THURSDAY CONCURRENT SESSION #1

S-1.
Racial differences in cancer screening among women

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Objective: Women who do not receive recommended cancer screening are at higher risk of morbidity and mortality; knowing which women are less likely to receive cancer screening can help target quality improvement initiatives to patients most in need. The aim of the present analysis was to examine differences in receipt of cancer screening by race within a community sample from one geographic location while controlling for other key variables. We hypothesized that White women would be more likely to receive cancer screening than women from other racial and ethnic groups. **Design:** This was a cross-sectional survey of selected underserved areas of Chicago conducted by trained interviewers in 2015 and 2016. Multistage probability sampling was used. One or two randomly selected adults per household were interviewed in English or Spanish. For this analysis, only women were included. The outcome variables were (1) colon cancer screening up-to-date among those over 50, defined as colonoscopy within 10 years, sigmoidoscopy within 5 years, or stool testing within 3 years; (2) mammogram within 2 years among those aged 50-75; and (3) pap smear within 5 years among those aged 21-65. The primary predictor was race/ethnicity, classified as non-Hispanic White, non-Hispanic Black, Hispanic, or other. Covariates included income, employment, education, use of a translator, disabilities, health insurance, age, BMI, comorbidities, smoking status, marital status, healthcare discrimination, and trust in healthcare practitioner. Descriptive statistics were used to examine data, then univariable logistic regression models were constructed to examine relationships between predictors and outcomes. Factors with $P < 0.05$ were entered into multivariable analyses. **Results:** There were 866 women total. The mean age was 43.5, and 12% were White, 36% were Black, 49% were Hispanic, and 3% were other races/ethnicities. Sixty percent of participants had total household income under the poverty level, and 54% percent had a high school education or less. Of the women over 50, only 58% had colon cancer screening up-to-date, and Black, Hispanic, and "other" women were less likely to have up-to-date screening compared to White women [OR 0.61 (0.28, 1.35), 0.38 (0.17, 0.84), 0.65 (0.16, 2.70)] respectively; p=0.049). However, when adjusted for other factors, race was no longer significantly associated with colon cancer screening. Among women aged 50-75, 80% reported having received a mammogram within the past 2 years. Race was not significantly associated with up-to-date mammogram in univariable analyses (p=0.070), but in multivariable analyses, Black women were more likely to have received a mammogram compared to White women [OR 4.91 (1.46, 16.51), p=0.010]. Among women aged 21-65, 83% reported having cervical cancer screening in the last 5 years, and there were no differences by race (p=0.791). Other factors associated with up-to-date colon cancer screening in multivariable analyses included no physical disability [OR 3.22 (1.32, 7.94), p=0.010], a diabetes diagnosis [OR 3.10 (1.52, 6.31) p=0.002], and higher trust in their healthcare practitioner [OR = 2.24 (1.18, 4.79), p=0.029]. Other factors associated with up-to-date mammogram included employer-based health insurance [OR 3.21 (1.06, 9.75), p=0.040], a diabetes diagnosis [OR 4.00 (1.20, 13.10), p=0.024], and report of less racial discrimination from healthcare practitioners [OR 10.81 (2.06, 56.58), p=0.005]. Other factors associated with up-to-date cervical cancer screening were no physical disability [OR 2.25 (1.02, 4.95), p=0.043] and no history of hysterectomy [OR 5.38 (2.94, 9.88), p<0.001]. **Conclusion:** Within this community sample, there were racial/ethnic differences in receipt of cancer screening. Black and Hispanic women were less likely to have up-to-date colon cancer screening relative to White women, while White women were less likely to have up-to-date mammograms relative to Black women. Racial and ethnic differences in preventive care persist, but other factors, such as disability and health insurance coverage, also influence receipt of preventive care.

Sources of Funding: The Sinai Community Health Survey 2.0 was funded by the Chicago Community Trust (C2013-00,630, C2014-01,723, C2015-04,294). Dr. Thomas is supported by a grant from the National Institute on Aging (K23AG052628). Dr. Thurston is supported by a grant from the National Heart, Lung, and Blood Institute (K24HL123565).

S-2.
Associations of Self-reported Endometriosis and Female Sexual Dysfunction from the Data Registry on Experiences of Aging, Menopause, and Sexuality (DREAMS)

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Objective: Endometriosis is a chronic, debilitating condition, affecting approximately 80 million women worldwide. Studies have found that women with endometriosis have a higher risk of sexual dysfunction, including difficulty with sexual desire, arousal, lubrication, and orgasm. Although endometriosis affects more than 10% of reproductive-aged women, it can also affect 2-5% of postmenopausal women. Those diagnosed with endometriosis prior to menopause may still have symptoms of dyspareunia and a negative impact on sexual function postmenopause. Data regarding the association between endometriosis and female sexual dysfunction are sparse. The aim of this study was to evaluate the relationship between self-reported endometriosis and female sexual dysfunction (FSD) utilizing validated surveys. **Design:** This cross-sectional analysis was conducted among sexually active women aged 18-60 years who presented to women's health clinics at Mayo Clinic in Rochester, Minnesota, Scottsdale, Arizona, and Jacksonville, Florida from May 2015 to 2021. Associations between self-reported history of endometriosis and FSD were evaluated by two fitting multivariable logistic models. FSD was determined utilizing a combined endpoint of Female Sexual Function Index ≤ 26.55 and Female Sexual Distress Scale-Revised ≥ 11. In the first model, the association between endometriosis and FSD was adjusted for multiple variables known to impact female sexual function including age, BMI, race/ethnicity, menopause status, relationship status, education, hormone therapy, and hormonal contraceptive use. The second model adjusted for the variables in model 1 as well as history of abuse within the last year, co-morbidities including, diabetes, heart disease, high blood pressure, osteoporosis, history of stroke, anxiety (GAD-7), depression (PHQ-9), and relationship satisfaction (KMSS-M). **Results:** Of 7118 patients (mean age 51.3), 92.2% were white, 84.5% were partnered, 64.9% were college graduates, 78.4% were peri- or postmenopausal, 8.7% reported a history of endometriosis, and 57.2% met the criteria for FSD. Women with self-reported endometriosis were more likely to be overweight/obese (p=0.004), current or former smokers (p<0.001), less educated (p<0.001), have a history of heart disease (p=0.001), high blood pressure (p=0.001), osteoporosis (p<0.001) and stroke (p<0.001). They were also more likely to have undergone both hysterectomy and bilateral salpingo-oophorectomy (p<0.001), use hormone therapy (p<0.001), have anxiety (GAD-7; p<0.001) and depressed mood (PHQ-9; p<0.001), compared to women without endometriosis. Women with a history of endometriosis were more likely to have FSD (62.4% vs 56.7%, p=0.006). After adjusting for menopause status, women with self-reported endometriosis remained more likely to have FSD (OR=1.24, 95% CI 1.04-1.47, p=0.014). In multivariable analysis, the association between self-reported endometriosis and FSD was no longer statistically significant (model 1 OR 1.18 (95% CI 0.99-1.42) and model 2 OR 1.10 (95% CI 0.91-1.34). **Conclusion:** Women with self-reported endometriosis were more like to have FSD. However, this relationship may be explained by other factors, such as anxiety, depression, hormone therapy use, or the presence of other chronic medical conditions. This finding highlights the opportunity for healthcare practitioners to evaluate and address other potential contributors to FSD in women with endometriosis. Understanding these potential associations will guide clinical decisions, counseling, and treatment of FSD in women with endometriosis.

