledged in current literature. A new data finding in this research discovered participant’s living an experience described as a disappearance of spontaneity and consummation of sex. Also, this research uncovered a lived experience described by participant as having engaged and exciting sexual thoughts and seemingly being physically prepared for sexual intercourse but resulted in physical unresponsiveness. It is the recommendation of this researcher that health care providers who attend to persons at risk of menopausal adverse effects of screening menopausal opportunities. Continued research on this unique population of postmenopausal aged females and males would help define evidenced-based care that positively and accurately reflects patient needs. Sources of Funding: None

Changes in Female Sexual Function Index scores in postmenopausal women with hypoactive sexual desire disorder treated with flibanserin at a specialty clinic

Soni Jaymaid, MD, M.E. Cheillah, MD, MPH, Louise Brown, Doctorate of Pharmacy. HerMD, Clayton, NC

Objective: The primary study objective was to evaluate flibanserin’s real-world clinical effectiveness. The U.S. flibanserin is approved to treat hypoactive sexual desire disorder (HSDD) in premenopausal women and in Canada to treat premenopausal and naturally postmenopausal women 60 years of age. However, data on treatment effectiveness outside of the research setting are limited. Therefore, this retrospective chart review study was conducted to bridge this knowledge gap. Design: Structured data (partner and menopausal status, medications, medical history, and weight) were extracted from predefined fields in the clinic’s electronic health record (EHR) system using on-demand requests. Free-text encounter notes served as the data source for subjective unstructured data (benefits and tolerability), and Female Sexual Function Index (FSFI) scores were used as an objective measure of clinical effectiveness. Patients with low今年是21hall (score of 2 or FZ2.0) and a 1 year treatment period through the clinic’s EHR system (Flibanserin Patient [FP]), seen between September 1, 2015, and August 31, 2020, are included in this analysis. FPs were further categorized as either FP Users or FP Non- Users based on verified flibanserin usage. FSFI scores were captured via on-chart charting methods. Hard copies of the questionnaire were initially completed, scanned, and saved as a PDF in the patient’s EHR, and later scores were captured electronically using an iPad. FSFI scores obtained using hard copies were calculated manually, and scores captured electronically were automatically calculated. FSFI scores for FP Users were recorded on an excel spreadsheet using a unique patient identifier and FSFI completion dates. Completed FSFI score dates were reviewed to ensure they coincided with documented flibanserin usage in the encounter notes and the dates listed under the RxPlan section of the patient’s EHR. For an FSFI score change to be considered valid, it must have occurred during documented flibanserin usage with a baseline score before initiating flibanserin and at least one on-treatment follow-up score. Results: FPs accounted for 256 (6%) of clinic patients seen during the study period. Among FP Users (n=147), 47 (32%) had valid FSFI score changes: 24 postmenopausal and 23 premenopausal women. The average time between baseline and follow-up FSFI score change was approximately 4 months (range 1 – 15 months), with 2 months the most frequent. Valid FSFI score changes in postmenopausal FP Users are shown in the table. Subjective HSDD benefits were documented in the encounter notes of 18 (75%) of these women. The most frequently prescribed concomitant medications were testosterone in 16 (67%) and IntraRosa 10 (42%) in postmenopausal FP Users. Conclusion: The treatment of HSDD is multifaceted, and flibanserin is just one component of care. Therefore, the benefits reported here may or may not be related to flibanserin alone. However, our findings from FSFI scores obtained at a specialty clinic in postmenopausal women may also be observed in certain postmenopausal women in clinical practice. More extensive studies are needed to verify these findings. Sources of Funding: Sprout Pharmaceuticals

The Lived Experience of Perceived Changes in Sexual Desire and Responses

Sonya O. Carothers, PhD. Nursing, Wilkes University, Wilkes-Barre, PA

Objective: Sexual desire and responses may change due to natural menopause and could potentially negatively impact a once-healthy sexual relationship between a heterosexual couple. The objective of this study was to describe the lived experience perceived changes in sexual desire and responses from a menopausal female or a male partner of a menopausal female. The approach used to reveal the true essence of a participant’s lived experience of perceived changes in sexual desire and responses which highlighted perceptions, feelings, and personal reactions. The theoretical framework used for this study was Meleis’ (2010) tranformational theory of nursing defined as “a passage from one fairly stable state to another fairly stable state” (Chick & Meleis, 1986). In transitions theory, a clinician considers inhibitors and facilitators of successful transitions along with factors that facilitate successful transitions while considering, the recipient’s personal meaning and attitude. In-depth interviews were used for data collection and research took place at a specialty clinic in southeast Texas, and via ZOOM because of the COVID-19 pandemic. Results: Participant’s ages ranged from 43 years to 68 years. 95% were married. 75% had 20 or more years the same partner. 75% were African American, 5% Asian, 10% Caucasian, and 10% Hispanic. 75% had been diagnosed with menopause through grade 12, 25% of elevated college, 20% had a 4-year degree, and 40% had beyond a 4-year degree. Results are presented as developed themes. Theme 1: An uncomfortable experience with decreased desire. 84% of females experienced a decreased or non-existent sexual desire because of pain due to menopause. 100% of males described the same experience. Theme 2: Conflicting messages of desire. 75% of females gave a conflicting message saying she had no sexual desire yet voiced she enjoyed sex. All males were consistent with their responses. Theme 3: Physical and mental metamorphosis. 83% of females experienced thinking she should have the desired avenged vaginal sex, but her body had responded as such. 25% of males perceived a strong erection but in essence he lacked rigidity. Theme 4: A sense of duty 92% of females felt obligated to perform her “wifely duty”. 87.5% of males did not feel obligated. Theme 5: The discrepancies in sexuality. 87.5% of females described the differences between their own desires and males with sex resulted in decreased sexual desire because of preparation needed beforehand. Females because of having to apply a vaginal lubricant and males because of the need to use erectile dysfunction medication. Theme 6: A natural part of aging. 31% of females described age affects her physical appearance and perceived this influenced her mate partner’s desire. 62.5% of males said age correlated with other life-abilities affecting sexual desire, but not because of his partner’s menopausal state. Theme 7: Love conquers all. 81% of females stressed her decrease in sexual desire was not reflective of her love for her partner. 75% of males emphasized changes in his partner’s sexual desire or response did not negatively affect his love for his partner. Conclusion: This phenomenological inquiry subsidized a gap in the literature by creating new data that provided insight into lived experiences of perceived changes in sexual desire and responses during the menopause transition or after menopause from the perspective of both females and males which is scarcely acknowledged in current literature. A new data finding in this research discovered participant’s living an experience described as a disappearance of spontaneity and consummation of sex. Also, this research uncovered a lived experience described by participant as having engaged and exciting sexual thoughts and seemingly being physically prepared for sexual intercourse but resulted in physical unresponsiveness. It is the recommendation of this researcher that health care providers who attend to persons at risk of menopausal adverse effects of screening menopausal opportunities. Continued research on this unique population of postmenopausal aged females and males would help define evidenced-based care that positively and accurately reflects patient needs. Sources of Funding: None
Overview of valid FSFI score changes in postmenopausal Flibanserin Patient Users

<table>
<thead>
<tr>
<th>FSFI Score Change</th>
<th>Average</th>
<th>Median</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>9</td>
<td>7.25</td>
<td>-3.2</td>
<td>28.3</td>
</tr>
<tr>
<td>Desire</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>2.4</td>
</tr>
<tr>
<td>Arousal</td>
<td>1.4</td>
<td>1.2</td>
<td>-2.4</td>
<td>6</td>
</tr>
<tr>
<td>Lubrication</td>
<td>1.5</td>
<td>1.2</td>
<td>-1.2</td>
<td>6</td>
</tr>
<tr>
<td>Orgasm</td>
<td>1.7</td>
<td>1.0</td>
<td>-0.4</td>
<td>6</td>
</tr>
<tr>
<td>Satisfaction</td>
<td>1.6</td>
<td>1.6</td>
<td>-0.8</td>
<td>6</td>
</tr>
<tr>
<td>Pain</td>
<td>1.5</td>
<td>0.4</td>
<td>-0.8</td>
<td>6</td>
</tr>
</tbody>
</table>

*Higher scores indicate greater levels of sexual functioning

P-11. Telehealth-focused Educational Curriculum and Sessions for Health Center Care Teams on Post Menopause: TEACH-PM
Monica M. Christmas, MD,1 Lisa Masinter, MD,1 Elizabeth Adetoro2, Madison Weigand2, Isra M. Hasnain2, Katherine Brito2, Jennifer Morrison3. 1Obstetrics & Gynecology, University of Chicago Division of the Biological Sciences, Chicago, IL; 2University of Chicago Pritzker School of Medicine, Chicago, IL; 3AllianceChicago, Chicago, IL

Objective: 1. To educate community health center (CHC) primary care providers, within the AllianceChicago and Health Choice Networks (HCN), on best practices to deliver care and counseling to patients around menopause symptom management with an emphasis on utilizing telehealth to optimize access to care. 2. To obtain baseline knowledge, knowledge gained and perceived value and outreach of the program through pre- and post- assessment of participants at each session. Design: Four webinars took place from July 2021 to February 2022. Dr. Monica Christmas MD, FACOG, NCMP, director of Menopause Program and Center for Integrated Women’s Health at UChicago Medicine, served as the content expert, and led the development of the TEACH-PM curriculum. The TEACH-PM curriculum included topics such as best practices for delivering virtual care around menopause and strategies for managing menopause symptoms. Primary care providers within the AllianceChicago and Health Choice Networks who previously registered to receive notifications on upcoming network webinars were invited to participate through email notifications. The dates of all 4 lectures were provided in the notification along with registration instructions. The lectures were recorded and made available to network providers who were not able to join during the live lectures. Individuals registered for the sessions were asked to complete a general survey capturing demographics pertaining to their clinical background, patient population and knowledge base around menopause care. We evaluated knowledge gained and perceived value, and outreach of the program through pre- and post- assessment of participants at each session. Results: Over 100 participants from CHCs in the HCN and AllianceChicago network attended the four live sessions. Of those that completed the baseline survey, their specialty background was as follows: 11% Internal Medicine, 33% Family Medicine, 22% OB/GYN and 33% other specialties. Of those that completed the CE evaluation, 88% “Strongly Agree” that they intend to apply the knowledge and/or skills acquired to their practice team and are better able to collaborate with a multidisciplinary care team. For those that took the post series survey, we asked them to identify areas where they plan to implement changes in their practice because of information from the sessions. 78% of respondents plan to implement changes in patient education, 44% in treatment plan, and 33% in patient diagnosis. Conclusion: Data on menopause care in underserved populations is scarce. This project updated CHC providers with the most current practices involving menopause management and telehealth and revealed deficits in current menopause care in CHC networks. The menopause transition is a pivotal point where intervention and treatment may improve quality of life and decrease overall morbidity and mortality.

Sources of Funding: Funding provided through grant obtained through the Pfizer Global Medical Grants Independent Medical Education Program.

Webinar | Title | Learning Objectives
--- | --- | ---
July 14, 2021 | Menopause basics: what, when, why? | • Discuss menopause basics • Explain the implications of menopause on overall health and wellbeing • Identify differences in menopause symptoms based on racial/ethnic identity • Recognize the attitudes and perceptions of menopause • Apply knowledge about the menopause experience to improve care in underserved populations • Discuss benefits and barriers to utilizing telehealth to manage menopause in the CHC environment
October 13, 2021 | Menopause Hormone Therapy (MHT): the good, the bad, the treatment | • Identify types of MHT • Explain the indications for MHT • Discuss use of MHT in medically complex patients • Describe racial/ethnic differences in the use of MHT • Recognize tools to enhance the patient-provider experience
December 8, 2021 | Non-hormonal Menopause Treatment Options: an Evidence-Based Approach: From Prescription Therapy to Complementary and Alternative Medicine | • Review evidence-based non-hormonal treatment options for management of VMS and GSM • Discuss new treatments for management of VMS in the future • Explore complementary alternative medicine approach to menopause care • Develop framework for patient-centered mindset for utilizing telemedicine
February 9, 2022 | Menopause is More than Hot Flashes and Vaginal Dryness: Strategies for managing sexual dysfunction, physical changes, mental changes and sleep disturbances | • Understand mental and physical changes related to menopause • Recognize sexual dysfunction and sleep disturbances in context of menopause • Explain treatment options for managing menopausal symptoms outside of VMS and GSM • Outline strategy for integrating menopause care into workflow

P-12. What is the association between menopause and urinary symptoms? A Systematic Review
Monica M. Christmas, MD,1 Shilpa Iyer, MD,1 Juraj Letko, MD,1 Cassandra Daisy, BS,1 Sumiko Maristany1. 1University of Chicago Pritzker School of Medicine, Chicago, IL; 2University of Chicago Department of Obstetrics and Gynecology, Chicago, IL

Objective: The term genitourinary symptoms of menopause (GSM) has been coined to better encompass the variety of symptoms experienced during menopause. It is unclear, however, if the included urinary symptoms of dysuria, urinary urgency and frequency, recurrent urinary tract infections (UTI), and urge and stress incontinence (UUI, SUI) are attributable to menopause, age, or a combination of other risk factors. Our objectives were to define the association between menopause and urinary symptoms, and to systematically review the effects of systemic or vaginal menopausal hormone therapy for urinary symptoms. Design: This systematic review included randomized controlled trials (RCTs) that enrolled menopausal women with primary or secondary outcomes of dysuria, frequent UTI, urgency, frequency, or incontinence. We systematically searched for and identified studies published through electronic databases and other resources. Of the 5,265 papers identified, 29 RCTs were included (Table 1-2.). We found that systemic estrogen therapy (ET) did not improve urinary symptoms over placebo. However, vaginal estrogen therapy improved a wide array of urinary symptoms in postmenopausal women including dysuria, urinary frequency, UUI, SUI, and reduced the risk of recurrent UTIs. Conclusion: The relationship between menopause and lower urinary tract symptoms (LUTS) is unclear; however, treatment with local estrogen therapy appears to have some benefits. Future prospective trials assessing urinary symptoms in those with primary ovarian insufficiency, premature menopause, and perimenopause may help determine if there is an association between decreased estrogen levels and LUTS.

Sources of Funding: Internal funds from the Department of Obstetrics and Gynecology University of Chicago.
Table 1. Characteristics and main findings of included systemic estrogen trials

<table>
<thead>
<tr>
<th>Study Title</th>
<th>Author Year</th>
<th>Country of Origin</th>
<th>Treatment</th>
<th>N</th>
<th>Treatment Duration</th>
<th>Findings</th>
<th>Jadad Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urinary incontinence in postmenopausal women treated with estrogen: a double-blind clinical trial</td>
<td>Walter 1978  Denmark</td>
<td>Oral estrogen × placebo</td>
<td>29</td>
<td>20 days</td>
<td>Significant decrease in self-reported frequency urgency, and urge incontinence in estrogen group (estrogen × placebo) vs placebo alone; no DO on any micturition (urinary diary (ADI); p&lt;0.05). No change in uric acid or creatinine in either group</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Osteitis is the etiologic basis of recurrent urinary tract infections in postmenopausal women</td>
<td>Kloth 1992  Norway</td>
<td>Oral estradiol × placebo</td>
<td>40</td>
<td>3 weeks</td>
<td>Both groups had reduced UTI frequency but no statistical significance between groups; pill pill the treatment group decreased from 6.5 to 5.5 to 0.0.</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Efficacy of estrogen supplementation in the treatment of urinary incontinence: The Continence Program for Women Research Group</td>
<td>Fanti 1996  United States</td>
<td>Oral conjugated estrogen and medroxyprogesterone cyclically × placebo</td>
<td>43</td>
<td>3 months</td>
<td>No change in incontinence episodes, nocturia, frequency, or patient perception of improvement in the treatment group.</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Low dose estrogen prophylaxis for recurrent urinary tract infections in elderly women</td>
<td>Cardozo 1999  United Kingdom</td>
<td>Oral estradiol × placebo</td>
<td>72</td>
<td>6 months</td>
<td>No statistical significance between groups.</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>The effect of estrogen supplementation on post-menopausal urinary stress incontinence: a double-blind placebo-controlled trial</td>
<td>Jackson 1999  United Kingdom</td>
<td>Oral estradiol valerate × placebo</td>
<td>37</td>
<td>6 months</td>
<td>No significant effect of estrogen on UI. No change in frequency, nocturia, or pelvic floor or urethral closure pressure.</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Effects of oral estrogens and progesterons on the lower urinary tract among female nursing home residents</td>
<td>Overland 2001  United States</td>
<td>Oral estrogens and progesteron × placebo</td>
<td>32</td>
<td>12 months</td>
<td>There was no significant difference in urinary frequency, nocturia, urgency, and bladder capacity between the treatment and placebo groups.</td>
<td>3</td>
<td></td>
</tr>
</tbody>
</table>

Table 2. Characteristics and main findings of included vaginal estrogen trials

<table>
<thead>
<tr>
<th>Study Title</th>
<th>Author Year</th>
<th>Country of Origin</th>
<th>Treatment</th>
<th>N</th>
<th>Treatment Duration</th>
<th>Findings</th>
<th>Jadad Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local estrogen treatment in women with urogenital atrophy symptoms</td>
<td>Simmaci 2001  Croatia</td>
<td>Estradiol vaginal tablets × placebo</td>
<td>62</td>
<td>12 months</td>
<td>Urinary dysuria, atrophy symptoms in estrogen group decreased from 8.1% to 15.5% vs placebo 47.6% to 35.6% (p&lt;0.01). The following symptoms improved in the estrogen group compared with placebo: incontinence, 31.7% to 15.3% (p=0.002); UTI 25.9% to 4.2% (p=0.034); frequency/month 47.4% vs 9.8% (p&lt;0.001).</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Vaginal noradral for the treatment of lower urinary tract symptoms in postmenopausal women: A double-blind placebo-controlled study</td>
<td>Cardozo 2001  United Kingdom</td>
<td>Vaginal estradiol × placebo</td>
<td>110</td>
<td>9 months</td>
<td>Vaginal estradiol had no effect on frequency and nocturia.</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>A randomized, open, parallel group study on the effect of oral estradiol-releasing vaginal ring (estradiol ring) on recurrent urinary tract infections in postmenopausal women</td>
<td>Eriksson 1999  Norway</td>
<td>Estradiol-releasing vaginal ring × no ring</td>
<td>108</td>
<td>9 months</td>
<td>Proportion of subjects with ring than remained UTI free was significantly higher than those who did not.</td>
<td>3</td>
<td></td>
</tr>
</tbody>
</table>

P-13. Inflammatory Cytokines are Associated with Lower Trabecular Bone Score at the Lumbar Spine in Postmenopausal Women

JANHAVI M. DAMANI, Integrative and Biomedical Physiological Science, 1 Mary Jane De Souza, PhD2, Connie J. Rogers2 1 Integrative and Biomedical Physiology Program, The Pennsylvania State University - University Park Campus, University Park, PA; 2 Hunk Institutes for the Life Sciences, The Pennsylvania State University - University Park Campus, University Park, PA; 3 Department of Kinesiology, The Pennsylvania State University - University Park Campus, University Park, PA; 4 Department of Nutritional Sciences, Penn State University Park, The Pennsylvania State University - University Park Campus, University Park, PA, US, academic, University Park, PA

Objective: Osteoporosis is characterized by reduced bone mineral density (BMD) and is estimated to affect over 200 million women worldwide. Due to the adverse effects associated with pharmacological drugs for osteoporosis, there is increasing interest in the potential of nutritional interventions to mitigate postmenopausal bone loss. Prunes (dried plums) are rich in bioactive phenolic compounds that may target inflammatory pathways, which are upregulated in a hypovestrogenic environment and consequently promote bone loss. The overarching goal of the study was to evaluate the effects of one year of prune consumption as a dietary supplement (two doses: 50g/day and 100g/day) on BMD (primary outcome) and inflammatory mediators (secondary outcome) in postmenopausal women. The goal of the current analyses was to explore the relationship between inflammatory mediators and bone outcomes in postmenopausal women at baseline prior to prune supplementation to better understand which inflammatory cytokines may be most important in bone health in this population. Design: Postmenopausal women (n=235, 55-75 years old) with BMD T-score of <0.0 and >-3.0 at any site were recruited to participate in a single-center, parallel-arm, 12-month randomized controlled trial (RCT; NCT02822378) to evaluate the effects of 50g and 100g prunes compared to control group. All participants received 1200mg calcium and 800 IU vitamin D3 as standard of care. BMD was measured every 6 months using dual-energy X-ray absorptiometry. Blood was collected at baseline and after 12 months of prune consumption. Inflammatory mediators included serum C-reactive protein (CRP) and plasma pro-inflammatory cytokines (TNF-α, IL-6, IL-8, MCP-1). Results: 235 women (age 62.1 ± 5.0y) were randomized into Control (n=78), 50g Prune (n=79), or 100g Prune (n=78) groups with a compliance of 90.2 ± 1.8% and 87.1 ± 2.1% in the 50g and 100g Prune groups, respectively. At baseline, age at menopause was positively correlated with plasma IL-1β (p<0.05), and time since menopause showed significant negative correlations with BMD and bone strength measurements. At baseline, plasma TNF-α, IL-6L, IL-6, and IL-8 were negatively correlated with trabecular bone score at the lumbar spine (p<0.05). Furthermore, multiple regression analysis indicated that at baseline, in combination with BMI and dietary calcium intake, plasma TNF-α accounted for 27.1% of the variability in total hip BMD (p<0.05). Conclusion: At baseline, inflammatory markers and time since menopause were inversely associated with bone health parameters in postmenopausal women, suggesting that inflammatory markers may be an important mediator for postmenopausal bone loss. Thus, dietary factors such as prunes may represent a promising non-pharmacological intervention to attenuate inflammatory mediators that can contribute to bone loss in postmenopausal women.

Sources of Funding: California Prune Board

P-14. Prunes preserve cortical bone density and estimated strength in a 12-month randomized controlled trial in postmenopausal women: The Prune Study

Mary Jane De Souza1, Kristen J. Koltun2, Nicole C.A. Strock2, Hang Lee3, JANHAVI M. DAMANI, Integrative and Biomedical Physiological Science, 1 Mary Jane De Souza; 2 Connie J. Rogers, 3 Nancy I. Williams, 1 Integrative and Biomedical Physiology Program, The Pennsylvania State University - University Park Campus, University Park, PA; 2 Massachusetts General Hospital, Boston, MA; 3 University of Arkansas for Medical Sciences, Little Rock, AR; 4 Purdue University, West Lafayette, IN; 5 San Diego State University, San Diego, CA

Objective: Dietary consumption of prunes has favorable impacts on areal bone mineral density (BMD); however, more research is necessary to understand the influence on volumetric BMD (vBMD), bone geometry, and estimated bone strength. The purpose of this investigation was to evaluate the effects of prunes (50g or 100g/day) on vBMD, geometry, and strength in postmenopausal women during a 12-month dietary intervention.

Design: Single center, parallel arm 12-month randomized controlled trial (RCT; NCT02822378) to test effects of 50g and 100g prunes vs. a Control group on vBMD, bone geometry, and strength at the 4%, 14%, 38% and 66% tibial sites via peripheral quantitative computed tomography (pQCT). Generalized linear mixed effects modeling (GLMM) was used to assess changes over time among groups (p<0.05). Results: 235 women (age 62.1 ± 5.0y) were randomized into Control (n=78), 50g Prune (n=79), or 100g Prune (n=78) groups. Compliance was 90.2 ± 1.8% and 87.1 ± 2.1% in the 50g and 100g Prune groups. Dropout was 22% however, the dropout rate was 41% for the 100g Prune group (compared to other groups 10% Control; 15% 50g Prune; (p<0.001)). A group interaction for total vBMD was observed in Control vs 100g Prune (p<0.009), but not in Control vs 50g Prune groups (p=0.226) at the 14% diaphyseal tibia. Cortical vBMD decreased in the Control group from Baseline (1073.5 ± 5.0 mg/cm3) to 12 months (1068.0 ± 5.0 mg/cm3; p<0.001) but did not change in the 100g Group (Baseline: 1078.5 ± 5.0 mg/cm3; 12 months: 1078.5 ± 5.0 mg/cm3; p=0.798). A group interaction for the estimated strength (SSI) was also observed for Control vs. Pooled groups (p=0.024) such that strength decreased in the Control group from Baseline (1186.5 ± 18.1 mm3) to 12 months (1176.6 ± 18.2 mm3; p<0.001) but not the combined Prune group (1171.4 ± 17.1 mm3; 1166.4 ± 13.6 mm3; p=0.275). At the 38% diaphyseal tibia, a group interaction for total vBMD was observed for the Control

Barbara DePree, MD, NCMP, MM,1 Aki Shiozawa, DO, PhD2, Deanna King, MS, PhD3, Arianne Schild, MS4, Mo Zhou, PhD5, Hongbo Yang, PhD5, Shervin Mancuso, DO, FACOG6.1Women’s Specialty Hospital, Holland Hospital, Holland, MN; 2Astellas Pharma US Inc, Northbrook, IL; 3Analysis Group Inc Boston, Boston, MA

Objective: To evaluate the association between vasomotor symptom (VMS) severity and work productivity in a real-world population of women with symptoms of menopause (secondary objective; primary objective reported separately). Design: For this online survey, US women aged 40–65 y in peri- or post-menopause experiencing VMS ≥14 times/wk for ≥1 wk in the month before the survey were enrolled. Women were classified by VMS severity (mild/moderate/severe) based on self-rated response on the Menopause Rating Scale. The impact of VMS on daily activities and work productivity was assessed using the Work Productivity and Activity Impairment (WPAI) questionnaire and reported according to VMS severity. The impact of VMS-induced sleep disturbance on productivity was evaluated according to sleep quality. Results: Among 619 respondents (mean age 53.0 y; mean 5.7 y since last menstruation), VMS severity was mild in 88 (14.2%), moderate in 266 (43.0%), and severe in 265 (42.8%). A majority (90.8%)—including 81.8%, 86.8%, and 97.7% of women with mild, moderate, and severe VMS—reported that VMS impacts their sleep, and most of these women (83.1%, 75.0%, 73.2%, and 94.2%, respectively) reported that the sleep changes affect their productivity. Conclusion: VMS severity is positively associated with degree of impairment in daytime activities and work productivity. VMS associated with menopause commonly disrupt sleep, which in turn affects daytime productivity.

Sources of Funding: Astellas Pharma, Inc. Writing support provided by Traci Stuve, MA, of Echelon Brand Communications, LLC, an OPEN Health company, funded by Astellas.

Figure. VMS-Related Work Productivity and Activity Impairment (WPAI) in the Past Week

P-16. Association Between Vasomotor Symptom Severity and Sleep Outcomes in a Survey of US Women With Symptoms of Menopause

Barbara DePree, MD, NCMP, MM,1 Aki Shiozawa, DO, PhD2, Deanna King, MS, PhD3, Arianne Schild, MS4, Mo Zhou, PhD5, Hongbo Yang, PhD5, Shervin Mancuso, DO, FACOG6.1Women’s Specialty Hospital, Holland Hospital, Holland, MN; 2Astellas Pharma US Inc, Northbrook, IL; 3Analysis Group Inc Boston, Boston, MA

Objective: Vasomotor symptoms (VMS) associated with menopause can cause sleep disturbances and wake up2 times/wk for ≥1 wk in the month before the survey were enrolled. Women were classified by VMS severity (mild/moderate/severe) based on their response to the Menopause Rating Scale. The impact of VMS on sleep was assessed using the Patient-Reported Outcomes Measurement Information System (PROMIS) Sleep Disturbance (SD) Short Form (SF) 8a (primary endpoint), PROMIS Sleep-Related Impairment (SRI) SF 8a, and Pittsburgh Sleep Quality Index (PSQI). PROMIS measures were converted to T-scores (standardized so 50=mean of type of counseling. Sources of Funding: None.
The Contribution of HDL Subclasses to the Associations of HDL Function

P-18. Impact of Attending a Menopause Clinic on Symptom Management and Quality of Life

Erin Duralde, MD; Imke Janssen, 4; Maria Brooks, PhD

Objective: To assess the impact of attending this single institution midlife and menopause clinic via patient surveys issued before all new and returning visits on symptom levels, health-related quality of life (HRQOL), anxiety, and sexual function.

Design: In September 2021, we instituted a pre-visit survey of the most recent observation for each person to maximize average follow-up time. We used STATA 17 for descriptive statistics and t-tests for significance.

Results: All patients received the pre-visit survey; 390 completed surveys. After selecting only the most recent survey for each person, there were 176 new patient surveys and 214 returning patient surveys. The majority of patients were postmenopausal with about a quarter in perimenopause, with no difference between the groups. Approximately 10% had breast cancer, 5% chemotherapy, and 8% antiretroviral therapy. Few had history of other cancers, deep venous thrombosis, heart disease, stroke, or osteoporosis, and none had a pulmonary embolism. The majority (59%) had never tried any local or systemic hormonal therapy for their symptoms. We found statistically significant differences in outcomes on 4 out of 6 pre-validated survey instruments between new and returning women, selecting the most recent observation for each person to maximize average follow-up time. The SWAN Repository: U01AG017719

Sources of Funding: This study was initiated by Café Health, at the Women's Health Reassurance and Natural Health, and was generously supported by Café Health.

Submitted to: The Journal of Women's Health

P-19. The Contribution of HDL Subclasses to the Associations of HDL Function with Aortic Calcification in Pre- vs. Postmenopausal Women: The SWAN Heart and HDL Ancillary Studies

Samar El Khoudary, PhD,1 Xirun Chen,2 Sybil Crawford,3 Margaret Elango,3 Linda L. Lee,4 Olubola Akinwande,5 Eric Ford,6 Elizabeth Jackson5, Carol Derby6. 1University of Pittsburgh, Pittsburgh, PA; 2King Abdulaziz University, Jeddah, Saudi Arabia; 3University of Massachusetts, Worcester, MA; 4The University of North Carolina at Chapel Hill, Chapel Hill, NC; 5University of Alabama at Birmingham, Birmingham, AL; 6Albert Einstein College of Medicine, Bronx, NY

Objective: To assess associations of HDL subclasses with aortic calcification (AC) and/or carotid-endothelial cell adhesion (CEC) in women across the menopause transition.

Design: A total of 3302 women (47.0% White), aged 42 to 52 years, were enrolled in the SWAN study. Risk of CVD events progresses over the menopause transition, with the risk of CVD events across stages of the menopause transition not being examined. With its prospective design and precise longitudinal assessment of menopause-related factors (menopausal stage, age at menopause), the Study of Women’s Health Across the Nation (SWAN) is uniquely positioned to provide one of the most robust evaluations of the relation of menopause stage to incident CVD risk. We hypothesize that risk of CVD events increases as women transition over the menopause in a dose-related fashion. Design: A total of 3302 women (47.0% White), aged 42 to 52 years, were enrolled in the SWAN study. Risk of CVD events progresses over the menopause transition, with the risk of CVD events across stages of the menopause transition not being examined. With its prospective design and precise longitudinal assessment of menopause-related factors (menopausal stage, age at menopause), the Study of Women’s Health Across the Nation (SWAN) is uniquely positioned to provide one of the most robust evaluations of the relation of menopause stage to incident CVD risk. We hypothesize that risk of CVD events increases as women transition over the menopause in a dose-related fashion. Design: A total of 3302 women (47.0% White), aged 42 to 52 years, were enrolled in the SWAN study. Risk of CVD events progresses over the menopause transition, with the risk of CVD events across stages of the menopause transition not being examined. With its prospective design and precise longitudinal assessment of menopause-related factors (menopausal stage, age at menopause), the Study of Women’s Health Across the Nation (SWAN) is uniquely positioned to provide one of the most robust evaluations of the relation of menopause stage to incident CVD risk. We hypothesize that risk of CVD events increases as women transition over the menopause in a dose-related fashion. Design: A total of 3302 women (47.0% White), aged 42 to 52 years, were enrolled in the SWAN study. Risk of CVD events progresses over the menopause transition, with the risk of CVD events across stages of the menopause transition not being examined. With its prospective design and precise longitudinal assessment of menopause-related factors (menopausal stage, age at menopause), the Study of Women’s Health Across the Nation (SWAN) is uniquely positioned to provide one of the most robust evaluations of the relation of menopause stage to incident CVD risk. We hypothesize that risk of CVD events increases as women transition over the menopause in a dose-related fashion. Design: A total of 3302 women (47.0% White), aged 42 to 52 years, were enrolled in the SWAN study. Risk of CVD events progresses over the menopause transition, with the risk of CVD events across stages of the menopause transition not being examined. With its prospective design and precise longitudinal assessment of menopause-related factors (menopausal stage, age at menopause), the Study of Women’s Health Across the Nation (SWAN) is uniquely positioned to provide one of the most robust evaluations of the relation of menopause stage to incident CVD risk. We hypothesize that risk of CVD events increases as women transition over the menopause in a dose-related fashion. Design: A total of 3302 women (47.0% White), aged 42 to 52 years, were enrolled in the SWAN study. Risk of CVD events progresses over the menopause transition, with the risk of CVD events across stages of the menopause transition not being examined. With its prospective design and precise longitudinal assessment of menopause-related factors (menopausal stage, age at menopause), the Study of Women’s Health Across the Nation (SWAN) is uniquely positioned to provide one of the most robust evaluations of the relation of menopause stage to incident CVD risk. We hypothesize that risk of CVD events increases as women transition over the menopause in a dose-related fashion.
U01AG012505, U01AG012535, U01AG012533, U01AG012539, U01AG012546, U01AG012553, U01AG012554, U01AG012495, and U19AG006720. The content of this article is solely the responsibility of the authors and does not necessarily represent the official views of the NIA, NINR, ORWH or the NIH.

P-21. Hysterectomy in BRCA carriers: What are the differences between patients who have hysterectomy at the time of risk reducing BSO and those that opt for RRSO without hysterectomy?

Alexandra K. Iyer, MD1,2, Elektra Saltzman, MD1,2, Holly J. Pederson, MD1,4, 1Specialized Women’s Health, Cleveland Clinic, Cleveland, OH; 2Subspeciality Women’s Health, Cleveland Clinic, Cleveland, OH; 3Breast Services, Cleveland Clinic, Cleveland, OH; 4Genomic Medicine Institute, Cleveland Clinic, Cleveland, OH; Cardiovascular and Metabolic Sciences, Cleveland Clinic, Cleveland, OH

Objective: Risk-reducing bilateral salpingo-ooophorectomy is recommended for women with high-risk pathogenic genetic variants, namely BRCA1 and BRCA2, due to their increased risk of breast and ovarian cancers. BRCA1, particularly, is also associated with a slightly elevated risk of endometrial cancer. Thus, some women undergo hysterectomy at time of RRSO for risk-reduction, while others have hysterectomy to limit prostaglandinal exposure with anticipated hormone replacement therapy; however, there are no formal guidelines to perform risk-reducing hysterectomy in BRCA1/2 positive patients. Despite this, hormone replacement therapy until the time of natural menopause is guideline recommended not only for the treatment of symptoms that may occur due to surgical menopause, but also overall health and well-being of women. If a patient had planned hysterectomy with RRSO and requires HRT, they may experience postmenopausal bleeding either as a side effect of the therapy, or due to other underlying causes. Postmenopausal bleeding will then lead to an obligatory investigation to determine the cause of bleeding, which can lead to further financial, physical, and emotional burden to the patient. It is possible that consequently women may then undergo a subsequent hysterectomy. We will conduct a retrospective cohort study utilizing a database of BRCA positive patients followed at Cleveland Clinic to investigate the adherence to NCCN guidelines for surgical management of menopausal women. The purpose of this study is to gather guidelines for HRT, adherence to guidelines for osteoporosis screening, incidence of postmenopausal bleeding and treatments for bleeding, and incidence of subsequent hysterectomy.

Design: Retrospective cohort of BRCA 1/2 carriers from Cleveland Clinic

Results: Pending

Sources of Funding: None

P-22. Is Hormone Replacement Therapy Associated with Reduced Risk of Adhesive Capsulitis in Menopausal Women? A Single Center Analysis

Eliana Salzmann, MD, Emily K. Reinke, PhD, Elizabeth P. Wahl, MD, Anne C. Ford, MD, June Kennedy, PT, J.D.P.T., Jocelyn Wittstein, MD, Obstetrics and Gynecology, Duke University Medical Center, Durham, NC; 2Orthopaedics, Duke University School of Medicine, Durham, NC

Objective: Adhesive capsulitis (AC) is a common orthopedic disorder, characterized by spontaneous onset of shoulder pain and gradual loss of active and passive shoulder range of motion.1 Nearly a century since AC was first described, the etiology and pathophysiology remain unknown. It is recognized that AC mostly affects women aged 40 to 60 years old.1 There are several associated medical conditions including: thyroid disorders (Hashimoto’s thyroiditis),1 and breast cancer treatment.1 Given the lack of studies on AC, it is most commonly affected by AC, it is interesting that the role of estrogen in the pathophysiology has not been described. Estrogen is known to play an important role in MSK, stimulating new bone formation, promoting muscle growth and repair, maintain connective tissue integrity, and reducing inflammation. As such, the purpose of this study was to determine if hormone replacement therapy (HRT) is protective against adhesive capsulitis in menopausal women.


Design: A single institution electronic medical record system was queried to retrospectively review menopausal women between the ages of 45 and 60. Subjects included were those enrolled in a single electronic medical record system was queried to retrospectively review menopausal women. A single institution electronic medical record system was queried to retrospectively review menopausal women. We performed a retrospective cohort study utilizing a database of women not receiving HRT had greater odds of AC. This preliminary data will serve as a basis for larger multi-center and prospective studies to further evaluation this association.

Sources of Funding: None

P-23. Toward a continuous passive automatic detection of physiological hot flashes via wearable technology

Massimiliano di Zambotti, PhD1,2, Andreas Tietsa1, Nicola Arra3, Alison Polkhonkine4, Ann Garnier, BA1, Fiona Baker1. 1SRI International, Menlo Park, CA; 2Lisa Health Inc., Oakland, CA

Objective: The most common and disruptive symptom of menopause is hot flashes (HFs), affecting about 80% of women, with a median duration of 7 years. A HF is a heat dissipation response, characterized by sweating and peripheral vasodilation, as well as sensations of heat, flushing, anxiety, and chills. The physiological changes can be captured from measures of a sudden increase in sternum skin conductance (SC, hallmark of the phenomenon), reduction in blood pressure, and increased heart rate. HFs typically last a few minutes and vary in frequency between women, occurring several times per hour in some. No current commercially available solutions exist to automatically capture physiological HFs. Here, we present the first study exploring the potential of a wearable technology, computational power, and scientific knowledge about menopause and HFs, we developed and pilot-tested a novel consumer-oriented artificial intelligence (AI) based-algorithm for real-time HF detection via commercially available, multi-sensor, wearable technology. The objective of the current work was to present a proof-of-concept of a machine learning approach trained on a dataset of 366 physiological HFs recorded from eleven midlife women (51-64 y) tracked with both an ambulatory research-grade HF monitor (UIF Biologics) and an Empatica E4 wrist device across ~48 hours in free-living conditions. Additional sensors were used to measure environmental temperature and humidity (Button), activity levels and sleep (Fitbit Charge 4). None of the women had severe mental or medical conditions and were not taking current medications known to affect sleep and/or the cardiovascular system, including hormone therapy. An expert manually evaluated sudden increases in several continence tests using a blinded grading scale and a computer-based classification algorithm. The algorithm was trained and validated using the provided public data from the study. The trained model was used to process the raw data from two large datasets, one collected in our lab and the other from a large-scale clinical trial. The algorithm achieved an overall accuracy of >90% on the testing dataset (correctly detected 227 HFs out of a total of 240 HFs), and had an average of ~2 false alarms per hour of recording (detecting a HF when not present) largely due to HF misdetection during periods of sweating (no features were implemented in the current algorithm to limit this type of false-positives). The algorithm achieved >95% accuracy in tracking HF characteristics such as duration (lag between consecutive HFs). Accuracy was also partially dependent (up to 15% in absolute differences) on additional factors like signal noise (determined by augmenting the training dataset with 0-25% synthetically randomly generated signal drops and spikes), time of day, environmental temperature and humidity, sleep/wake state, physical activity level.

Conclusion: HFs in women have a negative effect on quality of life and are associated with increased cardiovascular risk. Longitudinal, passive tracking of HFs can ultimately advance our understanding of their effects on women’s health and wellness, and can be applied to improve clinical evaluation and management of menopause symptomatology. Among future directions, the algorithm’s performance needs to be tuned toward precision, and evaluated longitudinally on a large scale, considering factors known to affect signal quality and accuracy of measurement of HF physiology, including skin tone, body mass index, and age.

Sources of Funding: National Science Foundation (NSF) IIP-2111818 (to AG).


Jacqueline Giannelli1, Anna Barbieri2,3, Jannine Versi2, Alessandra Henderson1, Cesare Piemonte4,5,6, Elektra Health, Ridgefield, CT; 2Mount Sinai Health System, New York, NY

Elektra Health is a digital health platform that supports women throughout their 10-year menopause journey via evidence-based education, on-demand virtual care, connected to caregivers, and over 500M women currently or soon to be navigating the menopause transition, adequate community and emotional support is generally lacking in the workplace. In June 2022, Elektra Health collected survey data from 203 US-based female professionals ages 40-55, with the aim of analyzing how employees are navigating menopause in the workplace, including impact of symptoms, assessment of workplace and employer support, and potential need for additional menopause resources.

Design: In June 2022, Elektra Health performed an analysis using thyroid disorder and 9.2% with diabetes; in the no HRT 12.4% were identified with a thyroid disorder and 14.3% with diabetes. Additionally, 4.0% of patients with HRT and 7.7% of those without HRT had AC. Those not receiving HRT had 99% greater odds of adhesive capsulitis compared to those receiving HRT; however, this association did not reach statistical significance (OR: 1.99; 95% CI 0.86, 4.58; p = 0.11). Conclusion: This is the first known study to evaluate the role of HRT in the development of AC amongst menopausal women in a single center. We concluded from our preliminary study that women not receiving HRT had greater odds of AC, however the study is limited by the available sample size. While the analysis is underpowered, the 95% confidence interval for the odds ratio contains values that support the hypothesis that HRT may be protective against AC. This preliminary data will serve as a basis for larger multi-center and prospective studies to further evaluation this association.

Sources of Funding: None
aggregated, anonymized data from 2003 female employees between the ages of 40-55 in the US, to identify menopause and workplace trends. A third-party platform called Elektra was used to ensure all employees polled were reflective of the reported experience of those symptoms in the workplace, as well as what support they would like from their employers, if any. Respondents answered the question, “Generally, how much more or less support would you like in managing menopause from your employer?” on a scale from “a lot more support” to “a bit more support”; “neither more nor less support”, “a bit less support”, or “a lot less support”. The responses “a lot more support” and “a bit more support” were combined into a new category, “more support wanted”, which was then analyzed by both age group and racial identity. Statistical analysis used a two proportion z-test. Analyses were conducted in R. Results: Out of 2003 respondents, 923 women were aged 40-45 (46%), 554 aged 46-50 (27.7%) and 526 aged 51-55 (26.3%). 1,555 women self-identified as White (77.6%), and 285 women self-identified as Black or African American (14.2%). Of the surveyed group, 32.6% reported that menopause impacted their work performance and 19.5% reported having left or considered leaving a job because of symptoms. The need for additional employer support for menopause was expressed by 876, or 43.7%, of the respondents. The proportion of 40-45 year old women wanting more menopause support from their employers was found to be significantly greater than the proportion of 46-50 year old women who wanted more support (z = 2.34; p < .05; (sig: alpha = 0.05)) and 51-55 year old women (z = 4.00; p < .05; (p=0.0003); (sig: alpha=0.05)) who wanted more support. A secondary finding was that the proportion of Black and African American women wanting more menopause support from their employers was significantly greater than the proportion of White women wanting more support (z=2.21; p < .05; (p=0.0134); (sig: alpha=0.05)).

Conclusion: The Elektra survey shows a significant impact of menopause on women in the workplace. There is clearly a strong interest for menopause support from employers, with the majority of women in the younger age cohort expressing an even greater need for additional help. We postulate that this difference represents a currently unmet need for education and intervention in the earlier phases of the menopause transition and/or demonstrates increased comfort of younger respondents in discussing this issue. The results of this study show that for younger workers, who are more interested in the well-being of their employees. Education and menopause related resources may reduce absenteeism, encourage retention of female managers, and reduce health costs. Additionally, support for menopause in the workplace has the potential for company cost-savings by minimizing employer turnover and maximizing brand reputation and company loyalty. More research is required to understand the nuanced preferences of working women experiencing menopause, as well as the types of support that are most effective in the workplace, and how to deliver high quality services while also respecting employees’ privacy.

Sources of Funding: Elektra Health

P-25.

Performance of Endometrial Cancer Case Finding Algorithms Among Women with Select Comorbidities in US Claims Data

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Objective: Although an algorithm to identify cases of endometrial cancer in insurance claims using International Classification of Disease version 9 Clinical Modification (ICD-9-CM) codes has been published, no such algorithm has been ascertained for ICD-10-CM codes. The objective of this study was to determine the overall positive predictive value (PPV) of an endometrial cancer case identification algorithm using ICD-10-CM diagnosis codes and among women having type 1 or type 2 diabetes mellitus (DM), obesity, or endometrial hyperplasia. Design: Study population consisted of women aged 50 years without prior hysterectomy or endometrial ablation, with at least 12 months enrollment in a health plan prior to diagnosis of endometrial cancer from 2016 through 2020. The algorithm variant A used diagnostic codes for malignant neoplasms of uterine sites (C54.x), excluding C54.2 (malignant neoplasm of myometrium) only. Both variants require at least 1 inpatient or 2 outpatient diagnoses (on different dates, separated by any interval). A random subsample of provisional cases was adjudicated via review of medical records as confirmed, probable, possible cases, or non-cases. Agreement in case determination among adjudicators was measured using the kappa coefficient (k). We estimated the PPV of each variant of the case finding algorithm with exact 95% confidence intervals (CI). Results: Of 3,145 provisional cases identified by algorithm variant A, medical records for 294 unique provisional cases were obtained and adjudicated, 288 of the 294 also were provisional cases per algorithm variant B. Among the women with a provisional case (n=294), the median age was 69.0 years (25th and 75th percentiles: 63.0, 74.0) years. Among those, 49.0% were obese, 42.5% had type 1 or type 2 DM, and 49.0% had obesity. Algorithm variant A identified the same provisional cases (n=223), but differed in identified of non-cases, and possible cases. There was a high level of agreement between adjudicators, κ=0.78. The overall PPV (95% CI) was 84.2% (79.2%-88.3%) for variant A and 85.8% (80.9%-89.8%) for variant B. Among obese women (n=142), PPV was 84.0% (84.7%, 92.9%) for algorithm A and 87.3% (79.6%, 92.9%) for variant B. Predictive values were highest among those with endometrial hyperplasia: PPV was 96.1% (88.8%, 99.2%) for variant A and 96.0% (88.9%, 99.2%) for variant B. Conclusion: Based on these results, both variants of the ICD-10-CM case finding algorithm were effective. Algorithm variant B identified fewer provisional cases not determined to be true positive cases than variant A.

Sources of Funding: TherapeuticsMD

P-26.