Sources of Funding: None

S-3.
Real-world treatment and resource utilization for menopausal symptoms in the United States

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Objective: Vasomotor symptoms (VMS) are the most frequently reported menopausal symptoms leading women to seek medical care. Current treatment options include hormonal as well as nonhormonal therapies (eg, selective serotonin reuptake inhibitors [SSRIs] or serotonin-norepinephrine reuptake inhibitors [SNRIs], herbal remedies, dietary supplements, lifestyle modifications). Our objective was to describe current treatment patterns for menopausal symptoms and associated healthcare resource use in the United States. **Design:** This noninterventional, observational study was performed with a convenience sample of 283 healthcare providers (HCPs) equally distributed by US region. Participating HCPs were gynecologists (38%), primary care physicians (43%), and advanced practice providers in gynecology (9%) and primary care (11%) who provided patient data; 87% of HCPs were in office-based private practice. Data on prescription and nonprescription therapy and menopause-specific healthcare resource use were abstracted from medical records of US women who initially presented with menopausal complaints (including VMS) between 1 Jan 2016 and 31 Dec 2019 and were aged 40 to 60 years. Data were collected from 16 Oct 2020 to 28 Jan 2021. **Results:** Data from 1,016 women (mean age [SD]: 53 [4.4] years) were analyzed; 342 were current (9%) or former (25%) smokers. Menopausal symptoms were the primary reason for making an appointment for 50% of the sample and were discussed at a routine visit by 49%. The most common symptoms at initial presentation were hot flashes (91%), sleep problems (50%), and vaginal dryness (47%). Half (513 [51%]) had menopausal symptoms for ≥6 months before reporting them to the HCP. At least one comorbidity was present in 646 (64%) women, most commonly hypertension (407 [40%]), headaches/migraines (184 [18%]), and diabetes (144 [14%]). Therapy for menopausal symptoms was recorded for 883 (87%) women, of whom 249 (28%) initiated prescription medication only, 272 (31%) initiated nonprescription therapy only, and 362 (41%) initiated both; 133 (13%) had no recorded therapy. Demographic characteristics were generally similar regardless of the use of therapy. Among the 611 women with a documented prescription medication for treatment of menopausal symptoms, the most prescribed therapies were estrogen (systemic or local) alone (244 [40%], includes compounded in 15 [2.5%]), combination estrogen/progestogen (228 [37%], includes compounded in 26 [4.3%]), SSRIs/SNRIs (126 [21%]), and other nonhormonal treatments (<5% each). Most (88%) women who were prescribed treatment did not receive prescriptions for more than one medication for menopausal symptoms. Estrogen-based treatments were initiated primarily because of established efficacy, HCP recommendation, and patient perception. Among the 634 women reporting a nonprescription treatment, the most common, excluding lifestyle interventions, was black cohosh (190 [30%]), chosen based on patient perception (94 [49%]), advice from family/friends (51 [27%]), and efficacy (41 [22%]). Therapy

modification was documented for 52 (27%) patients taking black cohosh, primarily owing to lack of efficacy (38 [73%]). Women had a mean (SD) of 2 (2.0) office visits related to menopause. Referrals to menopause specialists (5%) and endocrinologists (3%) and for procedures (hysteroscopy [5%], pelvic ultrasound [20%], and hysterectomy [0.3%]) were uncommon during the documented visits. Blood tests were performed for 46% of women. Visits to complementary healthcare providers were also uncommon (11%). **Conclusion:** Our findings point to several potential unmet needs of women with VMS associated with menopause: 51% delayed seeking care for ≥6 months, about 40% had no prescription medication documented, and 13% had no prescription or nonprescription therapy documented in their medical record.
Sources of Funding: Sponsored by Astellas Pharma, Inc. Writing support provided by Traci Stuve, MA, of Echelon Brand Communications, LLC, an OPEN Health company, funded by Astellas.

S-4.

Quality and readability of accessible online information on menopausal hormone replacement therapy in Canada: what are our patients reading?

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Objective: Background: Menopause hormone therapy (MHT) is the most effective treatment for vasomotor symptoms in menopause. However, most women do not feel fully informed about the benefits and risks associated with MHT use and are uncertain about current evidence on MHT. Recent studies have found that menopausal women resort to various media sources, including the internet, to inform decision-making. **Objective:** To assess the quality and readability of the top 24 MHT websites **Design: Methods:** The top 24 websites from Google, Bing, and Yahoo were identified using the search term "hormone replacement therapy". Five menopause specialists assessed website content quality using the DISCERN Instrument, Journal of the American Medical Association (JAMA) benchmarks, and Abbott's Scale. One reviewer evaluated website credibility using the Health on the Net Foundation Code of Conduct (HONcode) certification, and website readability using the Simple Measure of Gobbledygook (SMOG), Flesch-Kincaid Grade Level (FKGL) and Flesch-Kincaid Read Ease (FKRE) formulae. **Results: Results:** Scores for quality of information varied. The mean JAMA score was low at 2.3 ± 1.1 (out of 4). Only one website met all benchmarks. Fourteen websites (58%) had a good/excellent DISCERN score, while four (17%) had a poor/very poor score. For Abbott's Scale, both the mean authorship score at 2.2 ± 1.0 (out of 4) and mean content score at 45.9 ± 9.8 (out of 100) were low. Inter-rater reliability was high for all tools. Fifteen websites (63%) were HONcode certified. The mean FKRE score was 42.7 ± 10.3, mean FKGL was 12.3 ± 1.9 and mean SMOG grade level was 11.3 ± 1.5. Only one website presented content at a reading level recommended for the public. Websites meeting more JAMA benchmarks were significantly less readable ($p<0.05$). **Conclusion: Conclusion:** Although good quality MHT information exists online, most resources are inaccurate or incomplete. Overall, these resources are not considered comprehensible by the average woman. There is a need to disseminate accurate, comprehensive, and understandable MHT information online.
Sources of Funding: None

S-5.

Delivery of Menopause Care During a Pandemic: An Evaluation of Patient Satisfaction with Virtual Visits

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Objective: At the start of the coronavirus disease 2019 (COVID-19) pandemic, most patient visits in the Menopause Clinic at Mount Sinai Hospital, a tertiary care hospital in Toronto, Ontario, Canada were transitioned to telephone appointments. We aimed to evaluate patient satisfaction with telephone visits during the first wave of COVID-19 pandemic, determine the proportion of women preferring in-person visits and identify predictors of visit type preference. **Design:** In this cross-sectional study, patients with appointments in one provider's weekly Menopause Clinic during the first wave of the pandemic (March 23- July 15, 2020) were asked to complete an electronic survey. We recorded demographics and patient-reported cost to attend an in-person appointment (commute time, monetary expense and time away from work). For those who attended a pre-pandemic in-person appointment, visit type preference (telephone versus in-person) was determined. Participants completed a modified, 12-question Telemedicine Satisfaction Questionnaire (TSQ). The primary outcome was the mean composite satisfaction score (range: 1 to 5). Secondary outcomes were predictors of visit type preference. Chi square tests were used to compare proportions, and odds ratios were calculated. Binary logistic regression and multivariate analysis were performed to assess the factors associated with in-person versus telephone visit type preference. **Results:** During the first wave of COVID-19, 214 women made 246 visits to the clinic, attending mostly by telephone (221/246, 90%). Thirty-one percent (77/246) were new consults with the remaining being follow-up visits. Survey response rate was 72% (139/193). Mean age of participants was 53 years (SD 7.37 years) with most having education beyond high school (130/139, 94%) and living in the Greater Toronto Area (GTA) (117/139, 84%). The mean TSQ composite score was 4.23 (SD 0.72). Of patients who attended a pre-pandemic in-person appointment (118/139, 85%), a minority (24/118, 20%) preferred in-person appointments. Those favouring in-person visits were more likely to report a commute less than 30 minutes (OR 3.78, 95% CI 1.16-12.29, p=0.027), require less than 2 hours away from work (OR 4.05, 95% CI 1.07-15.4, p=0.04), and spend less than $10 to attend (OR 3.67, 95% CI 1.1-12.26, p=0.035) compared to patients favouring phone visits. **Conclusion:** There is high satisfaction among patients having Menopause Clinic telephone visits, with most preferring this type of appointment. In-person visits are still preferred among a minority of women, with predictors being short commute time, minimal time away from work and low monetary expense per visit.
Sources of Funding: None

THURSDAY CONCURRENT SESSION #2

S-6.

A Randomized, Double-blind, Placebo-controlled Trial to Determine the Safety and Efficacy of Estetrol (E4) for the Treatment of Patients with Confirmed SARS-CoV-2 Infection (COVID-19)

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Objective: Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) disease (COVID-19) is a serious respiratory viral infection with high morbidity and mortality. While COVID-19 mortality increases with age in both sexes, women worldwide are less likely to die of the disease than men, despite being more likely to become infected. In addition, pre-menopausal women with COVID-19 have less severe infections and lower mortality rates than post-menopausal women [1]. Estrogens modulate the immune system. There is increasing evidence that endogenous estrogens and those given as oral contraceptives or menopausal hormone therapy (MHT), may play an important role in improving COVID-19 outcomes. Recent large observational studies show MHT to be associated with significant reductions in mortality in women with COVID-19 [2, 3]. It is therefore hypothesized that estrogens could significantly reduce the severity of COVID-19 by their immunomodulatory and anti-inflammatory actions [4]. Estetrol (E4), the first Native Estrogen with Selective Tissue activity (NEST), is currently in a Phase 3 clinical study for relief of vasomotor menopausal symptoms. It is approved in the US, Canada and Europe as a combined oral contraceptive with drospirenone. E4's mode of action, metabolic and pharmacokinetic profiles, minimal impact on the liver, and favorable hemostatic profile, make it an ideal candidate for study in COVID-19, where the risk of venous thromboembolism (VTE) is increased. **Design:** This innovative, 2-part, double-blind, placebo-controlled, phase 2 study is expected to be the first prospective clinical trial of an estrogen in COVID-19. The study was designed to assess the ability of E4 to increase the percentage of patients hospitalized with moderate COVID-19 that will recover, reaching a score of ≤3 on the WHO ordinal scale (0–10), by Day 28 (primary outcome). The study also looked at the percentage of patients reaching a WHO ordinal scale score of ≥6 at 28 days, improvement in the time to recovery, and changes in SARS-CoV-2 viral load (secondary outcomes). Postmenopausal women not receiving MHT, and men aged ≥18 years who are at risk of severe COVID-19 due to lack of estrogens, were randomized to treatment with E4 (15 mg) or placebo within 48 hours of hospitalization for moderate COVID-19. They received study medication for 21 days (average length of COVID-19 viral shedding and disease) regardless of hospital discharge status, to maximize the potential benefits of E4 whilst minimizing the risk of VTE. Patients not already on oral anticoagulants were treated with low molecular weight heparin or equivalent as prophylaxis against VTE for the treatment period. **Results:** This study has now completed recruitment to Part A (170 patients, 65 of which were postmenopausal women). An additional 130 patients will be enrolled into Part B. When analysis of Part A data is complete, the 2-part design will allow the Sponsor to make an early decision to proceed to a confirmatory trial including the planned 130 patients from Part B as a distinct cohort in the Phase 3 study, aiming to obtain approval for an effective treatment for COVID-19 as quickly as possible. Results will be released imminently. **Conclusion:** Women are less likely to die of Covid disease than men. Pre-menopausal women with COVID-19 have less severe infections and lower mortality rates than post-menopausal women. Estetrol has the ideal profile for an estrogen that may be effective in reducing morbidity and mortality. Results of this randomized study will be presented 1. Scully et al., Nature Reviews Immunology. 2020. 2. Seeland et al., BMC Med. 2020. 3. Dambha-Miller et al., medRxiv. 2021. 4. Mauvais-Jarvis et al., Endocrinology. 2020.
Sources of Funding: Mithra Pharmaceuticals SA

S-7.

Endometrial Progesterone Receptor Expression with Softgel Vaginal Estradiol (4-µg or 10-µg) Inserts

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Objective: Endometrial expression of the estrogen-regulated progesterone receptor (PR) gene is an early, extremely sensitive marker of estrogen action and a surrogate marker of estrogen responsiveness in the uterus. Our objective was to evaluate endometrial PR expression in menopausal women who used a vaginal 4-µg or 10-µg estradiol (E2) insert versus placebo. **Design:** REJOICE was a randomized, double-blind, placebo-controlled trial that evaluated vaginal E2 inserted near the introitus of women with moderate to severe dyspareunia due to menopause. In this REJOICE post hoc analysis, 25 women with available biopsies were randomly selected from each of the 4-µg E2, 10-µg E2, and placebo groups. Endometrial biopsy tissue sections were immunostained with an anti-PR (A/B) monoclonal antibody (PgR1294; Agilent, Santa Clara, CA). Cell staining was quantified (Pathology & Histology Core, Baylor College of Medicine, Houston, TX), and mean expression levels between baseline and week 12 were analyzed by 2-sided t-tests. IRB approval was obtained. **Results:** PR expression results were available for all women, except three in the 4-µg E2 group. At baseline, mean endometrial PR expression levels ranged from 0.301 pmol/mg to 0.470 pmol/mg for all groups. Similar PR expression levels were observed after 12 weeks of treatment (0.312-0.432 pmol/mg). No significant differences in mean PR expression from baseline to week 12 were observed. **Conclusion:** No meaningful differences in endometrial PR expression were observed following 12 weeks of exposure to low-dose E2 vaginal inserts. This supports the hypothesis that exposure to a low-dose E2 insert placed near the vaginal opening will not be sufficient to increase estrogen responsiveness in the uterus.

Sources of Funding: TherapeuticsMD

S-8.