The Role of Intimate Partners in the Wellness of Menopausal Women

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Objective: Menopause can be associated with physical and emotional changes that can functionally affect and be influenced by intimate relationships with partners. Menopausal symptoms, such as vasomotor symptoms, vaginal dryness and adverse changes in sexual function may often occur due to aging and to the progressive decline of female hormones. These changes in sexual function may impact the menopausal woman’s intimate relationship. As social support can positively influence the experience of menopause, partners’ awareness of symptoms, knowledge of treatment, and their understanding and expectations of menopause may serve as a potential educational avenue to further support women as they navigate this transition. This review examines current attitudes and awareness of the partners of midlife and older women and explores the role partners play in their physical and psychosocial challenges. Design: A literature review of peer-reviewed articles was conducted through PubMed and Google Scholar. Results: Data suggest that social support from family, friends and intimate partners is associated with less isolation, improved quality of life, and decreased severity of menopausal symptoms. Qualitative studies explore how the relative abruptness of menopause symptoms can be profoundly distressing, manifesting in a decreased quality of life. Menopausal women and their partners report some mood changes as a major source of distress, as these changes may be negatively perceived by their partners and family members. The complex experience of menopause is also shaped by societal norms and negative cultural views towards aging. One study reported that menopausal women are seen negatively by premenopausal women, men, with men perceiving their women as more negative attitudes towards their women. Data also suggested that partners may have an influence on whether a woman seeks treatment for symptoms they may not have viewed as worrisome, as menopausal symptoms can vary widely, and may be perceived differently by individuals. Other studies often avoided discussing their symptoms with partners or seeking treatment due to their partners not believing these symptoms were actually present. Other studies suggest that a partner’s perceptions and attitudes towards menopause may be related to the severity of women’s menopausal symptoms, their own attitudes towards menopause, as well as their intimate relationships; however the causal relationship remains unclear. The limitation of this study is that men’s attitudes towards menopause focus on male partners. The Men’s Attitudes Toward menopause survey explored the awareness and attitudes of male partners, highlighting the need for education and awareness of symptoms. This study found that even often misattributed common menopause symptoms to other causes, including feeling emotionally down or depressed, being overweight, or another health issue unrelated to menopause. A randomized controlled trial conducted in Iran assigned the intervention group to a 3-month educational training program for husbands of women aged 45 to 55. The educational content included symptoms and complications of menopause, management options, and spouse support during perimenopause. The results revealed a significant difference between the men’s knowledge scores about menopause before and after intervention program, as well as significant differences in total satisfaction scores and scales of marital conflict, communication resolution, leisure activities, and marriage and children between women in the intervention group. Conclusion: The results of this review underscore the importance of partner education in providing social support to menopausal women, through their medical challenges as well as the social and relational difficulties. Further research that expands upon the role of partners’ attitudes toward menopause is warranted, especially to broaden the scope beyond heteronormative relationships. Possible interventions include comprehensive menopause education for partners on recognizing the signs and symptoms, treatment and management options, and the supporting role of the partner during the menopausal transition. Furthermore, it is imperative to acknowledge relational challenges and encourage open partner communication in the individualized counseling and treatment of menopausal women.

Sources of Funding: None

P-27.

Use of Probiotics in the Menopausal: Is there a Role?

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Objective: Menopausal health-related symptoms due to estrogen decline are typically managed with hormonal therapy. Alternative therapeutic strategies that are utilized by some women include dietary supplements, such as probiotics. There are data that suggest that probiotics and estrogens decline may increase the risk of adverse symptoms. However, the health benefits and safety of probiotics are generally less defined, as most dietary supplements are neither reviewed nor approved by the FDA. This review explores whether the use of oral probiotics in peri- and post-menopausal women may be beneficial in the relief of menopausal symptoms. A systematic review was conducted for peer-reviewed journal articles of randomized control trials from PubMed published from inception to April 2022, examining whether use of probiotics in peri- and post-menopausal women led to improvements in various menopause-related health outcomes. Results: Literature search yielded six double-blind, randomized control
trials. A summary of these trials is as follows. An increase in FSH levels following probiotic administration was suggested in one study, however, the baseline levels for the therapy arm (P=0.011) were significantly higher than the baseline of the group which was not supplemented, in which an increase in FSH was also observed. Another study reported that administration of milk fermented with Lactobacillus helveticus yielded increased serum calcium levels (P=0.05) and reduced serum PTH (P=0.01) compared to control milk, suggesting the possibility of improved calcium metabolism. Data that reported on the effect of combining administration of isoflavones with probiotics suggested that there were no benefits to alleviating VMS, such as vaginal dryness and sexual complaints. Another study with isoflavones and probiotics showed statistically significant decreases in endothelial and vascular dysfunction, except for increased VEGF levels (P<0.001). These studies suggest potential cardioprotective effects among obese postmenopausal women. Conclusion: There are few randomized control trials on whether probiotics can alleviate menopausal symptoms and health complications. Additionally, the results of the available few are difficult to generalize as studies used probiotics with different species and combinations with other supplements or alternative therapies, followed varying dosing regimens and with small cohort sizes. Despite a growing interest in alternative therapies, benefits of probiotics on peri- and post-menopausal health are not well-defined.

Sources of Funding: None

P-28. Reported practice patterns for use of hormone therapy in healthy patients and gynecologic cancer survivors
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Objective: Use of hormone therapy (HT) sharply declined after reports of increased cardiovascular and breast cancer risk from the Women’s Health Initiative study in 2002. Current clinical guidelines state it is best practice or clinicians to assess benefits and risks of HT use for each individual menopausal patient. This study aims to evaluate knowledge and practice patterns for HT use in clinicians treating healthy menopausal patients who are healthy, and those with history of gynecologic cancers. Secondary aims were: 1) to compare knowledge, attitudes and practice patterns between in-training and practicing clinicians and 2) to assess perceptions of training and preparation required to competently manage menopausal patients. Design: A web-based survey invitation was distributed to medical students, residents, fellows, and practicing clinicians in the department of Obstetrics and Gynecology, Family Medicine, and Internal Medicine at a large academic institution. The 30-question survey assessed basic demographics, provider knowledge of diagnosis and management of menopause. Questions also evaluated reported training experience and feelings of preparedness to manage menopausal patients. Descriptive analysis was used to summarize and report of survey results. Results: Sixty-six clinicians completed the survey. Most (74%) were female under 40 years old. Two-third of respondents are in-training and one-third are practicing. A majority of respondents correctly answered questions about the diagnosis, evaluation and initial HT treatment group for menopausal women. Regarding duration of treatment, 54.6% of respondents indicated they would prescribe HT in premature menopause patients until at least the natural age of menopause. Only 23.4% of respondents correctly selected the recommendation of 18.8%, 17.2% and 44.4% for patients with high grade serous ovarian cancer, early-stage endometrial cancer and cervical cancer, respectively. Reporting clinicians were much more likely to recommend vaginal HT in cancer survivors (46.9%, 37.5% and 60.9%, for each cancer, respectively). Among in-training students, residents, fellows, and practicing clinicians in the department of Obstetrics and Gynecology, Family Medicine, and Internal Medicine at a large academic institution.

Sources of Funding: None

P-29. Patient Characteristics and Menopause Symptoms Recorded During Intake at a Boston Menopause Specialty Clinic
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Results: To gather information on the patient characteristics of women presenting to a dedicated menopause clinic in Boston Massachusetts in a large academic medical center, and to identify self-reported bothersome symptoms motivating a new patient visit. Design: We performed a cross-sectional study of patients seeking consultation for menopause or sexual health-related midlife concerns at the Brigham and Women’s Hospital’s specialty menopause clinic between September 2021 and June 2022. Patients completed a structured response survey including questions about the symptoms motivating their visit. We used STATA 17 to calculate descriptive statistics on frequency and percentages of non-mutually exclusive symptoms on interest. Results: Of the 208 patients who completed intake surveys, the average age of presentation was 52.3 years, with most women self-reporting post-menopausal status (53.1%), while 24.6% reported perimenopause, and 13.7% were unsure of their status. The top three reasons selected out of thirteen options for the visit were sleep problems (64.5%), hot flashes (60.2%), and memory and/or concentration problems at (53.6%). Out of this cohort, 59.7% reported never trialing any kind of hormone therapy, while 38.4% had tried a local and/or systemic method in the past. Conclusion: This study of patients attending a dedicated menopause clinic in a densely populated northeast metropolitan area highlights several important gaps in the care for women in midlife. The most frequently bothersome symptoms, affecting more than half of all patients, were sleep disturbances, hot flashes, and brain fog. Meanwhile, vaginal dryness and loss of sexual desire affected nearly half of all patients. This suggests these symptoms were not yet alleviated by primary and/or specialty care. There may be regional differences in symptoms and patient motivation to disclose them, requiring further study.

Sources of Funding: None

Table 1. Symptoms Motivating First Visit

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hot flashes</td>
<td>127 (60.2)</td>
</tr>
<tr>
<td>Memory/concentration problems</td>
<td>113 (53.6)</td>
</tr>
<tr>
<td>Headaches</td>
<td>60 (28.4)</td>
</tr>
<tr>
<td>Mood swings</td>
<td>83 (39.3)</td>
</tr>
<tr>
<td>Sleep problems</td>
<td>136 (64.5)</td>
</tr>
<tr>
<td>Loss of sexual desire</td>
<td>102 (48.3)</td>
</tr>
<tr>
<td>Arousal/orgasm problems</td>
<td>58 (27.5)</td>
</tr>
<tr>
<td>Reduced genital sensation</td>
<td>40 (19.0)</td>
</tr>
<tr>
<td>Vaginal dryness</td>
<td>101 (47.9)</td>
</tr>
<tr>
<td>Painful intercourse</td>
<td>64 (30.3)</td>
</tr>
<tr>
<td>Genital pain</td>
<td>12 (5.7)</td>
</tr>
<tr>
<td>Pelvic pain</td>
<td>19 (9.0)</td>
</tr>
<tr>
<td>Other</td>
<td>21 (10.0)</td>
</tr>
</tbody>
</table>

P-30. Biopsychosocial Factors for Opioid Use Disorders Among Midlife and Aging Women
Caitlyn A. Horton. Women’s Health Institute, Robert Wood Johnson University Hospital, New Brunswick, NJ

Objective: Opioid overdose deaths are steeply rising for every population with midlife women seeing the greatest percent increase.1,2 Midlife women currently receive the greatest number of opioid prescriptions at a rate almost twice that of midlife men.3 The CDC recommends physicians adopt a biopsychosocial approach to pain management to prevent and treat Opioid Use Disorders (OUDs).4 A more holistic approach would consider the unique biopsychosocial factors experienced by midlife women that set them apart from other members of their sex and age group. Of those prescribed opioids, back and joint pain make up nearly 40% of prescriptions.5 Midlife and older women are also more likely to report mental health issues compared to younger women, and those with OUDs are more likely to have psychiatric comorbidity than adult men.6 Instability in one’s community contributes to an increased risk of developing an OUD, with decreased financial stability and the death of a loved one being factors impacting midlife and older women at increased rates.7 As a result of their age and sex, midlife women experience increased stigma for OUDs.8 The stigma midlife women with OUDs face can be a potential barrier to seeking out treatment and isolate them further from their community. Disruption in care and community can contribute to the rapidly rising opioid overdose death rates amongst this population. Design: A review of existing research on OUDs and midlife and aging women was conducted. Available literature are sparse regarding the biopsychosocial factors associated with OUDs by age and sex, especially for midlife and older women. OUD treatment and prevention practices that consider biopsychosocial factors have been shown to aid midlife women. Women-centered treatment programs are designed to specifically cater to the needs of midlife women and encourage a
stigma-free space.1,3 These programs may offer child care, domestic counseling, and mental health screenings. As midlife women receive the greatest number of prescription opioids, state drug monitoring programs can prevent multiple prescriptions from being filled and prevent overprescription.4 Conclusion: While understanding the unique OUD risks for midlife and older women, prescribing physicians should refer to CDC and Medicare pain management guidelines. Harm reduction practices to prevent overdose, like naloxone education and accessibility can be adapted to highlight this population. For those with chronic pain conditions that need this intervention, co-prescribed naloxone alongside their opioid prescriptions should be considered. Further research should be done to measure the correlation of each biopsychosocial factor for midlife and older women and OUDs, as well as researching the general impact of OUDs by age and sex.


Sources of Funding: None

P-31. A Randomized Trial of Continuous Transdermal Nitroglycerin to Suppress Hot Flashes by Inducing Nitrate Cross-Tolerance in Perimenopausal and Postmenopausal Women

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Objective: Physiologic studies indicate that nitric oxide (NO) plays a key role in mediating hot flush-related vasodilatation, with local blockade of NO synthase appearing to suppress cutaneous vasodilatation during hot flash episodes. Nitroglycerin (NTG) is an organic nitrate medication that is converted to NO in the vascular wall and initially triggers vasodilatation; however, continuous use of NTG for more than 24 hours results in rapid development of nitrate tolerance, including cross-tolerance to endogenous nitrates such as NO. We sought to determine whether continuous administration of transdermal NTG could decrease the frequency or severity of hot flashes by inducing nitrate cross-tolerance in peri- and postmenopausal women. Design: The Flushing Reduction Associated with Nitroglycerin (FRAN) trial was a randomized, double-blinded, placebo-controlled trial in women aged 40 to 62 years who were postmenopausal or in the late menopausal transition, reported an average of at least 7 hot flashes per day, and did not have coronary disease or multiple risk factors for coronary disease. Women were recruited from the San Francisco Bay area from 2017-2022 and randomly assigned in equal ratios to uninterrupted daily use of transdermal NTG patches (participant-directed dose escalation from 0.2 to 0.6 mg/hour) or identical-appearing placebo patches for 12 weeks. Validated symptom diaries assessed change in the daily frequency of any hot flashes (primary outcome) from baseline to 5 and 12 weeks of treatment. Secondary outcomes included changes in the daily frequency of moderate-to-severe hot flashes and daily hot flash severity score (calculated as the total number of hot flashes weighted by hot flash severity) by diary over these time periods. Results: Among the 141 women randomized (70 to NTG, 71 to placebo), mean (SD) age was 54.6 (3.9) years, 20.6% were in the late menopausal transition, 6.4% had undergone bilateral oophorectomy, and 73.0% were naturally postmenopausal or had undergone hysterectomy. At baseline, participants reported an average (SD) of 10.8 (3.5) hot flashes per day, including 8.4 (3.6) moderate-to-severe hot flashes per day. Sixty-five (92.9%) of women in the NTG group and 69 (97.2%) in the placebo group completed follow-up at 5 and 12 weeks. Over 5 weeks, the average daily frequency of any reported hot flashes decreased by 41.7% in the NTG versus 32.7% in the placebo group (P<.01, Table figure); the average daily frequency of moderate-to-severe hot flashes decreased by 44.7% in the NTG group versus 35.1% the placebo group (P=.06, Table figure). By 12 weeks, however, the average frequency and severity of hot flashes had decreased by more than 40% in both groups and did not differ substantially between groups (P<.50, for both, Table figure). Over two thirds of women assigned to NTG initially reported headache, compared to 5.6% assigned to placebo (P<.01), but only one participant in each group continued to report headache at 12 weeks (P<.10). Conclusion: Although continuous use of NTG may induce cross-tolerance to NO as a mediator of hot flush-related vasodilatation, it did not result in greater sustained improvements in hot flush frequency or severity over 12 weeks in peri- or postmenopausal women relative to placebo.

Sources of Funding: National Institute on Aging grant R01AG050588

Table: Change in frequency and severity of hot flashes over 5 and 12 weeks, by treatment group

<table>
<thead>
<tr>
<th>Nitroglycerin</th>
<th>Placebo</th>
<th>Between-Group Difference</th>
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<tr>
<td>Mean (95% CI)</td>
<td>Mean (95% CI)</td>
<td>Mean (95% CI)</td>
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</table>
| P-32. Post-Traumatic Stress Symptoms and Inflammation Among Midlife Women

Karen P. Jakubowski, PhD, Pauline Maki, PhD, Mary Y. Carson, PhD, Yuelong Chang, PhD, Rebecca C. Thurston, PhD. 1University of Illinois Chicago, Chicago, IL; 2University of Pittsburgh, Pittsburgh, PA.

Objective: Trauma is common and related to poor health among midlife women. Post-traumatic stress disorder (PTSD) symptoms following traumatic or extremely stressful experiences are related to adverse physical health outcomes, including chronic pain and obesity. However, limited work has examined relations between PTSD symptoms and inflammatory markers among midlife women. Inflammation plays a critical role in the pathophysiology of numerous chronic diseases. We tested whether PTSD symptom severity was associated with elevated markers of inflammation among midlife women after accounting for potentially confounding factors. Design: Participants were 272 women aged 45-67 years old free of cardiovascular disease, stroke, or dementia. Women completed a validated survey for past-month PTSD symptom severity (PTSD Checklist-Civilian Version; total score range: 17-85); reported medical history and medication use via interview; and provided body mass index (BMI) and a fasting blood draw for interleukin-6 (IL-6) and high sensitivity C-reactive protein (hsCRP). Women were excluded from analyses if they had an autoimmune disorder (N=13) or were taking immunosuppressive medications (N=2), and for hsCRP analyses, had values of hsCRP>10 mg/L (suggestive of acute infection; N=26). Relations between PTSD scores and IL-6 (log) and hsCRP (log) were assessed in linear regression models, adjusting for age, race/ethnicity, education, BMI (log), and other anti-inflammatory medication use (e.g., NSAIDs). Results: The analytic sample included N=257 and N=232 women in IL-6 and hsCRP analyses, respectively. Women were on average 59 years old; 2% identified as Asian or Pacific Islander, 17% Black, 2% Multiracial, and 79% White. On average, women reported low to moderate severity of PTSD symptoms (M=24.7, SD=8.5). Women who reported greater PTSD symptoms had higher IL-6 [B(SES)=-.03 (9.0), p=.03, multivariable; Figure]. There was no significant association between PTSD scores and hsCRP (log) (B(SES)= .01 (4.9), p=.54, multivariable). Conclusion: PTSD symptoms were related to elevated IL-6 after adjusting for confounders. Results are consistent with prior work that suggests associations between trauma and IL-6, but not hsCRP. Results underscore the importance of assessing trauma and PTSD among midlife women in routine clinical care. There is potential value in treatment of PTSD symptoms to promote the health and wellbeing of aging women.

Sources of Funding: K23HL159293; RF1AG053504; K24HL123565

Sources of Funding: None

Figure 1. PTSD symptom severity and IL-6 (raw means). PTSD displayed as tertiles for illustrative purposes.
Burden of Insomnia Among Osteoporosis Patients: A US Retrospective Claims Database Analysis

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Objective: We have previously associated insomnia with accelerated bone loss, a greater likelihood of osteoporosis, and an increased risk of bone fractures. This study sought to determine the incremental all-cause healthcare resource utilization (HCRU) and costs associated with insomnia in a cohort of patients with osteoporosis. Design: This retrospective study used the IBM MarketScan Commercial and Medicare Supplemental Databases (Jan 2014-Dec 2019) to identify patients: (1) age ≥18 years; (2) with ≥1 ICD-9-ICD-10 codes for insomnia OR with ≥2 prescriptions for zolpidem immediate release (IR) OR trazadone ≤150mg OR benzodiazepine; (3) with ≥12 months of continuous enrollment pre/post-index date (earliest diagnosis or medication fill date); and (4) with ≥2 ICD-9-ICD-10 codes for osteoporosis. Patients with sleep disorders other than insomnia were excluded. The resulting patients (“insomnia cohort”) were 1:1 matched on age, sex and Elixhauser Comorbidity Index (ECI) score to osteoporosis patients without insomnia or other sleep disorders (“control cohort”). HCRU and costs were reported per patient per month (PPMM) over the 12-month follow-up period. Generalized linear models were used to compare adjusted outcomes between cohorts controlling for covariates including sex, age, ECI, geographic region, antidepressant use, antihypertensive use and anti-hyperglycemic use. Results: For each cohort, 5,194 osteoporosis patients (mean age 67.5 years, 97.9% female, 7.1 ECI score) were identified. In adjusted analyses, significantly more patients in the insomnia cohort had at least one inpatient admission per month (p<0.0001), had at least one ambulatory visit per month (p<0.0001) and mean outpatient visits were significantly higher (p<0.0001) relative to the control cohort. However, mean number of inpatient admissions and mean number of ED visits were not significantly different between cohorts. After adjusting for covariates, mean total PPPM costs were significantly higher in the insomnia cohort than in the control cohort ($2,030 and $1,490, respectively; mean ratio [MR] = 1.36; p<0.0001). Mean PPPPM costs for inpatient visits (MR = 1.05; p<0.0001), ED visits (MR = 1.13; p<0.05), and outpatient costs (MR = 1.38; p<0.0001) were also higher for the insomnia cohort. Conclusion: In patients with osteoporosis, comorbid insomnia was associated with more intensive HCRU and higher costs relative to those without insomnia. These results suggest that insomnia has a meaningful impact on the health and related health care resource utilization of patients with osteoporosis.

Sources of Funding: Eisai Inc.

P-34. Burden of Insomnia Among Peri-/Post-Menopausal Women Undergoing Hormone Replacement Therapy: A Retrospective Claims Database Analysis

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Objective: One in four menopausal women experience insomnia, often due to vasomotor symptoms, hot flashes and night sweats. Insomnia is also common in post-menopausal women, in part due to decreasing levels of estrogen. At the same time, insomnia is associated with increased economic costs in the general population. The purpose of this study was to evaluate the impact of insomnia on all-cause healthcare resource utilization (HCRU) and costs in peri/post-menopausal women undergoing hormone replacement therapy (HRT). Design: This retrospective study used the IBM MarketScan Commercial and Medicare Supplemental Databases (Jan 2014-Dec 2019) to identify patients: (1) age ≥18 years; (2) with ≥1 ICD-9-ICD-10 codes for insomnia OR with ≥2 prescriptions for zolpidem immediate release (IR) OR trazadone ≤150mg OR benzodiazepine; (3) with ≥12 months of continuous enrollment pre/post-index date (earliest diagnosis or medication fill date); and (4) with ≥2 ICD-9-ICD-10 codes for osteoporosis; and relative to non-insomnia controls, insomnia patients had higher HCRU and costs. These results suggest that insomnia adds to the economic burden in peri-/post-menopausal women undergoing HRT.

Sources of Funding: Eisai Inc.

P-35. Effects of Clairvee™ oral probiotic supplementation on women’s vaginal odor in an open-label experience trial

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Objective: Hormonal fluctuations during menopause can cause an imbalance in the vaginal microbiome, leading to symptoms such as malodor, vulvovaginal irritation, and discomfort. Clairvee™ is an evidence-based oral probiotic formulation shown to balance the vaginal microbiome and provide relief from vaginal itching and discharge. The purpose of this open-label experience trial was to assess Clairvee’s impact on self-reported vaginal odor. Design: This study nationally enrolled women from 3 different medical centers. To enroll, women visited their health care provider, verbally confirmed they did not have a vaginal infection, and responded yes to the following question: During the past week, have you experienced odor from your vulva or vagina? Trial enrollment did not control for menopausal status nor use of concomitant local or systemic hormones or vaginal moisturizers. Women (age 24-70) who were enrolled in the study and reported vaginal odor at baseline were included in the present analysis (n=33). Each Clairvee capsule contained 400 mcg dietary folate equivalent (DFE), 5 billion CFU Clairvee vaginal blend comprised of Lactobacillus acidophilus (BLA-14) and Lactobacillus rhamnosus (BLI-90), and 50 mg lactoferrin. Participants were instructed to take one capsule daily for 15 consecutive days each month. Participants reported on their experience via online questionnaires at baseline, after taking the product for two weeks, and every two weeks thereafter. The efficacy of Clairvee™ was measured via Symptom Severity Questionnaire (VSQ); rating of the severity of vaginal symptoms, including itching, discharge, burning, and odor, using a four-level scale (absent; mild; moderate; severe); and product satisfaction/experience questions. VSQ is 21 yes (1) or no (0) questions with four scales: Symptoms, Emotions, Life-style and Sexual impact. The total score was the sum of the first 15 questions if non-sexually active or the 21 questions if sexually active. A higher score indicates greater severity of symptoms. Subjects were compensated for their participation in the study. Wilcoxon sign rank tests were run for non-parametric symptom severity four-level scale data and paired t-tests were run for the VSQ-21 combined scores. Data are reported as percent change and mean and standard deviation where applicable. Results: Thirty-three women completed 4 weeks of supplementation. After two weeks, 63% of women reported an improvement in odor, and after four weeks, 75% of women reported an improvement. The improvements in odor were statistically significant at both weeks 2 and 4 (p<0.01). In addition, 30% of the women reported an absence of odor at weeks 2 and 4. Of the women that were sexually active, VSQ-21 combined scores improved significantly after 4 weeks (13.33 ± 4.9 baseline vs. 7.57 ± 3.8, *p < 0.01, n=20). VSQ-21 also improved significantly after 2 weeks (7.11 ± 4.9, *p < 0.01, n=19). All women (100%) experienced improvement in one or more symptoms including itching, discharge, burning, dryness, odor, irritation, and painful urination within 4 weeks (n=31). When asked about the 15-day on and 15-day off regimen of Clairvee, 78% of women reported that the dosing regimen was convenient. Additionally, over half of the women were satisfied with Clairvee after 2 weeks. Conclusion: The results of this open-label experience trial demonstrated that Clairvee improved vaginal odor in a population specifically experiencing vaginal odor at baseline. Furthermore, over half of the women were satisfied with Clairvee after 2 weeks. These results reveal general satisfaction with the product, while results revealed benefits in the vaginal microbiome.”