Effect of Abaloparatide on Fracture Incidence and Bone Mineral Density in Postmenopausal Women with Osteoporosis at Highest Risk for Fracture

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Objective: Identifying postmenopausal women at very high risk for fracture (fx) is critical to counseling on appropriate parenteral therapies that can rapidly improve bone mineral density (BMD) and reduce fx risk. For many high risk patients, the goal is to prevent a second or subsequent fx. Medicare claims data have shown that in women ≥65 years old with an incident fx, 10% will sustain another fx in the next year and 30% by 5 years. In the 18-month phase 3 ACTIVE study in women with postmenopausal osteoporosis, abaloparatide (ABL) significantly increased BMD, and decreased vertebral, nonvertebral, and clinical fx risk vs placebo (PBO), and major osteoporotic fx (MOF) risk vs teriparatide (TPTD) and PBO. The objective of this post hoc analysis was to evaluate efficacy of ABL in a subgroup of patients meeting ≥1 of the high/very-high fx risk criteria defined in the 2020 AACE guidelines. **Design:** In ACTIVE, 2,463 postmenopausal women with osteoporosis were randomized 1:1:1 to double blind daily ABL 80 µg or PBO, or open-label TPTD 20 µg SC for 18 months. Four criteria of highest fx risk were defined based on AACE 2020 guidelines and available data in ACTIVE (fx within the past 12 months or prevalent vertebral fx; very low T-score at baseline < -3.0 at any site; multiple fx at baseline since age 45y, very high fx risk probability by FRAX: MOF >30% or hip >4.5%). A subgroup of patients meeting ≥1 of 4 criteria were evaluated. **Results:** 2,026 patients met ≥1 highest fx risk criteria (ABL: n=664, TPTD: n=685, PBO: n=677). Demographic and baseline clinical characteristics were balanced among groups. ABL and TPTD were both associated with significant reductions in new vertebral fx risk vs PBO (ABL: 4[0.72%], TPTD: 6[0.99%], PBO: 28[4.77%], both $p<0.0001$ vs PBO). Numerical reductions in nonvertebral and wrist fx, and significant reductions in clinical fx ($p<0.05$) and MOF ($p<0.01$) were observed with ABL vs PBO. Kaplan-Meier estimated cumulative incidences were as follows: nonvertebral fx: 3.0%, 3.0%, 5.3%; clinical fx: 4.0%, 4.3%, 9.0%; MOF: 1.6%, 3.0%, 6.8%; and wrist fx: 1.1%, 2.1%, 2.1% in ABL, TPTD, and PBO groups, respectively. Significant BMD gains from baseline at lumbar spine, total hip, and femoral neck were observed with ABL and TPTD vs PBO at 6, 12, and 18 months ($p<0.0001$ all). Significantly greater BMD gains were observed with ABL vs TPTD at the lumbar spine (6 and 12 months; $p<0.05$), total hip (all timepoints; $p<0.01$), and femoral neck (all timepoints; $p<0.01$). No new safety signals were identified. **Conclusion:** Risk stratification for women with osteoporosis guides optimal treatment recommendations. Among a subpopulation of postmenopausal women with osteoporosis enrolled in ACTIVE who had high/very-high fx risk at baseline, 18 months of ABL resulted in significant reduction in vertebral fx, clinical fx, and MOF incidence, and numerical reductions in nonvertebral fx and wrist fx incidence vs PBO. ABL was also associated with significant BMD gains from baseline vs PBO. Overall findings are consistent with those of the original ACTIVE study population and confirm the value of ABL as first line treatment option for women with postmenopausal osteoporosis at high/very-high fx risk.

Sources of Funding: Radius Health, Inc.

S-9.

Role of BH4 Deficiency as a Mediator of Oxidative Stress-Related Endothelial Dysfunction in Postmenopausal Women.

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Objective: Cardiovascular disease risk is lower in premenopausal women compared with men but rises dramatically after the menopause transition presumably due to the loss of vascular-protective estrogen. Estrogen-deficient postmenopausal women have endothelial dysfunction, measured by brachial artery flow-mediated dilation (FMD_{BA}), a major risk factor for cardiovascular disease. Endothelial dysfunction is mediated in part by reduced nitric oxide (NO) bioavailability, secondary to oxidative stress. Under physiological conditions, endothelial NO synthase (eNOS) produces NO from the interaction with L-arginine and tetrahydrobiopterin (BH_4), an essential cofactor for normal eNOS function. However, BH_4 can become limited when there is decreased synthesis or oxidation *via* the BH_3 radical to BH_2 by peroxynitrite and other oxidases (i.e., NADPH oxidase), resulting in increased production of reactive oxygen species (ROS) and decreased NO. Vitamin C (VITC) administrated intravenously at a supraphysiological dose (~2-3g) is a commonly used acute mechanistic probe to evaluate the tonic suppression of vascular function by ROS. VITC is a potent scavenger of ROS, but a weak scavenger of peroxynitrite. BH_4 reacts with peroxynitrite 6-10x faster than VITC, suggesting that VITC alone may not fully protect BH_4 from oxidation by peroxynitrite. In support of this, FMD_{BA} is increased, but not fully restored, in postmenopausal women following acute intravenous VITC or oral BH_4 supplementation. *In vitro* studies demonstrate that co-administration of VITC with BH_4 prevents eNOS uncoupling and reductions in NO by peroxynitrite; however, this remains untested in humans. Accordingly, we assessed the separate and combined effects of VITC and BH_4 to determine whether co-administration of VITC+BH_4 restores FMD_{BA} in healthy estrogen-deficient postmenopausal women to premenopausal levels. **Design:** Healthy premenopausal and postmenopausal women not on vascular-altering medications (e.g., anti-hypertensive or lipid lowering medications) or taking hormonal contraceptives or hormone therapy were recruited to complete a randomized, cross-over, placebo-controlled acute intervention study. Endothelial function was measured using brachial artery flow-mediated dilation (FMD_{BA}) measured via duplex ultrasonography as the percent change in brachial artery diameter in response to reactive hyperemia following 5-minutes of forearm ischemia. FMD_{BA} was measured during acute intravenous infusions of saline (control) and VITC (~2-3g) approximately 3-hours after a single dose of oral BH_4 (Kuvan®, 10mg/kg) or placebo (randomized cross-over, separated by 4 days) in premenopausal (n=14, 36±9 years) and postmenopausal (n=19, 58±5 years) women. **Results:** Under the placebo condition, FMD_{BA} was reduced in postmenopausal compared with premenopausal women during the saline infusion (5.6±2.1 vs. 11.6±4.2%, $p<0.001$), and was selectively increased in postmenopausal women during VITC (to 8.6±3.3%, $p<0.001$). Acute BH_4 treatment selectively increased FMD_{BA} in postmenopausal women during saline (to 7.2±2.5%, $p<0.001$). FMD_{BA} did not change with VITC ($p=0.11$) or BH4 ($p=0.85$) in premenopausal women. FMD_{BA} also did not significantly change during co-administration of VITC+BH_4 in either group ($p=0.14$). FMD_{BA} remained significantly reduced in postmenopausal compared with premenopausal women (premenopausal: 11.6±4.2 vs. postmenopausal after BH_4+VITC: 8.4±3.2%, $p=0.03$). **Conclusion:** Both VITC and BH_4 treatment alone improve FMD_{BA} in healthy estrogen-deficient postmenopausal women. Co-administration of VITC+BH_4 does not restore FMD_{BA} to levels of premenopausal women, suggesting additional mechanisms may be involved.

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S-10.

Justifying bilateral salpingo-oophorectomy at hysterectomy: A large retrospective cohort study

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Objective: 1) To evaluate the proportion of patients with justified bilateral salingo-oophorectomy (BSO) at hysterectomy based on pathologic diagnosis. 2) To determine rate and predictors of avoidable BSO based on preoperative considerations, surgical characteristics and pathologic diagnosis. **Design:** A retrospective review of hysterectomies at 7 Ontario, Canada hospitals (4 academic, 3 community) from July 2016 to December 2019 was performed. Cases by gynecologic oncologists were excluded. Data was extracted from health records (ICD-10 coding) and electronic medical records. Of patients who had concomitant BSO, patient demographics (age, body mass index, ASA class, preoperative diagnosis), surgical factors (presence of adhesions and endometriosis) and surgeon characteristics (academic vs community, generalist vs fellowship-trained) were recorded. A BSO was considered justified if pathologic diagnosis was endometriosis or any malignant or premalignant diagnosis except for gestational trophoblastic neoplasia, cervical cancer or cervical dysplasia. Criteria for avoidable BSO were: age less than 51 years; preoperative diagnosis of cervical dysplasia or benign diagnosis other than gender dysphoria, risk reduction or premenstrual dysphoric disorder; absence of intraoperative endometriosis and adhesions; and unjustified final pathology. Independent samples t-test and Chi-square tests compared patients with avoidable BSO to those who had at least one criterion for BSO. Multivariate analyses identified factors most strongly associated with having an avoidable BSO. **Results:** During the study period, 4191 hysterectomies were completed with 1422 (33.9%) patients having concomitant BSO. Final pathologic diagnosis justified BSO in a most patients (1035/1422, 72.8%) with the most common

pathologic diagnoses being endometrial cancer (439/1422, 30.6%), endometrial hyperplasia (275/1422, 19.3%) and endometriosis (200/1422, 14.1%). The remaining cases (n=387) were unjustified with 42/1422 (3%) BSOs deemed avoidable. Compared to cases with at least one criterion for BSO, avoidable BSOs were more frequently completed by generalists (68.3% vs 48.6%, OR 2.01, 95% CI 1.04 to 4.08, p=0.044), and in patients with preoperative diagnoses of abnormal uterine bleeding (61.9% vs 26.2%, OR 3.75, 95% CI 1.96 to 7.43, p<0.001) and/or fibroids (52.4% vs 19.3%, OR 3.26, 95% CI 1.70 to 6.23, p<0.001). **Conclusion:** Final pathologic diagnosis justified most BSOs at hysterectomy. However, BSO was avoidable in 3% of women, underscoring the need to standardize practice among gynecologic surgeons.

Sources of Funding: None

TOP-SCORING ABSTRACT PRESENTATIONS

S-11.

Longitudinal association between cardiovascular fat and cognitive function among midlife women: The Study of Women's Health Across the Nation (SWAN) Cardiovascular Fat Ancillary Study

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Objective: A worsening cardiovascular profile after menopause may contribute to the fact that women are disproportionately affected by dementia. Cardiovascular fat (CF) deposition, found to be higher in postmenopausal women compared with premenopausal women, is a novel risk factor for cardiovascular disease (CVD). As a metabolically active organ, CF may impact cognitive function through neuropathological pathways by changing secretion of inflammatory cytokines and adipokines. The quality of CF can be reflected by its radiodensity. Associations of CF volume and radiodensity with cognitive function are not clear among midlife women as well as by race groups, which may be critical for these associations considering the lower epicardial adipose tissue (EAT) volume among Blacks, with higher risk of CVD and higher prevalence of Alzheimer's disease, compared with Whites. We aimed to assess associations of CF volume and radiodensity with future cognitive performance among midlife women and check if there is racial differences in these associations. **Design:** Volume and radiodensity of CF including EAT, total heart adipose tissue (TAT), and perivascular adipose tissue (PVAT) surrounding the descending aorta were measured using computed tomography (CT) scan at one of the SWAN visits 4-7 as the baseline. Working memory (digit span backward), verbal episodic memory immeidate and delayed recall (East Boston memory), as well as processing speed (symbol digit modalities) were assessed repeatedly beginning at SWAN visit 4. Cognitive tests completed after the CT scan were examined after excluding the first two – to account for practice effects [mean number of assessments: 4.2 (SD=1.7)]. The association between each CF measure and each subsequent cognitive measure was evaluated separately using linear mixed models with random intercepts. We included volume and radiodensity of the same fat in the final models. The final models also adjusted for practice effect (only for processing speed), retention effect, site, education level, and race, as well as the following covariates measured at the CT scan: age, menopausal status, HDL-C, fasting glucose, triglyceride, waist circumference, and systolic blood pressure. **Results:** We included 487 women [mean age at CT: 50.9 (SD=2.9); 30.6% postmenopausal; 35.9% Blacks] without history of stroke at baseline. Their CF measures were assessed 2.7 (SD=1.5) years before the 1st used cognitive tests. In the final model (Table), a higher PVAT radiodensity was significantly associated with a worse performance in working memory. There was a significant interaction between PVAT radiodensity and race (p-value=0.01). One SD increase in PVAT radiodensity was significantly associated with 0.20 unit decrease in delayed recall among Blacks (p-value=0.03), but not White women. **Conclusion:** In midlife women, a higher baseline radiodensity of PVAT was associated with a worse performance in working memory later in life. Additionally, a higher baseline PVAT radiodensity at midlife was associated with lower future performance in verbal episodic memory among Blacks, but not White women.

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Table: The relationship between CF and cognitive performance

Standardized CF^	Working memory		Processing speed		Immediate recall		Delayed recall	
	β(SE)	p-value	β(SE)	p-value	β(SE*)	p-value	β(SE*)	p-value
EAT Volume	-0.05(0.16)	0.77	0.94(0.66)	0.16	0.12(0.09)	0.17	0.03(0.19)	0.78
EAT Density	-0.22(0.14)	0.10	0.19(0.57)	0.74	0.04(0.08)	0.62	-0.04(0.02)	0.63
TAT Volume	0.02(0.15)	0.89	0.58(0.64)	0.36	0.12(0.08)	0.14	0.05(0.09)	0.61
TAT Density	-0.07(0.12)	0.56	-0.09(0.51)	0.86	0.08(0.07)	0.28	0.0008(0.72)	0.91
PVAT Volume	-0.01(0.12)	0.92	-0.03(0.52)	0.95	0.08(0.07)	0.24	0.13(0.07)	0.07
PVAT Density	-0.29(0.09)	<0.01	0.04(0.37)	0.92	0.02(0.05)	0.76	-0.03(0.05)	0.48

^Volumes of CF were log transformed

***The distribution of verbal episodic memory was skewed, so we applied linear mixed regression with robust standard error.**

S-12.