Sources of Funding: This study was funded by JDS Therapeutics, LLC, the parent company of Bonafide Health, LLC.

P-36. Effects of Clairvee® oral probiotic supplementation on women’s vaginal symptoms in an open-label experience trial

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Objective: Hormonal fluctuations during menopause can cause an imbalance in the vaginal microbiome, leading to symptoms such as malodor, vulvovaginal irritation, and discomfort. Clairvee™ is an evidence-based oral probiotic formulation shown to balance the vaginal microbiome and provide relief from vaginal itching and discharge. The purpose of this open-label experience trial was to explore the effects of Clairvee on vaginal symptoms in healthy and post-menopausal women. Design: This study nationally enrolled women from 3 medical centers. Women (age 24-82) visited their health care provider, confirmed they did not have a vaginal infection, and responded yes to the following question: During the past week, have you experienced odor from your vulva or vagina? Trial enrollment did not control for menopausal status nor use of concomitant local or systemic hormones or vaginal moisturizers. Each Clairvee capsule contained 400 mcg dietary folate equivalent (DFE), 5 billion CFU Clairvee vaginal blend comprised of

Sources of Funding: JDS Therapeutics, LLC, the parent company of Bonafide Health, LLC.
Lactobacillus acidophilus (BLA-14) and Lactobacillus rhamnosus (BHN001), and 50 mg lacoferin. Participants were instructed to take one capsule daily for 15 consecutive days each month. Participants reported their experience via online questionnaires at baseline and each two weeks thereafter. The following efficacy endpoints were measured: Vulvovaginal Symptoms Questionnaire (VSO); rating of the severity of vaginal symptoms, including itching, discharge, burning, and odor, using a four-level scale (absent; mild; moderate; severe); and product satisfaction/experience questions. VSO is 21 yes (1) or no (0) questions in 4 scales: Symptoms, Emotions, Life-impact, Sexual impact. Total score was the sum of the first 17 questions if non-sexually active or the 21 questions if sexually active. A higher score indicates greater severity of symptoms. Wilcoxon sign rank tests were run for all four parametric symptom severity four-level scale data, and paired t-tests were run for the VSO-21 combined scores. Results: The number of women reporting an improvement in vaginal burning, itching, irritation, dryness, odor, and painful urination improved significantly at week 6 (P<0.05). The number of women reporting an improvement in symptom severity improved significantly at week 4 for all vaginal symptom severity questions (P<0.05) (Table 1). Additionally, the sexual health endpoints of the VSO were analyzed specifically and the findings after four weeks include: 40% of women saw an improvement in desire (n=42), 41% of women saw an improvement in sexual relationships (n=29), 41% of women saw a reduction in pain in sexual activity (n=29), 48% of women saw a reduction in dryness with sexual activity (n=29), 24% of women saw a decline in bleeding (e.g. spotting) with sexual activity (n=29), and 39% of women saw an average decrease in vaginal symptoms relating to sexual activity. Conclusion: This was an exploratory analysis that demonstrated the areas in which Clairvee can be effective in helping with symptoms related an imbalanced vaginal microbiome. The results of this open-label experience trial demonstrated that Clairvee significantly improved distressing vaginal symptoms including burning, itching, irritation, dryness, odor, painful urination, and discharge in the women who were specifically experiencing those symptoms at baseline.

Sources of Funding: This study was funded by JDS Therapeutics, LLC, the parent company of Bonside Health, LLC.

Table 1: Week 2 and 4 improvement percentages following Clairvee supplementation for women who experienced the indication at baseline (N = 46).

<table>
<thead>
<tr>
<th>Indication</th>
<th>Week 2</th>
<th>Week 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percentage n</td>
<td>Percentage n</td>
<td></td>
</tr>
<tr>
<td>Burning</td>
<td>70% *</td>
<td>95% *</td>
</tr>
<tr>
<td>Itching</td>
<td>59% *</td>
<td>92% *</td>
</tr>
<tr>
<td>Irritation</td>
<td>69% *</td>
<td>89% *</td>
</tr>
<tr>
<td>Dryness</td>
<td>52% *</td>
<td>74% *+</td>
</tr>
<tr>
<td>Odor</td>
<td>63%</td>
<td>75% *</td>
</tr>
<tr>
<td>Painful urination</td>
<td>100% *</td>
<td>67% *</td>
</tr>
<tr>
<td>Discharge</td>
<td>42%</td>
<td>60% *</td>
</tr>
</tbody>
</table>

P-37. Effects of Cross-Hormone Therapy in Aging Transgender Women – A Literature Review
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Objective: Hormonal therapy (HT) has become a mainstay medical treatment option for the management of gender dysphoria in transgender patients of both biological sexes. Adult trans women (birth-assigned males) generally are prescribed a combination of estrogen and an antiandrogen to induce the desired physical (ie, changes in body composition, facial/body hair, breast size, voice, reproductive/sexual function) and psychological effects. However, there is a need to counsel this population on the long-term effects of steroid hormone modulation on various organs. Systematic review of the data available on the effects of long-term HT come from studies of postmenopausal cisgender women. This review examined the effects of long-term hormone therapy on the cardiovascular system, breast tissue, bones, and blood in transgender women and the care received as they age. With the increasing de-stigmatization and acceptance of the transgender community, it is important that guidelines for appropriate and sensitive care be uniformly adapted by all practitioners. Design: PubMed/Medline, ScienceDirect, and Google Scholar were utilized with keywords including “elderly”, “transgender women”, “transwomen/transsexual”, “aging”, “hormone therapy”, and “cross hormone therapy”. Evidence-based reports and reviews since 2012 were given priority and expert opinions were sought when conflicting information was encountered. Older resources were considered when primary sources were needed. Given the paucity of data, all resources were given careful consideration. Results: There is very little literature or clinical experience relevant to the care of aging transgender women who have been on long-term hormone therapy. Exogenous sex hormones may interact with hormone-dependent metabolic pathways, affect some biochemical assays, and impact some or many clinical outcomes. There seems to be an association between long-term cross hormone therapy and cardiovascular diseases (including atherosclerosis, osteoporosis, diabetes mellitus, breast cancer, prostate cancer, osteoporosis, sarcopenia, bone, and blood). However, there are only limited data on the effects of long-term hormone therapy in this population. Conclusion: With the rising acceptance of the LGBTQ community over the past years, increasing numbers of aging transgender women will be interfacing with health care providers. The current hormone replacement therapy (HRT) recommendations are based on limited evidence from scant studies. The establishment of large, long-term cohort studies from different regions of the world, where different hormone regimens are used in clinical practice, will allow in advancing the understanding of long-term health benefits and risks in this aging population. Since transgender medicine is a fairly new professional focus, more research is needed in this area. This will help develop and establish evidence-based and concise enumeration of guidelines and standards of care applicable to these aging transgender women and empower them to make more informed decisions.

Sources of Funding: None

P-38. Association of primary ovarian insufficiency with handgrip strength in US women: a national population-based study
Hoon Kim, MD, MD, PhD, MCM1,2, Jiyeon Han1, Sung Woo Kim1,2, Seung Yup Ku1,2, Chang Suk Suh, MD, PhD1,2, 1Obstetrics and Gynecology, Seoul National University College of Medicine, Seoul, Korea (the Republic of); 2Obstetrics and Gynecology, Seoul National University Hospital, Seoul, Korea (the Republic of)

Objective: Postmenopausal women experience a progressive decrease in muscle strength. Handgrip strength (HGS) is a non-invasive measure to evaluate muscle strength or physical function. Although the effect of age at menopause on HGS has been studied, the effect of primary ovarian insufficiency (POI) has not been well recognized. We aimed to investigate the association of POI with HGS. Design: This study is based on a cross-sectional National Health and Nutrition Examination Survey (NHANES) in the United States. We analyzed the national representative data on 1,122 women in the United States aged 19-79 years from the NHANES from 2011 to 2014 when HGS was measured. HGS was determined as the maximum value in kilograms (kg) assessed using either hand. POI was defined when the study participant had experienced the last menstrual period before age 40. HGS was compared between women with and without POI, adjusting for potential confounders using a complex survey analysis. Results: A total of 60 women reported POI, representing an estimated population of 1,069,289 postmenopausal women accounting for the complex sampling and weighting methods used. Women with POI were more likely to be younger, obese, non-Hispanic black, less educated, and current smokers compared to those without POI. Women with POI had significantly lower HGS than that of women without POI (25.0 kg vs. 27.4 kg, P<0.001). This association did not change after controlling for age, ethnicity, education level, family income, high-risk alcohol intake, smoking status, physical activity, and use of hormone therapy (25.3 kg vs. 27.4 kg, P=0.04) Conclusion: There was a significant difference in HGS between women with and without POI in this nationally representative study of postmenopausal women. The association was not different after adjustment for potential confounders. More attention should be paid to women with POI.

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P-39. As the adenomyosis is diagnosed earlier, the menopause comes earlier
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Objective: Handgrip strength (HGS) is a non-invasive measure to evaluate muscle strength or physical function. Although the effect of age at menopause on HGS has been studied, the timing of menopause is important in determining treatment eligibility, and the anteroposterior diameter (APD) was measured. Simple linear regression analysis was performed to analyze the correlation between menopausal age and other factors. Results: Patients were diagnosed with adenomyosis at 44.28±6.04 years on average, and the mean APD was 5.75±1.25cm. Adenomyosis group experienced menopause significantly earlier than control group (50.58±4.52 years vs. 51.76±3.26 years, p = 0.011). Both APD (R² = 0.072, p = 0.016) and the age at diagnosis of
adenomyosis (R² = 0.516, p < 0.001) were positively correlated with the age at menopause.
Conclusion: Women with adenomyosis experienced menopause earlier, and there is a positive correlation between the age at menopause and diagnosis of adenomyosis.

Sources of Funding: This study was funded by funding grant number 2020RA2C1010293.

P-40.
Exploratory analysis of flibanserin’s postmarketing safety and tolerability among postmenopausal women
Sheryl A. Kingsberg, PhD1,2, Anthony Faragasso, MD,1 Louise Brown, PharmD1, Sharon Donatucci2, Sejal Patel, PharmD1,1 TriangleRxConsult, LLC, Wendell, NC; OBGYN, UH MacDonald Women’s Hospital, Cleveland, OH; Case Western Reserve University, Cleveland, OH; Pharmacovigilance, Sprout Pharmaceuticals, Raleigh, NC; Medical Affairs, Sprout Pharmaceuticals, Raleigh, NC.
Objective: Flibanserin is approved in the US for premenopausal women and in Canada for pre and naturally postmenopausal women, a60 years, to treat hypoactive sexual desire disorder (HSDD). Clinical trials suggest that flibanserin’s safety profile is similar among pre- and postmenopausal women. During a Phase 3 postmenopausal study, the most frequently reported adverse events (AEs) were dizziness (10%), somnolence (9%), nausea (8%), and headache (6%). This study explores postmarketing AEs received from postmenopausal women and their clinicians during flibanserin treatment. The primary objective of this safety study is to further characterize flibanserin’s safety profile among postmenopausal women treated in a clinical setting.
Design: This study is a retrospective exploratory analysis of AEs captured in a global safety database (August 15, 2015, to May 12, 2022). The database was queried for US reports of AEs in postmenopausal women using the Medical Dictionary for Regulatory Activities Search Strategy Version 21.1. Preferred Term (PT) “Product use in unapproved indication.” This PT was selected as postmenopausal use is an unapproved indication in the US. Reports were filtered to identify and exclude non-postmenopausal unapproved usages, such as use in males and premenopausal women with non-HSDD conditions. All reports stating postmenopausal use are included in this analysis. If reproductive status was not specified, age was used as an indicator. If age was unknown, the report was excluded. The average age for women of menopausal status was 51-75 years. Adverse events were categorized using PTs, and descriptive statistics were used to summarize the results. Results: Our search identified 195 unique reports of use in postmenopausal women (by a reported specific term or by age) with at least 1 AE during the study period. There were 166 reported AEs (16.4%) which were serious, and no fatalities. Adverse events by PT occurring in a5 reported events are summarized in the Figure. Dispensing data from one specialty pharmacy found that approximately 18% of flibanserin prescriptions were filled by women >50 years over the past year. No safety signals specific to postmenopausal women have been identified to date. Although informative, the lack of information on medical history, concomitant medications, and other potential interacting products limit the ability to make inferences on causality in most reported cases.

Sources of Funding: Sprout Pharmaceuticals, Inc.

P-41.
Global View of Vasomotor Symptoms and Sleep Disturbance in Menopause: A Systematic Review
Sheryl A. Kingsberg, MD,1 Renate Schulze-Rath, MD, MSc,2 Claire Mulligan, PhD,2 Carsten Moeller, PhD,2 Cecilia Caetano, MD,3 Johannes Bitzer, MD, PhD,1 University Hospitals Cleveland Medical Center, Cleveland, OH;3 Beacon Medical Communications, Brighton, United Kingdom;4 Bayer AG, Berlin, Germany;5 Bayer AG, Basel, Switzerland.
Objective: To assess the prevalence and incidence, stratified by race/ethnicity, of vasomotor symptoms (VMS) and sleep disturbance (SLD) in menopausal women worldwide. Treatment patterns for menopausal symptoms were also investigated.
Design: PubMed and Embase were searched on 27 April 2021 for epidemiological/observational studies reporting the prevalence or incidence of menopausal symptoms or treatments in menopausal or middle-aged women, published from 2000 to 2021. Papers focusing only on subpopulations of menopausal women with comorbidities (e.g. diabetes) were excluded. Quality was assessed using the Joanna Briggs Institute Checklist for Prevalence Studies, with scores of 7–9, 4–6 and 0–3 considered to represent good, moderate and poor quality, respectively. Results: 3799 records were screened and 27 papers (19 studies) were identified that reported the prevalence of VMS, SLD or treatment stratified by race/ethnicity (no relevant incidence data were found). Quality was rated as good, moderate and poor in 21, 5 and 1 papers, respectively. VMS were reported in 17 papers (hot flushes, 11 papers; night sweats, 5 papers; VMS overall, 7 papers). SLD was reported in 10 papers (difficulty falling asleep, 3 papers; frequent waking, 3 papers; problems with morning waking, 2 papers; SLD overall, 9 papers). For both symptoms, the reported prevalence varied widely (examples shown in Table). Potential sources of variation included not only race/ethnicity and menopausal stage, but also differences in patient questionnaires, symptom definitions and recall periods. Nevertheless, some common patterns emerged. For example, 5 studies compared the prevalence of hot flushes, night sweats or VMS overall between Black women and White, Hispanic, and/or Asian (Japanese or Chinese) women; all showed the highest prevalence in Black women, while Asian women had the lowest prevalence (depending on menopausal stage in 2 studies). The prevalence of SLD overall was compared between Black, White and Asian women in 2 study populations; both showed the highest prevalence in White women and lowest prevalence in Asian women. SLD overall was more common than VMS overall in Asian women but not in Black women. Treatment patterns were reported in 10 papers (menopausal hormone therapy [HT] or complementary/alternative therapy, 8 papers; sleep medication, 3 papers). The prevalence of treatment use varied widely but showed some common patterns. HT use was compared between White women and Black and/or Asian women in 4 studies, while 3 studies compared sleep medication use between White and Black women; all these studies showed a higher prevalence of treatment use in White women, reflecting prevalence patterns of SLD but not VMS. Conclusion: The highly variable review of epidemiological data on HT, VMS, SLD and use of HT/VMS sleep medication across studies and races/ethnicities may be related to individual and cultural factors as well as differences in study design. Black women had a higher prevalence of VMS and a lower prevalence of HT use than White women. SLD was more common than VMS in Asian women. These results highlight the need for standardized measures of menopausal symptoms, individualized counselling and treatment approaches, and a focus on under-served minorities.

Sources of Funding: Bayer AG

Table. Prevalence of VMS and sleep disturbance overall by race/ethnicity and menopausal status
<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>Prevalence (as reported in included studies) by menopausal status, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-menopausal</td>
<td>Menopause transition</td>
</tr>
<tr>
<td>Mixed/unclassified</td>
<td>Pre-menopausal</td>
</tr>
<tr>
<td>VMS overall</td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>45.6</td>
</tr>
<tr>
<td>White</td>
<td>31.2</td>
</tr>
<tr>
<td>Hispanic</td>
<td>35.4</td>
</tr>
<tr>
<td>Japanese</td>
<td>17.6</td>
</tr>
<tr>
<td>Chinese</td>
<td>30.5</td>
</tr>
<tr>
<td>Sleep disturbance overall</td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>43.4-42.8</td>
</tr>
<tr>
<td>White</td>
<td>24.7-36.1</td>
</tr>
<tr>
<td>Hispanic</td>
<td>25.9-46.6</td>
</tr>
<tr>
<td>Japanese</td>
<td>28.2-74.9</td>
</tr>
<tr>
<td>Chinese</td>
<td>31.6-77.9</td>
</tr>
</tbody>
</table>

*Prevalence data for pre-, peri- and post-menopausal women combined, or for middle-aged women with unspecified menopausal status

P-42.
Gender-Based Preferences on Telemedicine
Sairah Khan, MD,1 Juliana M. Kling, MD, MPH1,2, Suneele Vegunta, MD,2 Paru David, MD, MD, Mina Al-Badri, MBChB, MD,3 Internal Medicine, Mayo Clinic Arizona, Scottsdale, AZ; Women’s Health Internal Medicine, Mayo Clinic Arizona, Scottsdale, AZ;3 Center for Women’s Health, Mayo Clinic Minnesota, Rochester, MN.
Objective: Vasomotor symptoms (VMS) affect up to 80% of menopausal women, yet 75% of women reported their symptoms are not treated.8 Although likely multifactorial in nature, Engen gender-based disparities in healthcare may also play a role. For example, women are more likely to report delays in healthcare access.3 This was likely exacerbated by the Coronavirus (COVID-19) pandemic when an estimated 30-40% of U.S. adults reported delaying or avoiding medical care.9 To improve access to care, telemedicine framed a new path for healthcare and the objective of this study was to further examine potential gender-based differences in telemedicine preference to expand medical care.
Design: Patients were seen in the outpatient setting of Mayo Clinic (Minneapolis, Arizona, and Florida) were given surveys at random following their medical appointment. A total of 80 surveys were sent to patients from all sites, with a total of 120 returned from these sites between May 2020 and 11/2021. The survey utilized a scale of 1 (least) to 5 (most favorable) to assess characteristics of visits, such as ease of scheduling. Results were presented as type 3 sums of squares and least squares for the model-adjusted probability at each combination of gender and visit type.
Results: Of the 476,777 responses, 409,496 visits were in-person compared
to 12,159 via telephone and 55,122 by video. Women made up 47.5% of the survey respondents compared to 37.3% men. The average age of respondents was 63 years of age for in-person visits, 66 years of age for phone visits, and 79 years of age for video visits. Compared to men, women found telehealth appointments easier to schedule (77.3% women rated 5/5 versus 75.6% men). Telehealth did not impact quality of care (87.1% women rated 5/5 versus 87.8% men), or shared decision-making (85.0% women rated 5/5 versus 86.3% men). Overall, women were just as likely to recommend their telehealth practitioner to others (87.4% women rated 5/5 versus 88.7% men). Conclusion: Given the pervasiveness of VMS in menopause, and the opportunity to correct a widening gap of care access caused by COVID-19, telemedicine allows practitioners to individualize care for women in this patient setting.

**Sources of Funding:** None

**Patient Demographics**

<table>
<thead>
<tr>
<th>In-person (N=409496)</th>
<th>Phone (N=12159)</th>
<th>Video (N=53122)</th>
<th>Total (N=478777)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Woman</td>
<td>63.6</td>
<td>66.3</td>
<td>59.2</td>
</tr>
<tr>
<td>Man</td>
<td>63.6±1.7</td>
<td>66.3±1.8</td>
<td>59.2±1.5</td>
</tr>
<tr>
<td>Gender Identification</td>
<td>Woman: 5202 (47.1%)</td>
<td>5208 (42.8%)</td>
<td>28477 (51.7%)</td>
</tr>
<tr>
<td></td>
<td>Man: 151215 (36.9%)</td>
<td>5089 (41.9%)</td>
<td>12175 (39.3%)</td>
</tr>
<tr>
<td>Other/Choose Not to Disclose</td>
<td>65290 (15.9%)</td>
<td>1861 (15.3%)</td>
<td>4824 (8.7%)</td>
</tr>
</tbody>
</table>

| Patients satisfied of telemedicine visits (video, phone). Figure: Percent of Respondents Fully Recommending (5/5) Practitioner by Gender and Visit Type |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| Ease of Scheduling                              | Woman (N=33679) | Man (N=20642)   | Other (N=7660)  |
| Concern Demonstrated by Practitioner            | 25284 (77.3%)   | 20122 (75.6%)   | 4714 (70.2%)    |
| Explanations Provided by Practitioner           | 25127 (87.1%)   | 23390 (87.8%)   | 5559 (82.3%)    |
| Shared-Decision-Making                          | 28345 (85%)     | 22086 (86.3%)   | 5398 (79.8%)    |

| Patients that responded 5/5 satisfaction for telemedicine visits (video, phone). Figure: Percent of Respondents Fully Recommending (5/5) Practitioner by Gender and Visit Type |

P-44. **Menopause age and time from menopause completion are associated with handgrip strength and endurance in older females**

Emma J. Lee, PhD1, Chowdhury Tasnava Tashin2, William Stokes3, Nisha Panigrahy1, Miguel Anselmo2,3, Aline Glazov4,5, Tanya Melnick4,5, Marnie Vanden Noven3, Jason R. Carter4,5, Dawn A. Lowe2, Manda L. Keller-Ross1,2,3, Div. of Physical Therapy, Dept. of Rehabilitation Medicine, University of Minnesota Twin Cities, Minneapolis, MN; 2Div. of Rehabilitation Science, Dept. of Rehabilitation Medicine, University of Minnesota Twin Cities, Minneapolis, MN; 3College of Continuing Education, University of Minnesota Twin Cities, Minneapolis, MN; 4Doctor of Physical Therapy Program, St. Catherine University, Saint Paul, MN; 5Div. of General Internal Medicine, Dept. of Medicine, University of Minnesota Twin Cities, Minneapolis, MN; 1University of Minnesota Physicians, Minneapolis, MN; 2Dept. of Sport Science, Belmont University, Nashville, TN; 3Dept. of Health Development, Montana State University, Bozeman, MT; 4Office of Research and Economic Development, Montana State University, Bozeman, MT

**Objective:** Lower strength during a muscle-fatiguing exercise corresponds to a longer time to fatigue. Furthermore, older adults demonstrate a longer time to fatigue in submaximal isometric exercise than younger adults. In postmenopausal females, aging and the loss of estrogens contribute to diminished muscular strength. However, whether age at menopause completion affects strength and time to fatigue has not been explored, and it is clinically relevant to understand the complex relations between the timing of estrogen loss, aging, and muscular performance. Our purpose was to determine whether menopause age and/or time elapsed since completing menopause influence time to fatigue during an isometric handgrip exercise in postmenopausal females.