Literature Review of Hormone Therapy (HT) Containing Estradiol or Progesterone vs HT Containing Other Estrogens or Progestogens

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Objective: Risks for endometrial cancer, venous thromboembolism (VTE), cardiovascular diseases, stroke, breast cancer, cognition decline, and menopausal symptoms may differ between hormone therapy (HT) formulations. This systematic review aimed to determine reported differences in these risks with HT containing estradiol (E2) versus other estrogens and progesterone (P4) versus other progestogens. **Design:** PubMed and EMBASE were searched from inception through February 2021 for English-language publications examining safety risks and outcomes on bone health, vasomotor symptoms (VMS), and quality of life in postmenopausal women taking different HT formulations. Keywords included endometrium, endometrial, cardiovascular, coronary, venous thromboembolism (VTE), thrombosis, myocardial infarction, coronary artery bypass graft, stroke, coagulation, lipids, hypertension, blood pressure, mortality, breast, cognition, bone, hot flush, vasomotor symptoms, quality of life (QOL), weight, metabolic, and sleep, in conjunction with (E2 and menopause) or (P4 and menopause). **Results:** Seventy-one comparative studies of various designs were identified, including prospective, randomized trials; prospective, observational/interventional trials; retrospective or cross-sectional, observational studies; and systematic review/meta-analyses (26 comparing estrogens and 47 comparing progestogens). Although an increased endometrial cancer risk with P4-based HT was suggested in two observational studies,[1,2] data from randomized-controlled studies support that P4 offers similar endometrial protection as progestins when used at an adequate dose.[3,4] Large, observational studies found that similar or lower risks of breast cancer and cardiovascular diseases with E2 versus CEE[5-11] or P4 versus progestins.[12-21] E2 tends to provide better protection against declines in cognition and bone health versus CEE,[22-24] while P4 was similar to progestins for these outcomes in general.[22,25-28] Comparable effects between HT on VMS control were reported.[4,29-31] P4- versus progestin-based HT led to similar or better improvements on QOL and sleep.[31-35] **Conclusion:** Evidence suggests a differential effect of HT containing E2 or P4 versus those containing CEE or progestins, supporting a better safety profile with HT containing E2 and/or P4.

1. Allen NE. *Am J Epidemiol* 2010;172:1394-1403. **2.** Fournier A. *Am J Epidemiol* 2014;180:508-517. **3.** Writing Group for the PEPI Trial *JAMA*. 1996;275:370-375. **4.** Pelissier C. *Maturitas* 2001;40:85-94. **5.** Sweetland S. *J Thromb Haemost* 2012;10:2277-2286. **6.** Shufelt CL. *Menopause* 2014;21:260-266. **7.** Bakken K. *Int J Cancer* 2011;128:144-156. **8.** Shufelt C. *Menopause* 2018. **9.** Brusselaers N. *Ann Oncol* 2018;29:1771-1776. **10.** Tsai WC. *Sci Rep* 2016;6:24132. **11.** Vinogradova Y. *BMJ* 2019;364:k4810. **12.** Canonico M. *Stroke* 2016;47:1734-1741. **13.** Canonico M. *Arterioscler Thromb Vasc Biol* 2010;30:340-345. **14.** Fournier A. *Int J Cancer* 2005;114:448-454. **15.** Fournier A. *Breast Cancer Res Treat* 2008;107:103-111. **16.** Fournier A. *J Clin Oncol* 2008;26:1260-1268. **17.** Fournier A. *J Clin Oncol* 2009;27:5138-5143. **18.** Canonico M. *Circulation* 2007;115:840-845. **19.** Espie M. *Gynecol Endocrinol* 2007;23:391-397. **20.** Olie V. *Menopause* 2011;18:488-493. **21.** Cordina-Duverger E. *PLoS One* 2013;8:e78016. **22.** Wroolie TE. *Am J Geriatr Psychiatry* 2011;19:792-802. **23.** Wroolie TE. *Am J Geriatr Psychiatry* 2015;23:1117-1126. **24.** Zhu L. *Menopause* 2016;23:461-470. **25.** Sherwin BB. *Fertil Steril* 2011;96:399-403. **26.** Writing Group for the Pepi Trial. *JAMA* 1996;276:1389-1396. **27.** Zhu SY. *Gynecol Endocrinol* 2019;35:165-169. **28.** Zuo H. *Med Sci Monit* 2019;25:819-826. **29.** Utian WH. *Menopause* 2005;12:708-715. **30.** Greendale GA. *Obstet Gynecol* 1998;92:982-988. **31.** Gambacciani M. *Maturitas* 2005;50:91-97. **32.** Fitzpatrick LA. *J Womens Health Gend Based Med* 2000;9:381-387. **33.** Ryan N. *Clin Ther* 2001;23:1099-1115. **34.** Gao L. *Climacteric* 2018;21:69-74. **35.** Leeangkoonsathian E. *Gynecol Endocrinol* 2017;33:933-936.

Sources of Funding: TherapeuticsMD

S-13.

A Phase 3, randomized, placebo-controlled, 12-week, double-blind study, plus a non-controlled extension treatment period, to assess efficacy and safety of fezolinetant, a neurokin-3 receptor antagonist, in women with moderate-to-severe vasomotor symptoms associated with menopause

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Objective: To evaluate the efficacy and safety of fezolinetant vs placebo on the frequency and severity of vasomotor symptoms (VMS) associated with menopause. **Design:** This double-blind, placebo-controlled, multicenter Phase 3 study (NCT04003142) randomized women aged ≥40–65 years with moderate-to-severe VMS associated with menopause (minimum average of 7 hot flashes/day) 1:1:1 to once daily placebo, fezolinetant 30 mg or fezolinetant 45 mg. Co-primary efficacy endpoints: mean change from baseline to week 4 and 12 in: 1) frequency and 2) severity of moderate-to-severe VMS. Key secondary endpoint: mean change from baseline to week 12 in Patient-reported Outcomes Measurement Information System Sleep Disturbance–Short Form 8b (PROMIS) Total

Score. Other secondary endpoints: effect of fezolinetant vs placebo on weekly mean change in frequency and severity of moderate and severe VMS from baseline to week 12. Treatment-emergent adverse events (TEAEs) assessed fezolinetant safety and tolerability. After 12 weeks, women on placebo were re-randomized to fezolinetant 30 mg or 45 mg, and those originally on fezolinetant stayed on their dose for a 40-week extension period. **Results:** 501 women were randomized and 500 took ≥1 dose of medication (placebo n=167, fezolinetant 30 mg n=166, fezolinetant 45 mg n=167). Both fezolinetant doses statistically significantly reduced VMS frequency and severity at weeks 4 and 12 vs placebo (Table). Fezolinetant 45 mg, but not fezolinetant 30 mg, significantly reduced PROMIS-assessed sleep disturbance vs placebo at week 12. Improvement in VMS frequency and severity was observed as early as 1 week after treatment onset and was maintained throughout the 12-week placebo-controlled period. TEAEs were reported by 40% (fezolinetant 30 mg), 36% (fezolinetant 45 mg) and 32% (placebo) of women. Headache was the most common TEAE in the fezolinetant groups: 3% (fezolinetant 30 mg), 4% (fezolinetant 45 mg) and 2% (placebo). Serious TEAEs were reported by 2% (fezolinetant 30 mg), 1% (fezolinetant 45 mg) and 0% (placebo) of women; there were no drug-related serious TEAEs. **Conclusion:** Fezolinetant 30 mg and 45 mg once daily were efficacious for the treatment of moderate-to-severe VMS associated with menopause. Efficacy was evident by week 1 of treatment and maintained throughout the 12-week placebo-controlled period. Fezolinetant 45 mg improved patient-reported sleep. No safety signals of concern were apparent for either fezolinetant dose.

Sources of Funding: Astellas Pharma Inc.

Analysis Visit	Statistics	Placebo (N=167)	Fezolinetant 30 mg (N=166)	Fezolinetant 45 mg (N=167)
Co-primary: Frequency of moderate-to severe VMS				
Baseline	Mean (SD)	11.59 (5.02)	11.23 (4.88)	11.79 (8.26)
Week 4	Mean (SD)	8.08 (6.50)	5.79 (6.02)	5.67 (7.29)
	LS Mean Diff vs Placebo (SE), [Unadjusted P-value]	–	–1.82 (0.46), [<0.001]	–2.55 (0.46), [<0.001]
Week 12	Mean (SD)	6.73 (7.58)	4.80 (5.59)	4.49 (5.39)
	LS Mean Diff vs Placebo (SE), [Unadjusted P-value]	–	–1.86 (0.55), [<0.001]	–2.53 (0.55), [<0.001]
Co-primary: Severity of moderate-to severe VMS				
Baseline	Mean (SD)	2.41 (0.32)	2.44 (0.33)	2.41 (0.34)
Week 4	Mean (SD)	2.11 (0.56)	1.97 (0.65)	1.80 (0.74)
	LS Mean Diff vs Placebo (SE), [Unadjusted P-value]	–	–0.15 (0.06), [<0.021]	–0.29 (0.06), [<0.001]
Week 12	Mean (SD)	1.95 (0.68)	1.84 (0.79)	1.66 (0.79)
	LS Mean Diff vs Placebo (SE), [Unadjusted P-value]	–	–0.16 (0.08), [0.049]	–0.29 (0.08), [<0.001]
Key secondary: PROMIS total score				
Baseline	Mean (SD)	27.4 (7.0)	27.3 (6.6)	26.2 (6.6)
Week 12	Mean (SD)	23.8 (7.0)	23.0 (7.7)	21.2 (5.7)
	LS Mean Diff vs Placebo (SE), [Unadjusted P-value]	–	–0.7 (0.7), [0.381]	–2.0 (0.7), [0.007]
LS=least squares, SD=standard deviation, SE=standard error, VMS=vasomotor symptoms.				

S-14.

Sexual Violence and Cardiovascular Disease Risk: A Systematic Review and Meta-Analysis

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Objective: Cardiovascular disease (CVD) is a leading cause of death among adults. Over 35% percent of women worldwide report lifetime exposure to sexual violence. While adverse psychosocial factors broadly have been linked to CVD risk, it is unclear if sexual violence history is associated with increased risk for CVD. This study employed quantitative meta-analysis to investigate the association between sexual violence and CVD risk. **Design:** PubMed and PsycINFO databases were searched through March 1, 2021. Included studies had a measure of sexual violence (i.e., sexual abuse/assault, military sexual trauma, sexual harassment, sexual intimate partner violence) and at least one cardiovascular outcome (i.e., clinical CVD, subclinical CVD, select CVD risk factors) in persons aged 18 or older. Data were expressed as odds ratios (OR) or hazard ratios (HR) with 95% confidence intervals (CI) extracted from fully-adjusted models. OR and HR effects were pooled separately, given inability to statistically harmonize these effects, using random effects meta-analysis. Heterogeneity of effects was tested using Cochran's Q test. **Results:** Overall, 41 studies based on 1,990,211 adults (74.2% women) were included (94 effects expressed as OR and 7 effects expressed as HR). Effects were largely drawn from midlife samples. Results indicated that sexual violence was related to adult CVD risk (OR [95%CI] = 1.25 [1.10-1.41]; HR [95%CI] = 1.14, [1.03-1.26]). Results varied by cardiovascular outcome type, measurement method, and timing of violence, with larger effects for associations of sexual violence with cardiovascular health observed for: (1) clinical CVD outcomes (versus subclinical CVD or CVD risk factors), (2) self-reported health outcomes (versus direct measurement/medical record), and (3) sexual violence occurring in childhood (versus adulthood only). **Conclusion:** Exposure to sexual violence, particularly in childhood, is related to poorer cardiovascular health in midlife adults. These findings emphasize the need for providers to understand the sexual violence histories of their patients and the potential value of addressing sexual violence in CVD risk reduction efforts.

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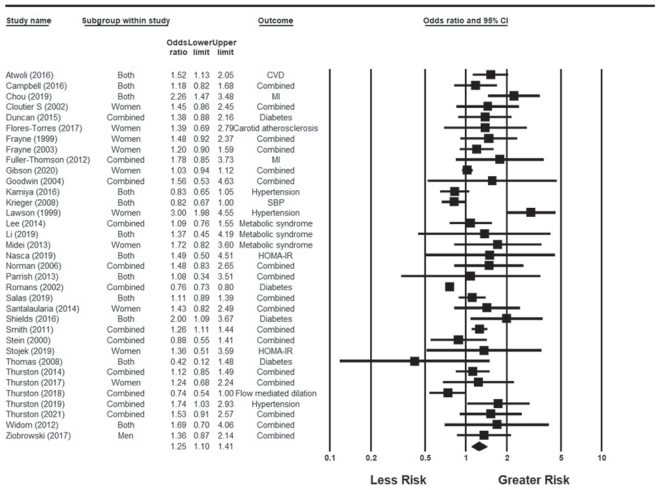

Figure. Forest plot of odds ratio (OR) effects aggregated within study. For Subgroup, "Both" = separate effects were not reported for women and men; "Combined" = separate effects were provided for women and men but aggregated within study for this analysis. For Outcome, "Combined" = average effect across multiple outcomes in the same study.

FRIDAY CONCURRENT SESSION #1

S-15.

Menstrual Cycle Phase, Menopausal Transition Stage and Symptom Severity: Observations from the Seattle Midlife Women's Health Study