**Design:** Participants completed two visits. Visit 1: Written informed consent; questionnaires (medical history, physical activity level); measurement of height/mass; assessment of isometric handgrip maximum voluntary contraction force (MVC); handgrip at 30% of MVC to voluntary fatigue; blood draw (estrone, estradiol). Results: Thirty-two participants completed all procedures (age: 62±4 yrs. [mean±SD]; BMI: 25.5±4.2 kg m²). Mean age at menopause was 51.4±4 yrs. (range: 40-56 yrs.), while time from menopause was 12±6 yrs. (range: 1-27 yrs.) Time to fatigue was significantly correlated with menopause age (r=-0.486, p=0.005) and time from menopause completion (r=-0.583, p=0.001). In addition, time to fatigue was significantly associated with MVC (r=-0.684, p<0.001), current age (r=0.385, p=0.030), and estrone (r=-0.374, p=0.038), suggesting that aging and menopause-related losses of sex hormones also contribute to muscular performance in older females. Estradiol was not significantly correlated with time to fatigue or MVC (p>0.230). Maximum voluntary contraction force was significantly related to time from menopause completion (r=-0.385, p=0.029) and to physical activity level (r=-0.449, p=0.010).

**Conclusion:** Menopause age and time since completing menopause contribute to time for a submaximal fatiguing handgrip exercise in postmenopausal females. Although these findings may be associated with the reduction in strength that occurs with aging, the duration of estrogen deficiency—appears to be implicated in submaximal isometric muscular endurance performance. The role of menopause age in mediating age-related strength losses merits further investigation. Because physical strength is vital for carrying out activities of daily living, these results may be relevant for developing interventions to preserve strength in aging females.

**Sources of Funding:** EL: F32HL160012; MKR: K01 AG064038-01A1

P-45. **Preclinical Alzheimer’s Disease Biomarker Risk Profile for Postmenopausal Women: An Exploratory Multimodal Neuroimaging Study**

Emma J. Lee, PhD1, Jeff Burns2, Jill Morris3, Eric Vidoni3, Jon Chutorian3, Amber Watts, PhD1, 1Psychology, University of Kansas College of Liberal Arts and Sciences, Lawrence, KS; 2University of Kansas Alzheimer’s Disease Research Center, Fairway, KS; 3Div. of General Internal Medicine, Dept. of Medicine, University of Kansas Medical Center, Kansas City, KS

**Objective:** Two-thirds of Alzheimer’s Disease (AD) patients are women. A variety of AD risk factors (e.g., genetic, medical, and hormonal) affect postmenopausal women more negatively. The Estrogen Hypothesis is the leading theory for these gender and sex differences. It underscores the neuroprotective effect of estrogen and how estrogen dysfunction may exacerbate or precipitate AD development. Very few studies have examined sex-specific AD risk factor differences between postmenopausal women and age-matched men during the preclinical stage. This exploratory multimodal neuroimaging study aimed to examine sex differences in cognitively normal older adults.

**Design:** We used a case-control design to examine sex differences in cognitively normal older adults. (1) Amyloid-β on 18F-AV-45 Florbetapir PET imaging, (2) Voxel-based morphometry, (3) Cerebral blood flow via ASL-MRI. We identified genetic,
medical, and hormonal AD risk factors associated with the neuroimaging outcomes with observed sex differences. Design: Sedentary older adults (N = 112, age 65+) without history of cognitive decline and with elevated amyloid and high threshold levels of cerebral amyloid were included in the analysis. All participants received 18F-AV-45 Flortetapir Amyloid PET scans and T1- and T2- weighted MRI scans. We selected brain regions of interest based on known AD pathology trajectory patterns and the Estrogen Hypothesis. We assessed demographic (age, education), genetic (APOE genotype status), and medical risk factors (fasting glucose, mean arterial pressure, waist to hip ratio, and android and gynoid body fat percentages). We conducted an exploratory analysis in a subset of women (n = 23) with reproductive health history examining AD biomarker differences by hormone replacement therapy (HRT) use. Results: Multivariate analysis of brain volumes models demonstrated differences between men and women for fit models hypothesized brain regions as measured by T1 weighted MRI models (F (5, 103) = 13.56, p < 0.001) and T2 weighted MRI models (F (5, 102) = 2.56, p = 0.017). Alpha for age, education, and intracranial volume, women exhibited lower volume in the hippocampus, amygdala, parahippocampal gyrus, insula, and caudate compared to men. Women showed higher blood flow compared to men in several brain regions, including the amygdala, temporal lobe, anterior cingulate cortex, prefrontal, superior parietal lobe, parahippocampal gyrus, and hippocampus. There was a sex difference in beta amyloid levels among hypothesized brain regions overall as measured by 18F-AV-45 PET imaging (F (5, 104) = 2.63, p = 0.028), however univariate analyses revealed no significant group differences for individual brain regions. For women, LASSO regressions selected non-optional fasting glucose, higher android fat percentage, and APOE ε4 carrier status as the most consistent and uniquely informative predictors for lower volume and higher blood flow among brain regions with observed sex differences in brain biomarkers. Age, education, and non-normal waist to hip ratio were associated with the observed differences in brain volume and cerebral blood flow for both sexes. Underpowered exploratory analysis of reproductive health history revealed no differences for HRT use (β = 0.19) or hysterectomy status (β = 0.16) among brain regions examined. However, group differences in hysterectomy status was associated with severity of menopause (β = 0.08) and non-hysterectomized women showed higher blood flow in the amygdala (p = 0.003) and temporal lobe (p = 0.010) compared to hysterectomized women.

Conclusion: Our findings suggest genetic and cardiovascular risk factors uniquely predict lower volumes and higher blood flow in AD brain regions in middle-aged or older women compared to age-matched men. Findings support the development of sex-specific strategies for modifiable risk factors during the AD preclinical stage. Future research is needed to better understand the mechanisms underlying sex differences in AD-related brain pathology.

Sources of Funding: Vira Health Ltd, Innovate UK health aging challenge

P-47.

Bone Mineral Density Changes over 52 Weeks in Perimenopausal Women with Uterine Fibroids Treated with Relugolix Combination Therapy vs Untreated Cohort

Ayman Al-Hendy, Rachel McLean, Dongmei Zhai, Michael R. McClung.1 Obstetrics and Gynecology, University of Chicago Department of Medicine, Chicago, IL; 2Myovant Sciences Ltd, Brisbane, CA; 3Oregon Osteoperosis Center, Portland, OR

Objective: Relugolix combination therapy (Rel-CT; relugolix 40 mg, estradiol 1 mg, norethindrone acetate 0.5 mg) is approved for the treatment of heavy menstrual bleeding (HMB) in premenopausal women with uterine fibroids (UF). This present analysis aimed to characterize longitudinal bone mineral density (BMD) changes over 52 weeks in potentially perimenopausal women (defined as age ≥ 45 years) with UF who were treated with Rel-CT in the Phase 3 LIBERTY Long-term Extension (LTE) study. As a reference, BMD changes from an age-matched independent cohort of women with UF from the National Health and Nutrition Examination Survey (NHANES) were evaluated.

Design: This prospective, observational NHS enrolled premenopausal women (18–50 years of age) with UF, to characterize longitudinal BMD changes over 52 weeks. The NHS was conducted in parallel with the pivotal Phase 3, 24-week, placebo-controlled LIBERTY 1 and 2 studies, and the subsequent LTE study in which eligible women were treated with open-label Rel-CT for up to an additional 28 weeks. BMD was measured by dual-energy X-ray absorptiometry at screening and Weeks 24 and 52 in both the NHS and LIBERTY studies. Analysis of BMD changes over 52 weeks was performed in the prespecifications of these potentially perimenopausal women who were exposed to Rel-CT in the pivotal LIBERTY studies and LTE, and in untreated women in the UF cohort of the NHS. For the LTE study, only women who were treated continuously with Rel-CT for up to 52 weeks were included; women with pre-existing osteoporosis or other medical conditions with disorders were excluded. The NHANES was a survey of the non-institutionalized U.S. population sampled in the NHS UF cohort and 63/163 (38.7%) women in the Rel-CT group of the LIBERTY LTE were potentially perimenopausal. Baseline demographics were generally similar between subgroups of potentially perimenopausal women in the NHS vs LIBERTY LTE: mean [standard deviation, SD] age (47.1 [1.58] vs 47.5 [1.78] years, respectively), mean [SD] body mass index (30.7 [7.15] vs 30.9 [5.00] kg/m²), and a history of never smoking (83.2% vs 74.6%). Results for BMD at baseline and Week 52 were reported alongside percent change from baseline data in Table 1. Conclusion: In potentially perimenopausal women with UF, minimal BMD changes were observed over 52 weeks of Rel-CT treatment in the LIBERTY LTE study. BMD changes with Rel-CT were consistent with changes observed in age-matched, untreated women with UF in the NHS, highlighting the preservation of BMD with Rel-CT through 52 weeks.

Sources of Funding: Myovant Sciences Ltd

Table 1. BMD Results in Potentially Perimenopausal Women in the NHS (untreated UF cohort) and LIBERTY LTE (Rel-CT group)

<table>
<thead>
<tr>
<th>Total hip</th>
<th>L1-L4 spine</th>
<th>L3 vertebrae</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHS (untreated UF)</td>
<td>LIBERTY LTE (Rel-CT group)</td>
<td>LIBERTY LTE (Rel-CT group)</td>
</tr>
<tr>
<td>Baseline BMD, t score</td>
<td>mean (SD) g/cm²</td>
<td>0.92 (0.20)</td>
</tr>
<tr>
<td>Rel-CT group</td>
<td></td>
<td>0.63 (0.16)</td>
</tr>
<tr>
<td>Week 52 BMD, t score</td>
<td>mean (SD) g/cm²</td>
<td>0.74 (0.21)</td>
</tr>
<tr>
<td>Rel-CT group</td>
<td></td>
<td>1.01 (1.03)</td>
</tr>
</tbody>
</table>

Percent change from baseline at Week 52, n (mean [SD])

<table>
<thead>
<tr>
<th>NHS (untreated UF cohort)</th>
<th>Rel-CT group</th>
<th>LIBERTY LTE (Rel-CT group)</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>mean [SD]</td>
<td>Relative change</td>
</tr>
<tr>
<td>72</td>
<td>-0.25 (0.62)</td>
<td>-1.7%</td>
</tr>
</tbody>
</table>

P-48.

Chemotherapy history and its association with menopausal symptoms and impaired quality of life in middle-aged or older postmenopausal women who are breast cancer survivors

MARIANA MERCADO-LARA. Grupo de Investigación Salud de la Mujer, Universidad de Cartagena, Cartagena, Colombia

Objective: to estimate the association between the history of chemotherapy with the presence of menopausal symptoms and the deterioration of the quality of life in postmenopausal women of middle-aged or older adults, survivors of breast cancer - cross-sectional study that is part of the CAVICESQ project (Quality of Life in Breast Cancer Survivors), approved by the ethics committees of the University of Cartagena, Colombia and endorsed by the Colombian Ministry of Science. The participants were postmenopausal women, with one or more years since the diagnosis of breast cancer and residents of Cartagena, Colombia. A form was applied that explored sociodemographic characteristics, data from the clinical history and the Menopause Rating Scale items (a tool that identifies the presence and severity of eleven menopausal symptoms and its associated counting score), chemotherapy history and its association with the presence of menopausal symptoms and the deterioration of quality of life in postmenopausal women of middle-aged or older adults, survivors of breast cancer - cross-sectional study that is part of the CAVICESQ project (Quality of Life in Breast Cancer Survivors), approved by the ethics committees of the University of Cartagena, Colombia and endorsed by the Colombian Ministry of Science. The participants were postmenopausal women, with one or more years since the diagnosis of breast cancer and residents of Cartagena, Colombia. A form was applied that explored sociodemographic characteristics, data from the clinical history and the Menopause Rating Scale items (a tool that identifies the presence and severity of eleven menopausal symptoms and its associated counting score).
allows knowing about somatic, psychological, urogenital deterioration and quality of life, be generally as severe). Statistical analysis was performed with EPI-INFO 7. Nineteen unadjusted logistic regressions were performed: dependent variable (each of the menopausal symptoms, presence of somatic, psychological, urogenital, or quality of life impairment, as well as severe impairment) and independent variable (history of chemotherapy). OR [95% CI] was calculated; p<0.05 value was statistically significant. Results: Results: 298 women aged between 37-90 years were studied, 176 (60.5%) aged 60 or less and 115 (39.5%) older than that age. 255 (87.6%) received chemotherapy and 36 (12.3%) did not receive chemotherapy, as part of their breast cancer treatment. The former was 58 ± 9.4 years old, BMI 26.8 ± 4.5, on average 69 ± 6.0 months since the diagnosis of breast cancer, 12.5 ± 7.7 years since the last menstruation and the 34.1% had presented early menopause. The second, 59.5 ± 8.2 years, 27.4 ± 3.8 BMI, on average 74.3 ± 8.3 months since breast cancer diagnosis, 11.9 ± 9.7 years since last menstruation and 30.5% had had early menopause (p=0.5). There were also no statistical differences in terms of marital status, family history of breast cancer, nutritional status, history of surgery or radiotherapy, sexual activity, or participation in social support groups, when compared according to history of chemotherapy. Hot flashes and joint muscle pain were the most frequent menopausal symptoms, affecting more than 60% of those studied. Half of the participants reported vaginal dryness, sleep disturbances, or physical-mental tiredness. The third part manifested irritability, anxiety, or depressive mood disorder. 20% reported sexual or bladder problems. Somatic impairment was identified in 59.1%, psychological impairment in 53.6%, urogenital impairment in 55.6%, and quality of life impairment in 61.1%. In turn, severe somatic impairment in 7.5%, severe psychological impairment in 3.4%, severe urogenital impairment in 15.8%, and severe impairment of quality of life in 12.7%. In both groups, according to the history of chemotherapy, the frequency of symptoms was the same. No differences were observed in the frequency of menopausal symptoms, in general deterioration or in severe somatic, psychological, urogenital, or quality of life deterioration, when comparing the two groups (p>0.05). In addition, history of chemotherapy for breast cancer was not associated with any of the menopausal symptoms or impairments in the quality of life domains that were assessed (p>0.05). OR: 0.55 [95% CI: 0.2-1.3] was estimated in the association between a history of chemotherapy and severe deterioration in quality of life. Conclusion: In a group of middle-aged or older Colombian postmenopausal women who were breast cancer survivors, a history of chemotherapy was not associated with the presence of menopausal symptoms or with somatic, psychological, urogenital, or quality of life impairment.

Sources of Funding: None.

P-49. Factors Associated with Sexual Disorders in Colombian Climacteric Women: A Cross-sectional Study.

ALVARO MONTERROSA-CASTRO1,2, Angelica Monterrosa-Blanco1,2. 1Grupo de Investigación Salud de la Mujer, Universidad de Cartagena Facultad de Medicina, Cartagena de Indias, Colombia; 2Universidad de Cartagena, Cartagena, Colombia.

Objective: Objective: to identify factors associated with sexual disorders in Colombian climacteric women using The Female Sexual Function Index, abbreviated version [FSFI-6]. Design: Cross-sectional study that is part of the CAVIMEC project [Quality of life in menopause and Colombian ethnic groups]. Healthy women, aged between 40-59 years, residing in urban or rural areas of the Colombian Caribbean, were invited to participate and were surveyed in 2019, face to face in their own residences by nursing assistants. They filled out a form that questioned sociodemographic characteristics and applied the FSFI-6 scale to identify sexual dysfunction and disorders of desire, arousal, satisfaction, coital pain, lubrication, and orgasm. The lower the score for each item and the scale, the worse sexuality. Anonymous, confidential and voluntary participation. For data analysis, EPIINFO 7 was used. Unadjusted logistic regression was performed: dependent variable sexual dysfunction and each of the sexual disorders, independent variables sociodemographic characteristics, a value of p<0.05 was considered significant. Study approved by the ethics committee of the University of Cartagena, Colombia.

Results: 1445 women were studied, mean age 47.5±15.5 years, 39.5% premenopausal, 26.9% in transition to menopause and a third postmenopausal. The IIEF-6 scale score was 15.4±9.5. Dysfunction was identified in 37.7%. The age range 55-59 compared to 40-44 was associated with a higher probability of sexual dysfunction and the six sexuality disorders explored by FSFI-6 <0.001). The same was observed with daily coffee intake, smoking, post menopause and lack of a stable sexual partner (p<0.001). The lack of studies was associated with sexual dysfunction OR: 1.87 [95%CI:1.13-3.0], p=0.001. Overweight and abnormal weight status were associated with a greater presence of desire and lubrication disorders (p<0.001). Performing activity outside the home was associated with a lower frequency of all disorders (p<0.01). Being married with respect to the descendant was associated with a greater presence of all sexual disorders (p<0.001), except orgasmic disorders Conclusion: Several factors: educational, ethnic, nutritional, work and habits, were associated with dysfunction or with other disorders of sexuality. It is recommended that, during the climacteric, sexuality disorders be addressed, and sociodemographic and personal factors be considered.

Sources of Funding: None.

P-50. Prevalence and association between possible eating disorder with subclinical hypothyroidism in postmenopausal women living in Colombia.


Objective: To identify the prevalence and association of symptoms and possible eating disorder with subclinical hypothyroidism in postmenopausal women living in two Colombian cities. Design: Cross-sectional study that is part of the Thyroid Project and Colombian Menopausal Women, approved by the ethics committee and endorsed by the University of Cartagena. Colombia. Postmenopausal women residents of the cities of Cartagena and Medellín, Colombia, were recruited in their own residences and participated anonymously and voluntarily by filling out a form after signing informed consent. A physician applied the form that explored sociodemographic characteristics, clinical history data and applied the items of the SCOFF scale (Sick, Control, One, Fat, Food). Tool that allows identifying symptoms related to eating disorders with dichotomous responses and establishing a possible eating behavior disorder. A nursing assistant took a peripheral venous blood sample to measure TSH and free T-4 with an ultrasensitive third generation chemiluminescence technique. Subclinical hypothyroidism was defined as TSH greater than 4.5mIU/mL with free T-4 between 0.7-1.9ng/dL. Statistical analysis was performed with EPIINFO 7. Adjusted and unadjusted logistic regression was performed to establish association, OR [95%CI]. Dependent variable (subclinical hypothyroidism) and independent variable the SCOFF scale items and possible eating disorder. p value <0.05 was considered statistically significant. Results: 363 postmenopausal women were included. Age 54.6±5.6 years, 69.9% residents in the city of Cartagena and 30.1% in Medellín. Hysterectomy: 26.7%, oophorectomy: 11.8%, diabetics: 9.5%, dyslipidemia: 31.6%, anxiety: 15.1%, depression: 12.2%, family history of thyroid disorder: 15.4%, thyroid nodules: 3.9% and thyroid surgery 1.3%. Subclinical hypothyroidism was found in 4% of those studied. With the SCOFF scale, it was found that 31% reported feeling sick because they considered their stomach uncomfortably full. 20% reported being worried about asking for control over how much they eat, believing they are fat when others say they are too thin, or having lost more than 6 kg in the last three months. 15% considered that food dominated their life. It was estimated that 98 (32%) of the participants had a possible eating disorder. In unadjusted logistic regression, considering that food dominated your life and having lost more than six kg in the last three months were associated with subclinical hypothyroidism (p<0.05). In the adjusted regression, neither the symptoms nor the possible eating disorder was associated with subclinical hypothyroidism (p<0.05). Conclusion: In a group of Colombian postmenopausal women, it was found that more than 20% had symptoms and 32% had a possible eating disorder, while 4% had subclinical hypothyroidism. No significant association was observed between the eating disorder assessment and subclinical hypothyroidism.

Sources of Funding: None.
Symptoms and possible eating disorders, n (%)  
<table>
<thead>
<tr>
<th>Symptom</th>
<th>All</th>
<th>With subclinical hypothyroidism</th>
<th>Without subclinical hypothyroidism</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you make yourself sick because you feel uncomfortable?</td>
<td>96 (53.6)</td>
<td>58 (58.4)</td>
<td>38 (38.4)</td>
<td>0.19</td>
</tr>
<tr>
<td>Do you worry you have lost control over how much you eat?</td>
<td>75 (42.7)</td>
<td>39 (39.8)</td>
<td>36 (36.4)</td>
<td>0.17</td>
</tr>
<tr>
<td>Have you recently lost one stone in a 3-month period?</td>
<td>86 (47.1)</td>
<td>46 (46.5)</td>
<td>40 (40.0)</td>
<td>0.02</td>
</tr>
<tr>
<td>Do you believe you’re too fat if others say you are fat?</td>
<td>32 (18.2)</td>
<td>23 (23.0)</td>
<td>9 (9.0)</td>
<td>0.00</td>
</tr>
<tr>
<td>Would you say the food dominates your life?</td>
<td>47 (25.7)</td>
<td>17 (17.3)</td>
<td>30 (30.0)</td>
<td>0.00</td>
</tr>
<tr>
<td>Possible eating disorder</td>
<td>98 (53.3)</td>
<td>57 (57.3)</td>
<td>41 (41.4)</td>
<td>0.03</td>
</tr>
</tbody>
</table>

Association with subclinical hypothyroidism, OR [95%CI], p

Sources of Funding: None


ALVARO MONTERROSA-CASTRO1, Angelica Monterrosa-Blanco2. 1Grupo de Investigación Salud de la Mujer, Universidad de Cartagena Facultad de Medicina, Cartagena, Colombia; 2Universidad de Cartagena, Cartagena, Colombia  

Objective: To estimate the prevalence of sexual problems according to the perception of loneliness in Colombian climacteric women at the beginning of the COVID-19 pandemic.  

Design: cross-sectional study that is part of the CAVIMEC+COVID STUDY research project (quality of life in the menopausal and Colombian ethnicities under pandemic conditions). Climacteric women (40-59 y) residing in Colombia participated between June 1 and 5, 2020 by filling out an electronic form. Participants were asked to apply their responses according to their perceptions between May 1 and May 30, 2020. In that period, because of COVID-19, confinements and curfews were decreed by the national government in some Colombian cities. In addition, infection and death curves were rising daily. The women participated voluntarily, anonymously, and confidentially, filling out an electronic form that asked about sociodemographic characteristics and applied the Jong Gierveld Loneliness Scale (JGLS) and Menopause Rating Scale (MRS) items. With JGLS, emotional loneliness, social loneliness and general loneliness were identified. With item eight of the MRS, sexual problems (changes in sexual desire, in sexual activity and satisfaction) were explored. Sample size calculation was performed with data from the Colombian population census of 2005 that established a projection of 25,772,783 women for 2020; of these, 2,859,309 were aged 40 to 59 years old. A sample size of 648 women was calculated in the Epidemiological Analysis Tools Tabled Data 3.1 (EPIDAT) software: 99% confidence level, 50% expected proportion, 1% significance and 5% absolute precision. Statistical analysis was performed with Stata-16. The research project has the institutional endorsement of the Universidad de Cartagena, Colombia. Results: 984 women filled out the form and was calculated in the Epidemiological Analysis Tools Tabled Data 3.1 (EPIDAT) software: 99% confidence level, 50% expected proportion, 1% significance and 5% absolute precision. Statistical analysis was performed with Stata-16. The research project has the institutional endorsement of the Universidad de Cartagena, Colombia. Results: 984 women filled out the form and was calculated in the Epidemiological Analysis Tools Tabled Data 3.1 (EPIDAT) software: 99% confidence level, 50% expected proportion, 1% significance and 5% absolute precision. Statistical analysis was performed with Stata-16. The research project has the institutional endorsemen...  

P-53. Fezolinetant for treatment of moderate-to-severe vasomotor symptoms associated with menopause: efficacy in women stratified by race using pooled data from two Phase 3 studies  

Genevieve Neal-Perry1, Petra Stute2, Marci English3, Deanna King, MS, PhD4, Misun Lee1, Antonia Morga3, Emad Siddiqui4, Faith D. Ottery3. 1UNC School of Medicine, Chapel Hill, NC; 2Inselspital, Bern, Switzerland; 3Astellas Pharma Global Development Inc, Northbrook, IL; 4Astellas Pharma Europe Ltd, Addlestone, United Kingdom  

Objective: The burden of vasomotor symptoms (VMS) is known to be higher in Black or African American women than White women. This pre-specified analysis investigated the efficacy of fezolinetant in Black and non-Black subgroups (as self-identified) using pooled data from two Phase 3 studies, SKYLIGHT 1 and SKYLIGHT 2 (NCT04003155; NCT04003142). In both studies the four co-primary efficacy endpoints were met and fezolinetant was well tolerated. Design: SKYLIGHT 1 and 2 were double-blind, placebo-controlled Phase 3 studies with an identical design. Women ≥40–65 y with moderate-to-severe VMS (average ≥7 hot flashes/day) were randomized to once-daily placebo, or fezolinetant 30 mg or 45 mg for 12 weeks. The four co-primary efficacy endpoints were mean change from baseline to week 4 and 12 in the frequency and severity of moderate-to-severe VMS. Results: The pooled group comprised 1022 women who were randomized and took ≥1 dose of medication. At baseline, VMS frequency was numerically higher for Black than non-Black women (Table). Fezolinetant 30 mg and 45 mg statistically significantly reduced VMS frequency at weeks 4 and 12 vs placebo in the overall population and in both Black and non-Black subgroups. In addition, fezolinetant 45 mg statistically significantly reduced VMS severity at weeks 4 and 12 vs placebo in the overall population and Black and non-Black subgroups. Conclusion: These data confirm a higher VMS frequency at baseline in the Black women who participated in this study compared with the non-Black women and overall population. This pooled analysis from SKYLIGHT 1 and SKYLIGHT 2 demonstrates efficacy at week 4 that was maintained through week 12 in both Black and non-Black populations.  

Sources of Funding: Astellas Pharma Inc. Medical writing support was provided by Sue Cooper of Excel Scientific Solutions and funded by Astellas Pharma Inc.
**P-54.**

**S-Equol improves the quality of life for postmenopausal healthy women with complaints from aging.**

Kenichi Oe, Yuichi Ukawa, Kazuya Mitsubishi. Healthcare SBU, Daiel Corporation, Tokyo, Japan

**Objective:** S-Equol is known as a substance produced from soy isoflavone, daidzein, by intestinal bacteria. It exhibits a higher estrogen-like activity than daidzein (1). The producing bacteria in their intestinal flora are known to alleviate menopausal symptoms, and how they vary over time is needed to further understand the extent of our findings.

**P-55.**

**Association between Rest-Activity Rhythms (RARs) and cognitive function in healthy early postmenopausal women.**

Alexandra Paget-Blanc, BS1, BS2, Rebecca C. Thurston, PhD1,4, Yuefang Chang, PhD1, Rachel A. Schroeder, BS1, Pauline Mak, PhD2,3, Graduate Program in Neuroscience, University of Illinois Chicago, Chicago, IL; Psychiatry, University of Illinois Chicago, Chicago, IL; Psychiatry, University of Pittsburgh School of Medicine, Pittsburgh, PA; *Psychiatry, University of Illinois Chicago, Chicago, IL; *Psychiatry, University of Pittsburgh School of Medicine, Pittsburgh, PA; *Psychology, University of Illinois Chicago, Chicago, IL; *Obstetrics & Gynecology, University of Illinois Chicago, Chicago, IL

**Objective:** As women are disproportionally affected by Alzheimer’s disease (AD), it is important to identify modifiable risk factors. Alterations in circadian rest-activity rhythms (RARs) are common among individuals with AD and may contribute to further progression of the disease. Individuals with AD and mild cognitive impairment exhibit altered actigraphy-assessed RARs characterized by increased sleep fragmentation and less robust activity patterns compared to healthy individuals. In cognitively unimpaired older women, rhythm fragmentation predicted future cognitive decline. These studies have largely focused on older individuals. Given that the neuroendocrine-disease process begins years before the onset of clinical dementia focusing on midlife women may help identify markers of cognitive health to distinguish normal from abnormal brain aging before the onset of the disease. Here we aim to determine whether disruption in RARs was associated with cognitive performance in cognitively unimpaired postmenopausal women. Design: Participants were early postmenopausal women based on STRAW+10 criteria. Exclusion criteria included: stroke/cerebrovascular accident, brain injury, brain tumor, dementia, Parkinson’s disease, use of hormone therapy or SSRI/SNRIs antidepressants in past 3 months. Participants completed actigraphy monitoring and neuropsychological assessment including measures of verbal learning and memory (California Verbal Learning Test;CVLT), working memory (Letter Number Sequencing), motor speed (Card Rotation Test), and processing speed (Symbol Digit Modalities Test;SDMT). Participants ingested 2 capsules daily for 12 weeks may improve problems associated with aging and contribute to the improvement of quality of life (QOL) and its safety in postmenopausal healthy women.

**P-56.**

**Novel Wrist-Worn Thermal Device for Management of Sleep-Disrupting Hot Flashes During Menopause.**

Nader Naghavi, PhD1, Sonja K. Billes, PhD1, Andrew Vetter, MS1, Molly Moor, PhD1, Mary Emma Searles, BS2, Nicholas Hathaway, MS3, Rebecca Spencer, PhD1, Pamela Pecke, MD1, Matthew Smith, PhD1, Embr Labs, Boston, MA; *Bayview Research, Pompano Beach, FL; Institute for Applied Life Sciences, University of Massachusetts Amherst, Amherst, MA

**Objective:** Menopausal hot flashes contribute to poor sleep and negatively impact quality of life. The Embra Wave is a noninvasive wearable thermal device that applies personalized cooling and warming to thermoreceptors on the inside of the wrist. New modes with cooling and warming experiences specificallyke for sleep and hot flashes and was introduced on the Embra Wave. This study evaluated the feasibility and preliminary efficacy of nighttime use of the Embra Wave for managing hot flashes and sleep during menopause.

**Design:** Self-described peri/postmenopausal women experiencing sleep-disrupting hot flashes and insomnia were enrolled. The study consisted of a 1-week baseline and 2-week intervention in which participants were provided the Embr and instructed to use it as needed. Primary outcomes were device use (recorded by the device) and subjective reports of sleep and hot flashes. Sleep was measured with the PROMIS Sleep Disturbance (PROMIS SD, range 0-100) and Sleep Related Impairment (PROMIS SRI, range 0-100) and Insomnia Severity Index (ISI, range 0-28). Hot flashes were assessed with the Hot Flash Related Daily Impairment Scale (HFRDIS, range 0-10), daily hot flash number and severity, and control over nighttime hot flashes (range 0-10). Additionally, participants completed the Perceived Stress Scale (PSS, range 0-40). Wilcoxon signed rank tests were used to compare outcome measures for baseline and 2-week intervention in which participants were provided the Embr and instructed to use it as needed. Primary outcomes were device use (recorded by the device) and subjective reports of sleep and hot flashes. Sleep was measured with the PROMIS Sleep Disturbance (PROMIS SD, range 0-100) and Sleep Related Impairment (PROMIS SRI, range 0-100) and Insomnia Severity Index (ISI, range 0-28). Hot flashes were assessed with the Hot Flash Related Daily Impairment Scale (HFRDIS, range 0-10), daily hot flash number and severity, and control over nighttime hot flashes (range 0-10). Additionally, participants completed the Perceived Stress Scale (PSS, range 0-40). Wilcoxon signed rank tests were used to compare outcome measures for baseline and 2-week intervention in which participants were provided the Embr and instructed to use it as needed. Primary outcomes were device use (recorded by the device) and subjective reports of sleep and hot flashes. Sleep was measured with the PROMIS Sleep Disturbance (PROMIS SD, range 0-100) and Sleep Related Impairment (PROMIS SRI, range 0-100) and Insomnia Severity Index (ISI, range 0-28). Hot flashes were assessed with the Hot Flash Related Daily Impairment Scale (HFRDIS, range 0-10), daily hot flash number and severity, and control over nighttime hot flashes (range 0-10). Additionally, participants completed the Perceived Stress Scale (PSS, range 0-40). Wilcoxon signed rank tests were used to compare outcome measures for baseline and 2-week intervention in which participants were provided the Embr and instructed to use it as needed. Primary outcomes were device use (recorded by the device) and subjective reports of sleep and hot flashes. Sleep was measured with the PROMIS Sleep Disturbance (PROMIS SD, range 0-100) and Sleep Related Impairment (PROMIS SRI, range 0-100) and Insomnia Severity Index (ISI, range 0-28). Hot flashes were assessed with the Hot Flash Related Daily Impairment Scale (HFRDIS, range 0-10), daily hot flash number and severity, and control over nighttime hot flashes (range 0-10). Additionally, participants completed the Perceived Stress Scale (PSS, range 0-40). Wilcoxon signed rank tests were used to compare outcome measures for baseline and...
study between November 2020 to March 2021 in the US; 26 had retrievable use data. Baseline data indicated mild sleep disturbance and impairment, subthreshold insomnia, and moderate stress (Table). Mean±SD baseline frequency of daytime and nighttime hot flashes was 15.5±15.0 and 14.8±9.0 per week. Mean±SD (median) device use per 24 hours was 5.2±4.7 (4.7) sessions and 2.3±2.5 (1.5) hours. PROMIS SD, PROMIS SRI, and ISI improved during the intervention compared to baseline (all p<0.01, Table). The intervention also resulted in reduced frequency of nighttime hot flashes, frequency of severe nighttime hot flashes, and increased control over nighttime hot flashes (all p<0.05, Table). In participants with greater baseline hot flash interference (HFRDIS score ≥3, n=15), larger improvements in PROMIS SD and SRI, and hot flash control were observed (p<0.05). Device use in PNS (baseline mean±SD 21.7±1.2 vs intervention 17.4±2.5, p<0.05). There was a positive correlation between the number of subjective hot flashes and number of sessions logged by the device (r=0.502, p<0.01). No adverse events were reported. Conclusion: Results support the feasibility of the Embr Wave for management of sleep-disrupting hot flashes and night sweats in menopausal women. The intervention was associated with improvements in subjective measures of sleep, hot flashes, and perceived stress. The correlation between number of device sessions and number of hot flashes supports use of the device for management of hot flashes. Future larger studies to evaluate the impact of daytime and nighttime use of the Embr Wave on hot flashes and other menopausal symptoms are planned.

Sources of Funding: Embr Labs

<table>
<thead>
<tr>
<th>Measures (N=31)</th>
<th>Baseline mean±SD</th>
<th>Intervention mean±SD</th>
<th>P-value</th>
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<tr>
<td>PROMIS SD T-score</td>
<td>55.7±6.9</td>
<td>52.2±6.2</td>
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<td>PROMIS SRI T-score</td>
<td>55.6±8.4</td>
<td>51.6±8.3</td>
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<td>ISI</td>
<td>11.8±4.2</td>
<td>9.2±4.6</td>
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<tr>
<td>HFRDIS</td>
<td>3.2±2.1</td>
<td>2.7±2.0</td>
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</tr>
<tr>
<td>Number of nighttime hot flashes (7-day cumulative)</td>
<td>14.8±9.0</td>
<td>12.0±9.2</td>
<td>0.025</td>
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<tr>
<td>Number of severe nighttime hot flashes (7-day cumulative)</td>
<td>3.2±2.7</td>
<td>2.3±2.6</td>
<td>0.011</td>
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<tr>
<td>Control over nighttime hot flashes</td>
<td>2.6±2.8</td>
<td>3.6±3.1</td>
<td>0.034</td>
</tr>
</tbody>
</table>

P-58. Menopause symptoms and eating habits of postmenopausal women in times of the SARS-CoV-2 pandemic

Mônica G. Nascimento1, Luna Bavyer1, Bruna Oliveira1, Priscilla R. e Silva Noli2, Matias Noli2, Ricardo dos Santos Simes1, Edmund Chada Baracat1, Isabel C. Esposito Sorpreso3, José M. Junior1. Obstetrics and Gynecology, Universidade de Sao Paulo Hospital das Clinicas, Sao Paulo, Brazil; 1Department of Public Health, Instituto Federal de Goiano, Goiania, Brazil; 3Universidade de São Paulo, Faculdade de Saúde Publica, São Paulo, Brazil

Objective: This study aimed to compare dietary intake and menopausal symptoms in postmenopausal women before and during the current pandemic scenario. Design: Cohort design with 271 integrants and Research participants were asked to complete health questionnaires during the SARS-CoV-2 pandemic. Data on eating habits were collected via telephone interview with the aid of the 24-hour food recall. To relate the data on eating habits, the foods and preparations were classified according to the degree of processing, following the NOVA classification: culinary preparations (sum of natural and minimally processed foods and culinary ingredients), processed foods and ultra-processed foods. The obtained data were typed and tabulated in Excel spreadsheet and analyzed in the Statistical Package for the Social Sciences (SPSS) program version 21.0.

Results: During the pandemic, 73 (26.6%) of postmenopausal women continued to participate in the study. Of these, 2.7% (2) were diagnosed with COVID-19 and 97.3% (71) were in social isolation. Regarding menopausal symptoms, the intensity of total and vasomotor symptoms during social isolation (17.73 ± 9.99) was lower compared to the pre-pandemic period (22.49 ± 10.53)(p=0.001). About food intake, the succession of food groups consumed by postmenopausal women followed the pattern of the pre-pandemic period (culinary preparations, ultra-processed and processed foods, respectively), with a significant exception of the intake of processed foods from 8.66 to 5.44 calories (p<0.001). Conclusion: Women showed a decrease in the intensity of menopausal symptoms during social isolation compared to the pre-pandemic period. Also, the food intake of postmenopausal women showed similarities between the pre-pandemic period and during social isolation, with a decrease in the intake of processed foods.

Sources of Funding: Conselho Nacional de Desenvolvimento Científico e Tecnológico (CNPq).

P-59. A Overview Of Systematic Reviews In Medicinal Plants And Herbal Formulations For The Treatment Of Climacteric Symptoms: A Lack Of Research On Southern Hemisphere Plants

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Objective: The purpose of this study is to examine the medicinal plants and phytotherapeutic resources that are used to treat climacteric and menopausal symptoms.

Method: The study was a systematic review of the available literature of the overview type. The theme was searched in the following databases: PubMed, Scielo, Virtual Health Library - PAHO, Scopus, Web of Science, and EMBASE; the search strategy for each database was constructed using the following key terms and their variants: Phytotherapy, herbology, menopause, postmenopause, and perimenopause, menopausal symptoms, and menopausal transition. The following criteria were used to determine eligibility: systematic reviews and meta-analyses; articles written in English, Spanish, or Portuguese; and dates ranging from 11/01/1994 to 11/01/2022.

Results: The following criteria were used to determine eligibility: systematic reviews and meta-analyses; articles written in English, Spanish, or Portuguese; and dates ranging from 11/01/1994 to 11/01/2022.

Conclusion: The majority of reviews identified examine the impacts of SARS-CoV-2, the plant with the most studies in the assessed literature, and its derivative products.

Sources of Funding: None
P-60. Social Media as Health Education Strategy for Women in The Menopause and Postmenopausal Transitions and Medical Students: A CAI-FABIO S. FORTES1,2, Camila C. Franciscutti1, Mariana Machado1, Nayara S. Sousa Santos1, Adriana S. Hashimoto1, Adriana S. Hashimoto1, Caroline da Silva Burch1, José M. Soares Júnior 1, Isabel C. Esposito Sorpreso 1. 1Ginecologia e Obstetricia, Universidade Anhembi Morumbi, Sao Paulo, Brazil; 2Instituto Federal Goiano, Goiania, Brazil

Objective: To analyze social media as a health education strategy for women transitioning to menopause and postmenopause. Design: Between May and June 2021, the Gynecology Discipline of the Obstetrics and Gynecology Department of the University of São Paulo Medical School conducted a descriptive, exploratory, qualitative study through the CAI-FABIO 2020-2021-funded project “Health Education for Women in the Transition to Menopause and Postmenopause.” The project was initiated by the University of São Paulo Undergraduate Pro-Rectorate. During the pre-implementation stage of the media channels, an online form was created using Google Forms and distributed via social communication platforms (Facebook, Instagram, and the researchers’ personal WhatsApp networks), where it was filled out by women in the transition to menopause and post-menopause using the “Snowball” sampling technique.

Sociodemographic data were collected, as were questions about the period’s meaning, recognition, and experience. Additionally, Google Trends provided information on the major trends in search tools for the following search terms: climacteric, menopause, pre-menopause, and post-menopause. Results: Medical students developed social media channels and a website dedicated to the gynecological field at the University of São Paulo Medical School: “287 women between the age of 40-83 years (SD = 14.3) submitted a form; 36.9% were from Brazil, 31% from the USA, 19% from Colombia, 16.5% from France, and 11.3% from Brazil.” Important, 70.3% (38/54) considered that, because of the menopause transition period in the qualitative studies were “mood swings,” “heat,” “loss of libido,” “vaginal dryness,” “irritation,” “tiredness,” “discomfort,” “aging,” “insomnia,” “weight changes,” and “changes.” The research culminated in the creation of a website, www.menopausando.com.br, as well as pages on the social media platforms Instagram, Facebook, and a SPOTIFY podcast aimed at educating women in the menopause transition and postmenopause about their health. In the first 60 days of the channels’ existence, 340 Instagram followers, 70 Facebook followers, and eight podcast episodes aired on the SPOTIFY platform were added, as well as three requests for interviews on television and radio channels due to the channels’ social media presence. Conclusion: The establishment of channels facilitated communication between undergraduate students and the community. Simple, low-cost, and with a large potential reach, aside from being an effective tool for preventative awareness and health promotion among women in menopause and postmenopause, enhances quality of life and menopausal symptoms in a playful and educational manner. This interest is reinforced by data from Google Trends, which indicates a similar trend in search terms. Thus, the exploratory study helped fund the development of the website “Menopausando” and other social media platforms (Facebook, Instagram, and Spotify) that were made by students with the help of their teachers. This allowed for fun learning, a lot of communication with the community, and the wide spread of knowledge.

Sources of Funding: Edital 01/2020-2021-funded project “Health Education for Women in the Transition to Menopause and Postmenopause”

P-61. Bioidentical Compounded Hormones. What do the patients know? Cross-Sectional Survey

Cristina A. Ramírez Colunga, Dra., Eva M. Márquez Mata, Selene Garcia-Luna, Ph.D, Arturo Morales-Martínez, Dr.,md., Luis H. Soria-Hernández, Dr.,md., Otto Valdés-Martínez, Dr., Centro Universitario de Medicina Reproductiva, Universidad Autónoma de Nuevo León, Monterrey, Mexico

Objective: To assess the knowledge, perceptions and preferences about the bioidentical hormone therapy in menopausal patients. Design: Cross-sectional online surveys about their knowledge and use of BCH were carried out on menopausal women that first-attended the Menopause clinic at a University Hospital in Monterrey, Mexico. The surveys were applied from May 15 to June 15, 2022 using the Google forms platform. Obtained responses were recorded on an Excel database and analyzed using GraphPad Prisim. Results: A total of 57 patients agreed to participate in the survey, 5% of whom were excluded for not fully responding to the questionnaire. Of the 54 women surveyed, the age span was 57 years (sd = 6.3). Less than 54% (30.4%) of the participants had heard or read anything about BCH. Their main source of information was a health professional (34.7%, 8/23), followed by internet sources (30.4%, 7/23) and a family member or friend (30.4%, 7/23). Importantly, 70.3% (38/54) considered that, because they are bioidentical, they are safer compounds than conventional hormones. Therefore, if they require HRT to attenuate symptoms related to menopause they would prefer to use BCH therapy (OR 555, 95% CI 32.52-57.53, p = 0.0001). In addition, 90.7% (49/54) of the participants considered that BCH does not represent a risk for the development of breast and endometrium cancer. As expected, the term “bioidentical” was a deceiving and confounding term, since the responders that referred not to have knowledge about the BCH considered the synonym of “natural” and that does not pose a risk to their health therefore would prefer to use BCH over conventional hormonal therapy if needed.

Sources of Funding: None

P-62. A Sex-based Analysis to Address the Question: Do Reproductive Hormones Associate with Cognitive Performance in Older People Living with HIV (PLWH)?

Nancy K. REAME, PhD, MSN, NCMP,1,2,3,4 Anael Gondain-Arroyo, MPD,1 Jose Gutierrez-Castellanos, MD, MPH,1,4,5,6,7,8,9 Rebecca Schnell, Ph.D, MPH1,1, School of Nursing, Columbia University Irving Medical Center, New York, NY; Department of Neurology, Columbia University Irving Medical Center, New York, NY; Department of Population and Family Health, Mailman School of Public Health, Columbia University Irving Medical Center, New York, NY

Objective: In PLWH, even when well-controlled, neurocognitive decline is accelerated with aging. Although sex differences are generally under-studied, women living with HIV (WLWH) versus affected men (MLWH) show cognitive vulnerabilities. Besides psychosocial influences, the role of menopause - when estradiol declines and FSH rises - has emerged as a possible sex-specific factor underlying these differences, but relative hormonal contributions are unclear. To better distinguish the influence of sex hormones on cognitive performance in PLWH, we conducted a sex-based bivariate and multivariate analysis of cognitive domain measures and selected reproductive hormones drawn from a larger community sample of non-white older PLWH previously characterized for cerebrovascular disease features (Gutierrez et al, 2020) and sex differences in white matter hyperintensities (NAMS poster, 2021, manuscript under review). Design: In the parent study, 85 participants aged 50-75 and living with HIV were enrolled in the cross-sectional study and completed a neuropsychological assessment, a blood draw, a demographic survey, health questionnaire and a magnetic resonance imaging (MRI) scan. Single plasma hormone measures for estradiol (E2), testosterone (T), dihydroepiandrosterone sulphate (DEAS) and follicle stimulating hormone (FSH) were determined via immunoassay. The neuropsychological evaluation consisted of a standard set of tests previously described (Gutierrez et al, 2020) to assess 6 cognitive domains: verbal intelligence, attention, recall, motor processing speed, language, and memory. After excluding hormonal users (n=6), data from 44 women and 35 men were analyzed to compare demographics, cardiovascular, dementia and HIV risk factors, log-transformed sex hormone values and cognitive domain score averages of the study participants. Bivariate and moderation analysis using multivariable general linear regression models was conducted. Results: As previously reported (NAMS, 2021), there were no differences in demographics, cardiovascular and dementia risk factors or HIV health status in this sample of PLWH (mean age 59.8±6.6 years, 55.7% female, 72% non-Hispanic black). Reproductive hormone differences as expected by sex, menopause status and age. In WLWH, cognitive domain Z scores were higher than in WLWH for language fluency, episodic verbal memory, executive attention but not different than in WLWH. Trends for modestly strong associations between FSH and motor processing speed (r=0.25, p-value<0.05) as well as for DHEAS and verbal learning memory (r=0.31, p-value<0.05) were seen but only in females. After controlling for age, education, cranial size, and white matter hyperintensity volume, there was a significant interaction between sex and FSH for motor processing speed (B=-1.0866, p-value=0.0006) as well as for motor processing speed (B=-0.6856, p-value=0.0009). For females, there was a positive relationship between FSH and motor processing speed (B=0.8176, p-value=0.0009), whereas for males, a negative relationship was NS (B=-0.6431, p-value=0.16). Females also showed a positive relationship between DHEAS and motor processing speed (B=0.2792, p-value=0.04), whereas for males, there was a negative relationship (B=-0.4064, p-value=0.013) Conclusion: In PLWH, FSH and DHEAS demonstrate sex-specific associations with cognitive performance - a measure of cognitive function that has been linked to neurocognitive vulnerabilities in WLWH.

Sources of Funding: National Institutes of Health [R01NR015737]

P-63. Effects of BotherSome Symptoms during the Late Reproductive Stage and Menopausal Transition: Observations from the Women Living Better Survey

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Objective: BotherSome symptoms during the late reproductive stage and menopausal transition sometimes interfere with women’s activities of daily living and relationships, yet little is known about the specific effects of different groups of symptoms. Aims of these analyses were to examine the effects of bother related to 5 symptom groups for women’s assessment of 4 outcomes: interference with everyday activities, interference with relationships, “not feeling like myself,” and self-ratings of health. Design: Participants responded to the online Women Living Better survey during 2020. In addition to rating 61 symptoms as bothersome on a scale from not at all bothered (0) to highly bothered (6), they also rated the degree to which they interfered with their activities and relationships indicating not at all (0) to a great deal (4). They
indicated the extent to which they didn’t “feel like myself” choosing none of the time (0) to all of the time (4) and rated their health from poor (1) to excellent (5). Symptoms were grouped using results of principal components analysis. Five symptom groups with the highest bother ratings were analyzed for this report, including: brain fog, volatile mood, fatigue/pain, VMS/sleep onset, and anxiety/vigilance symptoms. Two-stage hierarchical regression analysis was used to examine personal characteristics of the participants such as education, menopause-related factors, roles and stressors (stage 1) and the association between symptoms and VMS/sleep onset symptom groups.

Interference with relationships was correlated with being in a committed relationship and bother related to all 5 symptom groups. “Not feeling like myself” was related to having completed less education, reporting greater overall stress, brain fog, and fatigue/pain symptoms. Of interest was that VMS/sleep onset symptoms, often attributed to the menopausal transition, were not related to either “not feeling like myself” or self-ratings of health. Moreover, self-rated health was related only to fatigue/pain symptom bother. Conclusion: These findings suggest that the experience of symptoms that are typically unrelated to developmental event may be experienced as unrelated to one’s health. Further clarification of which symptoms can be attributed to perimenopause rather than other factors such as aging, will improve anticipatory guidance about perimenopause. Similarly additional investigation of the meaning of the phrase “not feeling like myself” could help guide patients’ expectations by 1.3 years (95% CI -3.2 to 0.7, p=0.21), but the results were statistically insignificant. Similarly, in the 1-3 ACE group, increases in the age at natural menopause by 0.3 years (95% CI -1.6 to 1.2, p=0.41), but the results were statistically insignificant. Similarly, in the 1-3 ACE group, increases in the age at natural menopause by 0.3 years (95% CI -1.6 to 1.0, p=0.07), and a history of ≥4 ACEs decreased the age at menopause by 1.3 years (95% CI -2.8 to 1.2, p=0.41), but the results were statistically insignificant. Similarly, in the 1-3 ACE group, decreases in the age at natural menopause by 0.8 years (95% CI -2.8 to 1.2, p=0.17), and a history of ≥4 ACEs significantly increased the odds of FSD compared to No ACEs group (p<0.001). In the univariate analysis, a history of ≥4 ACEs was related to more bothersome anxiety/vigilance, volatile mood, brain fog, and fatigue/pain symptoms. Of interest was that VMS/sleep onset symptoms, often attributed to the menopausal transition, were not related to either “not feeling like myself” or self-ratings of health. Further clarification of which symptoms can be attributed to perimenopause rather than other factors such as aging, will improve anticipatory guidance about perimenopause. Similarly additional investigation of the meaning of the phrase “not feeling like myself” could help guide patients’ expectations.

Marriam Saadedine, Doctor of Medicine1, Stephanie Faubion, MD, MBA1,2, Ekta Kapoor3, Kristin Mara1, Felicity Enders, PhD1, Paru Dave, MD3, Juliana M. King, MD, MPH1, 4Faculty of Medicine, American University of Beirut, Beirut, Lebanon; 2Division of General Internal Medicine, Mayo Clinic, Jacksonville, FL; 3Mayo Clinic Women’s Health, Rochester, MN; 4Division of General Internal Medicine, Mayo Clinic, Rochester, MN; Department of Quantitative Health Sciences, Mayo Clinic, Rochester, MN; Division of Women’s Health Internal Medicine, Mayo Clinic, Scottsdale, AZ.

Objective: Women globally continue to experience different forms of adversity including adverse childhood experiences (ACE). More than half of the women in the US have experienced an ACE in their lives. Beyond the immediate harmful impacts of childhood adversity, these life experiences are associated with reduced quality of life and lower life expectancy. ACE have also been associated with more severe menopause symptoms. However, the association between ACE and age at natural menopause has not been well elucidated. One study showed that women with a history of childhood physical abuse (her child’s sexual abuse) was associated with an earlier age at natural menopause. While menopause is a natural process, it has been linked with accelerated aging. Similarly, increasing age at menopause has been associated with a greater risk of mortality. The objective of this study was to evaluate the association between ACE and the age at natural menopause.

Design: A cross-sectional analysis from the Data Registry on the Experiences of Aging, Menopause, and Sexuality (DREAMS) was conducted using questionnaires completed by postmenopausal women who went through natural menopause (have gone 12 consecutive months without a period), and who presented to a women’s health clinic at Mayo Clinic, Rochester, MN from May 2015 to December 2016. History of childhood adversity was obtained with the validated ACE questionnaire. The association between ACE and age at natural menopause was measured using a linear regression model, adjusting for educational level, race/ethnicity, smoking, obesity, marital status, and employment status.

Results: A total of 350 women were included in the analysis with mean age at menopause of 50.9 years. At the time of the clinical visit, women were of mean age 59.2 years, white (92.9%), partnered (82%), educated (91.3%), 54% reported having at least one ACE. Women were classified according to the number of ACEs: no ACE, 1-3 ACE, and a 4 ACE. Nearly half (41.7%) reported 1-3 ACE and 12.6% had a 4 ACE. The age at natural menopause decreased sequentially as the number of ACE increased: 51.2 years with no ACE, 50.8 years with 1-3 ACE, and 50.3 with 4 ACE. In the univariate analysis, a history of 1-3 ACE decreased the age of menopause by 0.4 years (95% CI -1.7 to 1.0, p=0.6), and a history of ≥4 ACE decreased the age at menopause by 0.8 years (95% CI -2.8 to 1.2, p=0.41), but the results were statistically insignificant. Similarly, in the 1-3 ACE group, decreases in the age at natural menopause by 0.3 years (95% CI -1.6 to 1.0, p=0.07), and a history of ≥4 ACE decreased the age of menopause by 1.3 years (95% CI -3.2 to 0.7, p=0.21), but the results were statistically insignificant. Conclusion: While stressful life experiences like ACE can theoretically influence the age at natural menopause, further studies are needed to confirm these findings, and to assess for other factors that may influence the age at natural menopause.

Sources of Funding: None

P-66. Associations between Childhood Adversity and Age at Natural Menopause

Mariam Saadedine, Doctor of Medicine1, Stephanie Faubion, MD, MBA1,2, Ekta Kapoor3, Kristin Mara1, Felicity Enders, PhD1, Paru Dave, MD3, Juliana M. King, MD, MPH1, 4Faculty of Medicine, American University of Beirut, Beirut, Lebanon; 2Division of General Internal Medicine, Mayo Clinic, Jacksonville, FL; 3Mayo Clinic Women’s Health, Rochester, MN; 4Division of General Internal Medicine, Mayo Clinic, Rochester, MN; Department of Quantitative Health Sciences, Mayo Clinic, Rochester, MN; Division of Women’s Health Internal Medicine, Mayo Clinic, Scottsdale, AZ.

Objective: Women globally continue to experience different forms of adversity including adverse childhood experiences (ACE). More than half of the women in the US have experienced an ACE in their lives. Beyond the immediate harmful impacts of childhood adversity, these life experiences are associated with reduced quality of life and lower life expectancy. ACE have also been associated with more severe menopause symptoms. However, the association between ACE and age at natural menopause has not been well elucidated. One study showed that women with a history of childhood physical abuse (her child’s sexual abuse) was associated with an earlier age at natural menopause. While menopause is a natural process, it has been linked with accelerated aging. Similarly, increasing age at menopause has been associated with a greater risk of mortality. The objective of this study was to evaluate the association between ACE and the age at natural menopause.

Design: A cross-sectional analysis from the Data Registry on the Experiences of Aging, Menopause, and Sexuality (DREAMS) was conducted using questionnaires completed by postmenopausal women who went through natural menopause (have gone 12 consecutive months without a period), and who presented to a women’s health clinic at Mayo Clinic, Rochester, MN from May 2015 to December 2016. History of childhood adversity was obtained with the validated ACE questionnaire. The association between ACE and age at natural menopause was measured using a linear regression model, adjusting for educational level, race/ethnicity, smoking, obesity, marital status, and employment status.

Results: A total of 350 women were included in the analysis with mean age at menopause of 50.9 years. At the time of the clinical visit, women were of mean age 59.2 years, white (92.9%), partnered (82%), educated (91.3%), 54% reported having at least one ACE. Women were classified according to the number of ACEs: no ACE, 1-3 ACE, and a 4 ACE. Nearly half (41.7%) reported 1-3 ACE and 12.6% had a 4 ACE. The age at natural menopause decreased sequentially as the number of ACE increased: 51.2 years with no ACE, 50.8 years with 1-3 ACE, and 50.3 with 4 ACE. In the univariate analysis, a history of 1-3 ACE decreased the age of menopause by 0.4 years (95% CI -1.7 to 1.0, p=0.6), and a history of ≥4 ACE decreased the age at menopause by 0.8 years (95% CI -2.8 to 1.2, p=0.41), but the results were statistically insignificant. Similarly, in the 1-3 ACE group, decreases in the age at natural menopause by 0.3 years (95% CI -1.6 to 1.0, p=0.07), and a history of ≥4 ACE decreased the age of menopause by 1.3 years (95% CI -3.2 to 0.7, p=0.21), but the results were statistically insignificant. Conclusion: While stressful life experiences like ACE can theoretically influence the age at natural menopause, further studies are needed to confirm these findings, and to assess for other factors that may influence the age at natural menopause.

Sources of Funding: None

P-65. Approximating Systemic Estrogen Exposure from Vaginal Estrogen Cream Therapy

Mark Newman, MS, Doreen Saltiel, MD, JD, Desmond A. Curran. Precision Analytical, McMinnville, OR

Objective: It is not clear if vaginal application of estrogen results in clinically significant systemic effects, though this would likely only occur at high doses. Collecting real-world data regarding systemic estrogen exposure from vaginal estrogen use is difficult as serum methods used for approximating systemic estrogen exposure are not validated and may lead to inaccurate results. One objective of this study was to determine if high dose vaginal estrogen cream use showed expected dose-dependent increases in urinary estrogen levels. Secondly, cases with high dose vaginal therapy were examined to test the hypothesis that only removing estrogen from the vagina as a variable would fully remove any potential contamination for accurate analysis of systemic estrogen exposure.

Design: This was a retrospective observational study conducted using data from the database of a diagnostic laboratory (Clinical Trials ID: NCT04365093). Results included urinary concentrations of 10 different estrogen metabolites, so we included the potential for multiple other adverse health outcomes, as indicated by over 100,000 results, 58 postmenopausal women met inclusion criteria and had both baseline results and results while using a 0.1 mg dose of vaginal estrogen cream, Bisest (60% E3, 40% E2; applied to the labia daily). From this group, 30 women had an
additional measurement while using 0.25 mg and 17 women (non-overlapping) had a measurement at doses of 0.04 mg (E2) and higher may be absorbed systemically in significant amounts. This indicates a need for further investigation, ideally with larger, prospective studies. The sampling method and accompanying assay used in this study may represent an ideal tool for further study due to the ease of sample collection and the ability of urine to capture and represent a greater proportion of the pharmacokinetic patterns exhibited by estrogen cream.

Sources of Funding: None

P-67.

The Impact of 3,3′-Diindolylmethane on the Estrogen Profile of Postmenopausal Women Being Treated with a Transdermal Estradiol Patch

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Objective: This was a retrospective observational cohort study for which data were collected from a database containing 144,561 laboratory tests, Kruskal-Wallis tests, and paired t-tests were used to assess for differences between groups. Results: When compared to postmenopausal women using a transdermal E2 patch, of which 108 indicated that they were concurrently taking a DIM supplement and, if so, potentially similar MHT dose adjustment or other therapy changes.

Sources of Funding: None

P-68.

The Effects of Diet on Menstrual Pain

Sarah Sannoh. Rutgers The State University of New Jersey, New Brunswick, NJ

Objective: There were no studies found on the mental health profiles of honorably discharged veterans, why they were discharged, and much more information on the individuals included in the study. Is there research done on the mental health profiles of the honorably discharged and if so, do these studies include women? Objectives: Review articles on this topic to find background information Design: Methods: Searching article databases like PubMed and the Rutgers Library using search terms such as “menstrual health”, “menstrual health profiles”, “dishonorably discharged”, and “women”. Results: There were no studies found on the mental health of honorably discharged women from the armed forces. While we did find a few studies about the correlation between dishonorable discharge and a few different topics like drug addiction, none of these studies included gender at all in their studies. It was also unclear in these studies why the participants were dishonorably discharged in the first place. Being dishonorably discharged has a wide range of reasons for it, most commonly drug abuse or misdeeds in the armed forces, but it could have a correlation as to why certain women become dishonorably discharged in the first place.

Conclusion: More research is needed in this field, as we did not find any data that was specifically about the mental health profiles of dishonorably discharged women, and further studies would allow researchers to understand the mental toll that being dishonorably discharged has on women.

Sources of Funding: None

P-69.

Mental Health Profiles for Dishonorably Discharged Women

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Objective: Background: There is a vast amount of research discussing the impact of the American diet on health outcomes. Given that menstrual pain is a common complaint among adolescent girls, it is important to understand the factors that contribute to it.

Methods: Multivariate regression analyses to account for age, body mass index (BMI), E2 patch dose, and urinary creatinine confirmed the observed differences in estrone (p=0.004), 3,3′-dimethylbenzylamine (DMB) (p=0.004), 4-hydroxyestrone (p=0.01), 16-hydroxyestrone (p=0.02), however, E2 (p=0.19) and 16-hydroxyestrone (p=0.1) no longer reached significance for the effect of DIM. Although E2 was no longer significant in the multivariate analysis, the point estimate (beta=0.042) was similar to the findings in premenopausal women with a 9.2% decrease in urinary E2 concentrations at each increased dose of the E2 patch. Conclusion: These results are a substantial addition to the literature as there are not many published studies investigating the effects of DIM on MHT, especially with large sample size. Postmenopausal women on transdermal E2 patch therapy (and potentially other MHT formulations) who choose to concurrently use a DIM/ES supplement may have clinically significant changes in their estrogen profiles, potentially as a result of altered estrogen metabolism.

4-hydroxyestrone could combine to decrease the overall estrogenic impact of therapy on key clinical endpoints such as bone mineral density and symptom improvement. The presence and magnitude of these changes suggests that providers treating postmenopausal women with MHT should ask their patients if they are taking a DIM supplement and, if so, potentially consider MHT dose adjustment or other therapy changes.

Sources of Funding: None

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P-70. An animated educational video on cancer screening: resource to educate post-menopausal incarcerated women

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Objective: Menopause is an age-related physiological transition that usually occurs in women between the ages of 40 and 50. Addressing health issues relevant to post-menopausal incarcerated women is increasingly important as women ages 55 and older are one of the fastest-growing groups in prison and also are at high risk of developing cancer. Although data suggest that the general population and incarcerated individuals have similar prevalence rates for cancer; the incarcerated population has a higher mortality rate. The epidemiology of cancer is different in the prison population, as there is a greater prevalence of known risk factors such as smoking, HIV, alcohol, and limited screening. There is a disparity for screening in the prison population: 77.1% of prisoners are 1.5 times more likely to be overdue for screening compared to 50.5% of the general population. Delays in screening also could explain why most prisoners receive diagnoses of some types of cancer, such as colon cancer, in later stages. Additionally, prisoners have a higher lung cancer incidence rate than the general population; probably due to a higher rate of smoking than the general population. From these data, teaching animated videos on the importance of preventive health/cancer screenings were developed by the NJ Commission on Women’s Reentry (NJCWR) and the Women’s Health Institute (WHI). The objective of this project is to educate incarcerated menopausal women on the importance of cancer screening to contribute to reducing mortality in this group.

Design: The 2021 Powtoon website was used to create educational animations that were set in a correctional facility, with characters from various ethnic backgrounds to broaden representation. Voiceovers were used for individuals who prefer to listen, and speech balloons were used for those who prefer to read. Results: Animations on cancer screening relevant to post-menopausal incarcerated women to date include one on colorectal and one on lung cancer screening. The group is continuing to produce additional animated videos on other preventive health topics. To date, no formal data on acceptance by the women has been collected. Conclusion: The use of animated educational materials can be used to engage post-menopausal incarcerated women. They also are cost-effective and can represent diverse groups within the target population. Poor health literacy is shown to act as a barrier to healthcare for incarcerated individuals, limiting their ability to make informed health care decisions. Educating post-menopausal prisoners on cancer screening may improve self-advocacy and compliance with recommended testing, which could decrease health disparities. As there are growing challenges involving cancer care in prisons, it is essential to implement programs and conduct research on how these materials improve health education.

Sources of Funding: None

P-71. Mammmogram to Medical Home: Increasing Access to Care Nurse Practitioner Program

Angela Schlaffey, FNP. Mammmogram to Medical Home, The Rose, Houston, TX

Objective: Since 1986, The Rose has provided high quality breast care to all women, regardless of their ability to pay. Our mission is to save lives through quality health services and access to care for all. Texas has the highest number of uninsured individuals, and more than half of the state’s uninsured residents are below 200% of the Federal Poverty Level. Without insurance, without a medical home, these women do not have the advantages of routine screening; and health issues that could be easily resolved escalate to chronic disease. Approximately 10% of breast cancers are diagnosed in the early, most treatable stages. The National Breast Cancer Coalition estimates that if women of all ages were to have access to breast cancer care, up to 50% of breast cancers could be caught in the earliest stages. By offering this service, women will start with breast care in a medical home promoting healthy behaviors and early detection, reducing the risk of unnecessary treatments, and improving the overall health of all women, regardless of their ability to pay. The Rose announces the launch of the new “Mammogram to Medical Home” (M2MH) initiative.

Design: M2MH is a new outreach program that will provide women with access to care through a 12-week double blind period. Interested patients first call The Rose and apply for sponsorship. Once qualified, the woman is scheduled for a focused assessment/breast exam with a nurse practitioner. At the initial appointment the patient answers a brief medical history and health assessment. The nurse practitioner then reviews the information, performs a focused exam, clinical breast exam and educated on the importance of having a medical home. The patient is then given the appointment for mammogram. After the mammogram is completed, the report is sent to the NP. If the report is benign, the patient is then navigated into a medical home to increase access to primary care. The patient is followed for 1 year with phone calls with the goal of the patient to have at least 1 visit to the recommended medical home within a year from her breast exam visit at The Rose. Results: The program was launched in September of 2021 and the preliminary data is promising. To date, we have received 203 referrals, 87 patients have been enrolled into the program. 45 have been navigated into a medical home. Of eligible cancers were placed along with 2 biopsy excisional. Uninsured women who are diagnosed receive treatment through The Rose Patient Navigation Program. Conclusion: By offering this service, women will start with breast health care and be led into a relationship with a medical home to increase access to primary care resulting in a healthier community.

Sources of Funding: pending

P-72. Breast Cancer: The Effect of Endogenous and Exogenous Hormones

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Objective: According to the American Cancer Society, the lifetime risk of developing breast cancer is 1 in 8. The median age at diagnosis is 62, so this is more often a problem in postmenopausal women. The link between both endogenous hormones and exogenous hormones has not been defined. The number one cause of death in women is heart disease, yet they fear breast cancer and often do not want to consider hormone therapy due to this fear. In a recent publication, “Workshop on normal reference ranges for estradiol in postmenopausal women, September 2019, Chicago, Illinois” in Menopause: The Journal of The North American Menopause Society (Vol. 27, No. 6, pp. 614-624), estradiol levels in postmenopausal women were evaluated. Part of the conclusion was “The existing data provided substantial evidence to support estradiol to predict risk.” In this didactic and informative talk, the biochemistry and physiology of female hormones in the breast will be discussed. Published literature regarding the risks of hormone therapy for breast cancer will be reviewed. Studies identifying any link between endogenous hormone patterns and breast cancer will also be reviewed. Design: 1. Review Hormone physiology as it pertains to cancer. 2. Discuss estrogen detoxification pathways as they relate to breast cancer risk. 3. Review the published literature on HRT and Breast cancer risk, and address options for hormone therapy in the high-risk patient. 4. Review the published literature on endogenous hormones and breast cancer risk, including estrogen metabolites. 6. Provide strategies to shift the focus on breast cancer from early detection to prevention. Results: The results will be presenting the literature review. Conclusion: 1. Endogenous hormone levels contribute to breast cancer risk and should be monitored in high-risk patients. 2. Breast cancer risks due to hormone replacement therapy varies based on the dose, duration, and preparation of the hormone given. The risks can not be extrapolated to all types of hormones. 3. Differences in estrogen metabolism can affect breast cancer risk, and levels of estrogen metabolites could help further identify high-risk patients. 4. A more comprehensive prevention for the patient at high risk for breast cancer is possible.

Sources of Funding: None

P-73. Early response with fezolinetant treatment of moderate-to-severe vasomotor symptoms associated with menopause: pooled data from two randomized Phase 3 studies

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Objective: Women suffering from bothersome vasomotor symptoms (VMS) need effective, rapid relief. These analyses assessed early response with fezolinetant using pooled data from SKYLIGHT 1 and 2 (NCT04003155; NCT04003142). In both studies the four co-primary efficacy endpoints were met and fezolinetant was well tolerated. Design: SKYLIGHT 1 and 2 were double-blind, placebo-controlled Phase 3 studies with the same design. Women aged 40-65y with moderate-to-severe VMS (average ≥7 hot flashes/day) were randomized to once-daily placebo, or fezolinetant 30 mg or 45 mg for 12 weeks. Results: 1022 women were randomized and took ≥1 dose (placebo n=342, fezolinetant 30 mg n=339, fezolinetant 45 mg n=341). A trend in improvement in mean change from baseline in daily moderate and severe VMS frequency vs placebo was seen from day 1 (Figure). Significant reduction in frequency of moderate and severe VMS was evident from week 1 after start of treatment and was greater in both fezolinetant groups compared to placebo (SE) at week 1 was −1.59 (0.28), p<0.001 for fezolinetant 30 mg and −1.46 (0.28), p<0.001 for 45 mg. At week 4, these values were −1.89 (0.32), p<0.001 for fezolinetant 30 mg and −2.28 (0.32), p<0.001 for 45 mg. Significant improvement in severity of VMS was also seen as early as week 1 across all doses of treatment for both fezolinetant doses and was greater with fezolinetant than placebo. Improvements in VMS frequency and severity were sustained throughout the 12-week double-blind period. Conclusion: Pooled data from SKYLIGHT 1 and 2 show an effect of fezolinetant on VMS frequency from day 1, reaching statistical significance at weeks 1 and 4. An effect on VMS severity was seen as early as week 1. Both effects were maintained through the 12-week double-blind period.

Sources of Funding: Astellas Pharma Inc. Medical writing support was provided by Sue Cooper of Excel Scientific Solutions and funded by Astellas Pharma Inc.
P-74. Effect of fezolinetant treatment on patient-reported sleep disturbance: pooled data from two Phase 3 studies in women with moderate-to-severe vasomotor symptoms associated with menopause

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Objective: To assess the effect of fezolinetant on patient-reported sleep disturbance using pooled data from SKYLIGHT 1 and 2 (Phase 3; NCT04003155; NCT04003142). In these studies, fezolinetant significantly improved the frequency and severity of vasomotor symptoms (VMS) vs placebo and was well tolerated. VMS associated with menopause can significantly impact sleep. Design: SKYLIGHT 1 and 2 were double-blind, placebo-controlled studies with the same design. Women aged \( \geq 40 \)–65 y with moderate-to-severe VMS (average \( \geq 7 \) hot flashes/day) were randomized to once-daily placebo, or fezolinetant 30 mg or 45 mg for 12 weeks. Sleep was assessed using the Patient-Reported Outcomes Measurement Information System Sleep Disturbance – Short Form (PROMIS SD SF) 8b Total Score, Patient Global Impression of Change – Sleep Disturbance (PGI-C SD), and PGI of Severity – Sleep Disturbance (PGI-S SD).

Results: The pooled group comprised 1022 women who took at least 1 study dose. Fezolinetant 45 mg demonstrated a statistically significant improvement over placebo in sleep disturbance at weeks 4 and 12 using the PROMIS SD SF 8b, at weeks 4 and 12 using the PGI-C SD, and at week 4 using the PGI-S SD. Conclusion: Pooled data from SKYLIGHT 1 and 2 further demonstrate the beneficial effect of fezolinetant on sleep disturbance at week 4 using the PROMIS SD SF 8b, PGI-C SD, and PGI-S SD (Table).
moving from their feet to their heads. Sweating was the most negative characteristic of VMS (hot flashes and night sweats) were associated with greater heat, sweat, and anxiety. Our goal was to explore whether women who report NS differ in how changes in temperature and/or humidity may provoke hot flashes. Although participants were keen to wear the monitor for 24-hours, the BioLog monitor quit during 38% of the study period. However, the current frequency of hot flashes was negatively correlated with minimum temperatures (r=0.025, p<0.01) and mean temperature (r=0.196, p<0.01) levels of humidity, so that as humidity levels increased, the likelihood of hot flashes decreased. Additionally, participants were associated with more frequent and problematic hot flashes. The study reported here was conducted at the University of Massachusetts Amherst, Amherst, MA; 2Anthropology, University of Hawaii at Hilo, Hilo, HI

**Objective:** Hot flashes (HF) and night sweats (NS) are common during the menopausal transition. In literature, night sweats and hot flashes are often regarded as similar phenomena at different points in the 24-hour cycle and combined into one variable as vasomotor symptoms. HF can occur during the daytime or night and may or may not be associated with sweating, while night sweats are periods of intense sweating that occur during the nighttime. Our goal was to explore whether women who report NS differ in physiological and emotional experiences. VMS (hot flashes and night sweats) were examined by ANOVA. Pearson correlations were used to evaluate temperature, humidity, and hot flash frequencies (from the questionnaire and Biolog monitor). Logistic regression was also applied to examine temperature and humidity measures in relation to hot flashes while adjusting for menopausal status. **Results:** Mean ambient temperature ranged from 16.3 to 30.1°C (mean 22.6°C, s.d. 2.8); mean maximum humidity levels increased from 18.9% to 68.6% (mean 40.8%, s.d. 9.2). Minimum temperature was positively associated with minimum humidity (r=0.058, p<0.001) and mean temperature (r=0.163, p<0.001) levels of humidity. Hot flash bother was negatively associated with NS (correlation not at all at 31%, a little at 23%, somewhat at 23%, and a lot at 24%). In univariate analyses, maximum, minimum, and mean temperatures and humidity levels were not associated with hot flashes (yes/no) or with the bothersomeness of hot flashes. Temperature measures were not correlated with current frequency of hot flashes or with the frequency of objective or subjective hot flashes during the study period. However, the current frequency of hot flashes was negatively correlated with minimum temperatures (r=0.205, p<0.01) and mean temperature (r=0.196, p<0.01) levels of humidity, so that as humidity levels increased, the likelihood of hot flashes decreased. Increased numbers of participants were associated with more frequent and problematic hot flashes. The study reported here was conducted at the University of Massachusetts Amherst, Amherst, MA; 2Anthropology, University of Hawaii at Hilo, Hilo, HI

**Objective:** Vaginal atrophy (VVA) is a chronic condition that is caused by reduced estrogen levels during menopause. Ospemifene is a novel selective estrogen receptor modulator developed for the treatment of moderate to severe VVA symptoms in postmenopausal women. The objective is to perform a systematic literature review (SLR) and network meta-analysis (NMA) to assess the efficacy and safety of ospemifene compared to current therapies for the treatment of VVA. **Results:** In the total sample, 70% of participants experienced HF, and 63% experienced NS during the past two weeks. Women reported the highest frequency of HF at night (54%). In linear regression models, Hilo, HI

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P-79. Crila® Herbal Supplement is Associated with a Clinically Meaningful Effect on Symptoms Evaluated Using the Menopause-Specific Quality of Life Survey

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Objective: To assess the severity of menopausal symptoms with Crila® capsules taken twice daily, stratified by weight. As a novel, non-estrogenic, plant-based alternative, Crila is a proprietary extract from the patented cultivar Crinum Latifolium L var. crilae (Tram & Khanh; Design: 2019; A Prospective, Open-Label Dietary Supplement clinical study was approved by two Ethics Committees in Mexico to study oral Crila herbal supplements (Crinum latifolium L var. crilae Tram & Khanh) in menopausal women. In 2020-2021, women in Guadalajara and Queretaro took the estrogen-free botanical supplement twice daily over a 90-day period and evaluated their symptoms every 30 days according to MENQOL - a Menopause-Specific Quality of Life validated survey. Sixty-one women with menopausal symptoms received 4 to 10 capsules of Crila® for 3 months. This study was conducted utilizing a decentralized design at two centers in Mexico. Primary inclusion criteria: female subjects at least 45 years of age, BMI 26–30, and experiencing at least 35 vasomotor symptoms per week (average of 5/day) for the previous 3 months. Subject’s total study duration was 90 days from screening (Day 1) through conclusion of the Final Visit (Visit 4) (Day 90). Results: Sixty-one women finished the study. Impact of oral Crila® capsules on the severity of menopausal symptoms was assessed using the MENQOL. When compared to Visit 1, all 3 following visits have a significantly lower total score (P, 0.001 <0.05) (Figure 1, Table 2). Total score of Visit 2, significantly lower total score (P, 0.001 <0.05) compared to Visit 3 (P, 0.027 <0.05) and Visit 4 (P, 0.001 <0.05) (Table 1). Safety was assessed by frequency and severity of AEs, relationship of AEs to IP, vital signs, physical abnormalities. Crila® was well tolerated and none of the participants experienced any adverse reactions. Conclusion: Sixty-one women completed the study at the height of the COVID-19 pandemic. Data analysis confirmed 93% experienced symptom improvement. A decentralized design was key to study completion. The observed positive outcome supports the potential for larger sample size and longer duration studies.

Sources of Funding: Crila Health Pte. Ltd. (Singapore)

P-81. Designing and delivering a feminist research-informed return of results to midlife women: A method to understand and ‘foreground’ marginalized voices

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Objective: Midlife women’s experiences have not been adequately represented historically as most research is framed within and is interpreted by dominant conceptual categories largely developed by privileged individuals. Midlife women are thus a marginalized group with experiences that are shaped by a multiplicity of social locations including race, sexuality, class, and gender. Rather than starting with empiricist a priori categories of experience, this study initiated an inquiry informed by feminist standpoint theory. This is a method to understand and ‘foreground’ marginalized voices. We asked about the experiences of midlife women and subsequently returned the results to participants to clarify the research team’s interpretations. The purpose of this study was to design and deliver a feminist research-informed return of results (RoR) to midlife women as a part of a larger project to design an integrative medical group (IMGV) visit for peri- and post-menopausal individuals. Design: We conducted an engagement session with 9 midlife women and then employed qualitative analysis of the transcribed session. The research team then tabled themes, codes, and exemplary quotes. The data tables were presented during a RoR. Six of 9 engagement session participants attended the RoR. IRB ethics review was obtained. Results: The research team reviewed the data tables with midlife women and asked for corrections, confirmations, and clarifications. Participants provided corrections (e.g., we incorrectly listed Somalian and it was corrected to Somali). Participants also confirmed codes and themes in the data tables. Participants confirmed clarifications made and provided additional input. For example, after the engagement session, women’s thinking changed after hearing other women’s perspectives thus changing their perspectives. Several women mentioned that they had initiated care from a healthcare provider: one participant found a menopause group on Facebook and found the discussion there helpful. Participants emphasized the need for community- and language-specific tailoring to the IMGV; that the biggest identified need is education about this topic; and that gathering in a community to discuss these topics was deeply meaningful and life-changing. Dissemination of findings has included both traditional and non-traditional sources (social media, community, workshops, presentations). Conclusion: Midlife women’s experiences and perspectives provided a unique and critical input that helped the research team’s qualitative analysis of an engagement session transcript, thus ‘foregrounding’ participants’ lived experiences. Results indicate that participants were deeply engaged in the research and dissemination process and that there is a great need for more education about peri- and post-menopausal transitions, symptoms, and interventions.
**P-82.** Midlife Women’s Symptom Experience and Access to Medical and Integrative Health Care: Informing the Adaptation of an Integrative Medical Group Visit for Peri- and Post-Menopause

Lisa J. Taylor-Swanson, PhD, MAcOM1, Julie Fritz2, Kari D. Stoddard1, Belinda Anderson3, Melissa Cortez, DO1, Lisa Conboy2, Xiaoming Sheng, PhD, Naomi Flake2, Ana Sanchez-Birkhead, PhD, Louise Stark, PhD2, Marisol Jones, MBA2, Anna Camille Moreno, DO2, Sara Farah1, Luul Farah2, Dorienna Lee2, Heather Merkley, HHSc, RHA1, Lori Pacheco2, Wendy Sanders2, Fahima Tavake-Pasi2, Jeannette Villalta1, Cinnamon Geppelt, BSN, RN1, Paula Gardner, MD2, 1College of Nursing, University of Utah, Salt Lake City, UT; 2University of Utah Health, Salt Lake City, UT; 3Pace University, New York, NY; 4Harvard Medical School, Boston, MA; 5College of Health Professions, Weber State University, Ogden, UT; 6University of Massachusetts System, Boston, MA

**Objective:** Individuals in peri- and post-menopause often seek healthcare to better manage symptoms. However, many individuals who seek healthcare do not receive treatments for their symptoms. And, some lack access to providers of both medical care and evidence-based integrative health interventions such as acupuncture. Integrative medical group visits (IMGV) are a potential solution to this problem, which is the provision of medical care for multiple patients seen by one provider. The present study gathered the opinions of midlife women about interest in and desired elements of IMGV for peri- and post-menopause related symptoms and concerns.

**Design:** An Engagement Session with midlife women and two Community Advisory Board (CAB) sessions with community members and healthcare providers were conducted. In the Engagement Session, we sought to learn about midlife women’s experiences with peri-menopause, symptoms, barriers, and facilitators to accessing medical and integrative health providers, and their interest in and suggestions for the design of an IMGV. In the CAB sessions, we sought to inform the adaptation of an IMGV for peri- and post-menopause. Qualitative research methods were used to summarize session results. **Results:** Nine women participated in the Engagement Session. Eight community members and four healthcare providers participated in the two CAB sessions. Community members were diverse in terms of race/ethnicity, religious affiliation, and were highly educated. Themes included: an interest in participating in this conversation; that medical terms were mostly unfamiliar, and that terminology was less important than having a conversation; many symptoms were experienced; social factors affected participants, stressors the need for communication on this topic; receiving both unhelpful and helpful healthcare, a desire for whole person care; a need for information about what conditions Integrative Health interventions can treat, barriers to accessing both conventional and integrative care providers, and facilitators that included knowledge about insurance coverage. The group expressed great interest in the proposed IMGV model but expressed concerns about barriers such as a lack of time available, childcare, lack of insurance coverage, and language. Ideas for adaptation of the IMGV included: training community health workers, attention to midlife women’s pain and opioid prescriptions, choice of online, mobile, and in-person formats, and educational content for partners and family.

**Conclusion:** These findings highlight the importance of engagement of midlife women holders before and during the development of IMGV to address their great need among midlife women, particularly racially/ethnically diverse women, for education about peri- and post-menopause, evidence-based interventions, and self-care strategies.

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**P-84.** Safety, Tolerability and Usability of Oral Estradiol (E2) and Progesterone (P4) versus Two Formulations of Daré HRT1, an Intravaginal Ring Containing Biotidinal Estradiol (E2) and Progesterone (P4), in a Preclinical Pharmacological Study

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**Objective:** DARE-HRT1 is an ethylene vinyl acetate (EVA) co-polymer monthly intravaginal ring (IVR) of biotidinal 17β estradiol (E2) and progesterone (P4), being developed for treatment of moderate-to-severe vasomotor symptoms (VMS) with or without symptomatic vulvo-vaginal atrophy (VVA). **Design:** DARE HRT1-001 was a first-in-woman study of 28d treatment: 80 µg E2 + 4 mg/d P4 (IVR1) vs. 160 µg E2 + 8 mg/d P4 (IVR2) vs. oral E2 1 mg/d + oral P4 100 µg/d (ORAL). Participants completed a daily diary to record treatment emergent adverse events (TEAEs). At the end of treatment, IVR users completed an acceptability questionnaire. **Results:** Enrolled participants (n=34) were randomized to use IVR1 (n=10), IVR2 (n=12) or ORAL (n=12). Three participants were withdrawn from the study: two IVR2 users for unrelated TEAEs and one ORAL user for exclusionary pre-treatment laboratory criteria, thus 31 participants (IVR1=10, IVR2=10, ORAL=11) completed the study. Table 1 demonstrates that the TEAE profile of the IVRs were generally similar to the referent ORAL regimen. TEAEs were determined to be related to study product use more commonly with IVR2. However, one of the 12 IVR2 participants accounted for 26 of 47 reported TEAEs in that group. Endometrial biopsies were not performed routinely unless an endometrial stripe was >4 mm or for clinically significant postmenopausal bleeding (PMB). One IVR1 participant had an endometrial stripe increase from 4 mm at screening to 8 mm at end of treatment. Her endometrial histology was benign. Two other endometrial biopsies were also performed during the study for PMB and were benign. There were no clinically meaningful laboratory or vital sign abnormalities or trends identified in observed values or changes from baseline. Pelvic speculum examination identified no clinically significant abnormalities in any participant at any visit. Usability data are reported in Table 2, demonstrating both IVRs were highly acceptable. **Conclusion:** Both DARE-HRT1 IVRs, E2 80 µg/d + P4 4 mg/d (IVR1) and E2 160 µg/d + P4 8 mg/d (IVR2) were safe and well-tolerated in healthy postmenopausal women. TEAE profiles were comparable to the referent marketed ORAL regimen.

**Sources of Funding:** USA

**Table 1:** Proportion of participants reporting various TEAEs in each product group

<table>
<thead>
<tr>
<th>VARIABLE</th>
<th>NOGROUP TOTAL (%)</th>
<th>IVR1 (n=10)</th>
<th>IVR2 (n=12)</th>
<th>ORAL (n=11)</th>
<th>Fisher</th>
</tr>
</thead>
<tbody>
<tr>
<td>At least one TEAE</td>
<td>100%</td>
<td>97%</td>
<td>84%</td>
<td>73%</td>
<td>0.00</td>
</tr>
<tr>
<td>Mild TEAE</td>
<td>70%</td>
<td>97%</td>
<td>84%</td>
<td>73%</td>
<td>0.00</td>
</tr>
<tr>
<td>Moderate TEAE</td>
<td>10%</td>
<td>21%</td>
<td>0%</td>
<td>0%</td>
<td>0.63</td>
</tr>
<tr>
<td>Reproductive System TEAE</td>
<td>0%</td>
<td>7%</td>
<td>5%</td>
<td>5%</td>
<td>0.15</td>
</tr>
<tr>
<td>Gastrointestinal System TEAE</td>
<td>0%</td>
<td>23%</td>
<td>28%</td>
<td>6%</td>
<td>0.15</td>
</tr>
<tr>
<td>Neurologic System TEAE</td>
<td>0%</td>
<td>1%</td>
<td>0%</td>
<td>0%</td>
<td>0.87</td>
</tr>
<tr>
<td>Vaginal Shrinking or Postmenopausal Symptoms</td>
<td>0%</td>
<td>23%</td>
<td>33%</td>
<td>3%</td>
<td>0.15</td>
</tr>
<tr>
<td>TOTAL TEAEs REPORTED</td>
<td>30</td>
<td>29</td>
<td>32</td>
<td>11</td>
<td>NA</td>
</tr>
</tbody>
</table>

**TEAE Related to Study Product (n= total TEAEs) | 18% | 30% | 39% | 45% | 0.05**

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**Sources of Funding:** The research reported in this publication was supported (in part or in full) by the National Center for Advancing Translational Sciences of the National Institutes of Health under Award Number UL1TR002538. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. This work was also supported by funding from the Undergraduate Research Opportunities Program at the University of Utah awarded to KS.
**Objective:** Reliable changes in memory performance are observed in the menopause transition, suggesting that the menopause transition may be an inflection point for accelerated brain aging in women. Initial functional magnetic resonance imaging (fMRI) studies suggest that age changes may be in part to changes in the function of the hippocampus, a brain area rich in estrogen receptors. Typically, hippocampal function is measured in fMRI studies by a single cognitive probe, like a word memory task or at rest. An alternative and potentially more sensitive measure of hippocampal function is hippocampal amplitude, which is the standard deviation of the concatenated hippocampal time series across cognitive tasks that differ in relevance to memory processes. Here we examined whether age differences in hippocampal amplitude differed by menopause stage. We hypothesized that compared to a premenopausal group of women, peri- and postmenopausal groups would show larger age-related differences in hippocampal amplitude, indicative of accelerated hippocampal aging in the menopause transition and into the postmenopause. **Design:** Participants included 187 women aged 40-60 (mean 50.1 ± 5.8) years from the Perimenopause Substudy of the Human Connectome Project in Aging (HCP-A). Women were excluded if they were on hormonal medications or had a hysterectomy and/or oophorectomy. All participants completed two IMRI tasks, a Face-Name task that relies on the hippocampus and a Go/No-go task that does not rely on the hippocampus. We examined hippocampal blood oxygen level dependent (BOLD) amplitude across the two tests. All participants also completed the Rey Auditory Verbal Learning Test (RAVL), a measure of verbal learning and memory. Menopause status was determined using the STRAW+10 questionnaire. We performed regression analyses, with left and right hippocampal amplitude as the outcome measure and age, stage, and age-by-stage interactions, controlling for education, race, and APOE status. **Results:** The sample included premenopausal (N = 74), perimenopausal (N = 51), and postmenopausal (N = 62) groups of women, which differed in key factors that influence brain aging, including age, education, race and APOE status. All left- and right-hemispheric groups showed larger age-related differences in hippocampal amplitude, indicative of accelerated hippocampal aging in the menopause transition and into the postmenopause. **Conclusion:** The results of the current study should be seen as a starting point for future research on the role of menopause in age-related hippocampal changes. Further investigations are needed to confirm these findings and to understand the mechanisms underlying these changes.
education strategies might benefit from building on existing close relationships with women who have already experienced menopause. The current generation of women are sophisticated users of technology and would likely benefit from increased access to high quality menopause information and discussion forums online.

Sources of Funding: Keeler Intra-University Fellowship

P-88. The effect of acute exercise on hot flash experience in healthy perimenopausal individuals

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Objective: Hot flashes (HFs) are a thermoregulatory, heat dissipation event experienced by about 80% of women. The HF experience includes both the subjective perception and objective measurement of physiological HFs. Exercise is activity requiring physical effort that is planned and performed to maintain or improve health. Regular exercise has influences on thermoregulation, leading to a more efficient heat dissipation response. The relationship between HFs and acute exercise remains unclear with some finding increases in either objectively measured or subjectively reported HFs and others reporting decreases following exercise. As the HF experience has been associated with CVD risk, particularly in perimenopausal individuals, we seek to better understand the relation between physical activity and HF experience in this population. The objective of this analysis was to evaluate the effect of a single bout of moderate intensity exercise on the subjective and objective HF experience in perimenopausal women.

Design: Healthy perimenopausal (defined by the STRAW-10 criteria) individuals aged 43-54 who were not taking hormone therapy or other medications that may influence HF experience were enrolled. Habitual physical activity was evaluated through the International Physical Activity Questionnaire (IPAQ). Participants were tested under 2 conditions; one in which women did not undergo acute exercise, and in the second, women were given a dose of 30-minutes of moderate-intensity treadmill exercise, in addition to a 5-min warm-up and 5-min cool-down. Moderate exercise was defined as 64-76% of age-predicted max heart rate [206.9x(0.67xage)] and qualified with a rating of perceived exertion (Borg RPE) every 2 minutes during exercise. Participants were instructed to not exercise in the 12 hr prior to each study visit and during the 24 hr following the visit. After each session, participants were monitored for 24-hr for HFs. Objective HF experience was recorded via sternal skin conductance with an ambulatory monitor (Biolog, UFI, Morrow Bay, CA) and defined by a 23% increase in skin conductance over 30s and/or a distinctive HF pattern (rapid rise followed by a slow descent). For subjective HF experience, participants were asked to press a button on the monitor when they felt a HF or enter the data in the HF diary. Average temperature and humidity during monitor wear periods were also recorded. Frequency of HF of each type per hour of wear was calculated. Data were included if at least 10hr of HF monitor data was collected. Data were evaluated for assumptions of statistical testing. When data failed these assumptions, nonparametric tests were used to analyze the data. In this case, the Related Samples Wilcoxon Signed Rank Test was used to evaluate paired data, and Kendall’s Tau was used to evaluate correlations.

Results: Participants were 49.7±3.3 yr old and had a mean habitual physical activity of 4254±2485 MET-min/week. At this time, valid data for 2 testing visits was collected on 17 participants for objective data and 18 participants for subjective data. Data from 3 participants was excluded due to Biolog monitor malfunction such that <10hr of data was collected. There was a statistically significant reduction in objectively measured HFs between the non-exercise and exercise conditions (z=-2.04, p=0.041). The median frequency of objective HFs in the non-exercise condition was 0.13/hr, and 0.09/hr in the acute exercise condition. There was no difference between subjective HFs between conditions (non-exercise median = 0.05/hr, exercise median = 0.0411/Hr/hr, z=-0.408, p=0.683). Average temperature and humidity did not correlate with HF experience for either testing visit (all p>0.1). Conclusion: Our data indicate that acute exercise would not change the subjective HF experience in healthy perimenopausal women. Understanding the role of physical activity and exercise on HF experience can advance efforts to provide accurate information to women undergoing menopause and optimize therapies for this population.

Sources of Funding: None

P-89. An Argentinian Population Study on Menopause

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Objective: As life expectancy has increased, the menopause most women spend more than one-third of their lives after menopause A significant number, experience more bothersome menopausal symptoms. There a few data on women attitudes about seeking information on menopause and the adherence to prescription. On the other hand, little is known about the response of HFs regarding menopausal symptoms. The objective of this study is to describe various characteristics among this female population aged 40-80 years.

Design: A population based, cross-sectional study has been conducted from September 2020 to May 2022. A total of 1359 postmenopausal women, in Argentina, completed an online adapted self-questionnaire RENAME (Registro Nacional de Menopausia) regarding: age of menopause, educational level, smoking status, climacteric symptoms, access to healthcare providers and use of MHT or non hormonal therapies.

Results: The population mean age was 61.1 years (SD 7.3). Average age of menopause was 49.4 years (SD 4.77) Women were divided in groups according to educational levels: 53.1% university, 22.1% tertiary education, 19.4% completed high school. No association between hot flashes and educational status was observed. Regarding climacteric symptoms 52.9% (n=719) reported hot flashes, 47.1% (n= 640) night sweats and 32.3% (n=439) sleep disorders. More than a half 52.1% (n=708) complained of vaginal dryness, recurrent cystitis 10.2% (n=138), and 24.7% (n=335) painful intercourse. The great majority (72.7%) sought health counseling regarding symptoms from their physicians; 79% received medical advice, but only 47.9% received a prescription. 22.7% of these women used MHT, but only 12.7% continued it for more than 6 months. Non hormonal therapy was employed by 11.6% women and 4.3% used both therapies (hormonal and non hormonal). Conclusion: Based on the results of the present study, climacteric symptoms were highly prevalent. According to the literature, hot flashes, night sweats and vaginal dryness were the major complaints. Paradoxically, although they were fully informed about this period of life, few received either hormonal or nonhormonal treatment. HFs have a great role in improving patients’ acceptance and adherence to hormonal treatment. Continuing medical education in this field, is essential for postmenopause women care and treatment.

Sources of Funding: None

P-90. Did you have any of these symptoms?

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dyspareunia</td>
<td>10.5%</td>
</tr>
<tr>
<td>Hot flashes</td>
<td>22.8%</td>
</tr>
<tr>
<td>Recurrent cystitis</td>
<td>4.3%</td>
</tr>
<tr>
<td>Vaginal dryness</td>
<td>20.1%</td>
</tr>
<tr>
<td>Insomnia</td>
<td>13.8%</td>
</tr>
</tbody>
</table>

Results:

- **Dyspareunia**: 10.5%
- **Hot flashes**: 22.8%
- **Recurrent cystitis**: 4.3%
- **Vaginal dryness**: 20.1%
- **Insomnia**: 13.8%

Doctors and other health professionals may ask these questions to get a better understanding of a patient's symptoms and condition.