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Objective: Little is known about women's symptom experiences during the Late Reproductive Stage (LRS) of reproductive aging (Woods et al, 2021). Our aim was to determine effects of premenses and postmenses cycle phases and STRAW LRS (-3b and -3a) and Early Transition (-2) stages on symptom severity scores. **Design:** Women aged 35-55 years from the Seattle Midlife Women's Health Study (SMWHS) population-based cohort kept daily health diaries for 1-2 cycles or up to 80 days during years 1 to 3 of the study. A total of 301 women rated symptoms in the diary in year 1, including: dysphoric mood, vasomotor, somatic, neuromuscular, and insomnia symptoms using factors identified by Mitchell (1996). Premenses included days -1 to -5 of the cycle and postmenses days +6-10. Menstrual calendars were used to identify menopausal transition stages using STRAW+10 criteria for LRS (STRAW -3b), characterized by regular menstrual cycles over a year, and LRS (STRAW -3a), characterized by regularly occurring menstrual cycles with variation between subsequent cycles <7 days, reporting of subtle change in cycle length, number of days of flow, and/or amount of flow. Early transition (STRAW -2) was defined as persistent variation of >7 days in consecutive cycle lengths (Harlow et al 2012). Symptom Severity was calculated as the mean severity ratings for the symptoms in each group (dysphoric mood, vasomotor, somatic, neuromuscular, and insomnia symptoms) for each cycle phase (postmenses, premenses) for SMWHS year 1. Analysis of variance (2-way, mixed) was used to determine effects of menstrual cycle phase (postmenses, premenses), stages (LRS (-3b and -3a) and ET (-2), and interaction of phase and stage on symptom severity. **Results:** During year 1 of SMWHS, 65 women were in LRS (-3b), 172 in LRS (-3a), and 64 in ET. Dysphoric mood symptoms differed significantly within women across menstrual cycle phases, increasing from postmenses to premenses ($F=21.3$, (1,297), $p<.001$), but not between groups of women in the LRS (-3b and -3a) and ET stages ($F=2.2$ (2,297 df), $p=.115$), nor was there a significant cycle phase X stage interaction ($F=0.28$ (2,297 df), $p=.753$). Vasomotor symptoms differed significantly within women across menstrual cycle phases ($F=4.5$, (1,297 df), $p=.036$), but not between groups of women in the LRS and ET stages ($F=2.6$ (2,297 df), $p=.075$), nor was there a significant cycle phase X stage interaction ($F=0.12$, (2,297 df), $p=.886$). Somatic symptoms differed significantly by menstrual cycle phase ($F=13.4$ (1,297 df) $p<.001$), but did not differ by stage ($F=.89$ (2, 297 df) $p=.413$), nor was there a significant cycle phase X stage interaction ($F=.159$ (2,297 df), $p=.853$). Neuromusclar symptoms differed significantly by menstrual cycle phase ($F=10.6$ (1, 297 df) $p=.001$), but did not differ by stage ($F=1.112$ (2,297 df) $p=.330$), nor was there a significant cycle phase X stage interaction ($F=.795$ (2,297 df) $p=.453$). Insomnia symptoms were more severe premenses than postmenses but did not differ significantly ($F=2.991$ (1, 297 df) $p=.085$), nor was there a significant effect of stage ($F= 1.55$ (2, 297 df) $p=.214$) nor an interaction of cycle phase X stage ($F=.008$ (2,297 df) $p=.992$). **Conclusion:** Women in the late reproductive stages (-3b and -3a) and early menopausal transition experience significant menstrual cycle phase differences in vasomotor, dysphoric mood, somatic, and neuromuscular, but not insomnia symptoms. Overall mean symptom severity scores were higher during the early menopausal transition than during the LR stages, although the differences were not significant, replicating findings of the Women Living Better Survey (Coslov, Richardson & Woods, 2021). There were

no significant interactions between menstrual cycle phase and menopausal transition stages on symptom severity. Women experience premenses exacerbation of symptoms, whether in the LR without cycle irregularity or in the ET with cycle variability meeting STRAW criteria. Further study of symptom experiences during subsequent years of the SMWHS is needed to identify whether cyclicity in symptoms persists through the early menopausal transition stage and to support an integrated view of menstrual cyclicity and progression through menopausal transition stages in clinical practice with women during these complex stages of reproductive aging.
Sources of Funding: NONE

S-16.
Does a history of polycystic ovary syndrome predict more severe menopausal vasomotor symptoms?

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Objective: Vasomotor symptoms (VMS) are the most common symptom experienced by women in the menopause transition. In addition to their impact on mood, sleep, and quality of life, VMS are now recognized as a predictor for cardiovascular disease (CVD). Polycystic ovary syndrome (PCOS) is also a unique risk predictor for CVD in women. The association between PCOS and menopause symptoms, particularly VMS, is not known. The two conditions may be independent predictors of CVD risk in women or they may each be a marker of CVD risk with a common, shared pathophysiology. These relationships have not been studied. The objective of this study was to assess the association between a self-reported diagnosis of PCOS compared to women without self-reported PCOS and severity of menopausal symptoms, particularly VMS. **Design:** This was a cross-sectional study from the Data Registry on the Experiences of Aging, Menopause and Sexuality (DREAMS) performed in women aged 45-60 years who presented to women's clinics at Mayo Clinic Rochester, Minnesota, Scottsdale, Arizona, and Jacksonville, Florida between May 2015 and December 2019. The participants completed multiple questionnaires at the time of their clinic visit, including the Menopause Rating Scale (MRS) for assessment of menopause symptoms. The diagnosis of PCOS was based on self-report. The association between a prior diagnosis of PCOS and menopause symptoms, particularly the presence and severity of VMS, was studied utilizing a multivariable linear regression model for total scores, and a multivariable logistic regression model for presence/severity of VMS. Models were adjusted for menopause status, body mass index (BMI), depression, anxiety, and current use of menopausal hormone therapy. **Results:** The study population included 3308 participants of average age 53 years. Most were white, educated, and postmenopausal. Of these, 151 (4.6%) women reported a history of PCOS. Women with PCOS were more likely to report depression (56.3% vs 42.1%) and obesity (41.9% vs 22.5%) versus those without PCOS. Women with PCOS had a significantly higher mean overall MRS score (17.7 versus 14.7, p<0.001) and higher mean MRS domain scores in the somatic (6.7 vs 5.6, p<0.001), psychological (5.8 vs 4.9, p=0.016), and urogenital (5.2 vs 4.3, p<0.001) domains when compared to women without PCOS. The differences remained significant in the somatic and urogenital domains, but not in the psychological domain, after adjustment for BMI, depression, anxiety, menopausal status, and hormone therapy use. However, women with PCOS were no more likely to experience severe or very severe hot flashes [OR 1.31 (0.81-2.10), p=0.27] than those without PCOS, and this lack of significance persisted following adjustment. **Conclusion:** This large cross-sectional study confirms an association between a history of PCOS and the overall burden of menopause symptoms in midlife women. Contrary to our hypothesis, a history of PCOS did not associate with VMS severity in midlife women. The mechanisms underlying the correlation between PCOS and menopause symptoms in the psychological and urogenital symptom domains requires further study, although the well-known association between PCOS and mood disorders may explain the high psychological symptom burden in these women during the menopause transition.
Sources of Funding: Dr Kapoor receives funding from the NIH/National Institute on Aging Grant U54 AG044170.

S-17.
Does Migraine Associate with Vasomotor Symptoms?

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Objective: Migraine is prevalent, affecting approximately 20% of women with 2-3:1 female predominance. Sex hormones appear to play a significant role in migraine and are linked to migraine prevalence rates, as well as characteristics with women experiencing more migraine-related symptoms and disability compared to men. Migraine is also associated with cardiovascular events and mortality in women. Similarly, menopausal vasomotor symptoms (VMS) appear to be a biomarker of cardiovascular disease (CVD) risk. One prior study has investigated the association between migraine and VMS and found that a history of migraine predicted an increased frequency of VMS in women during the menopause transition. The objective of this study was to further examine a potential link between a history of migraine and VMS. **Design:** A cross-sectional analysis from the Data Registry on the Experiences of Aging, Menopause and Sexuality (DREAMS) was performed based on questionnaire data completed by women aged 45-60 years who presented to women's clinics at Mayo Clinic Rochester, Minnesota; Scottsdale, Arizona; and Jacksonville, Florida between 5/2015 and 12/2019. History of migraine was obtained by self-report at the time of the visit. Menopause symptoms were assessed by the Menopause Rating Scale (MRS). Associations between migraine history (Y/N) and the outcomes of menopause symptoms or hot flashes (severe/very severe, moderate, or mild vs none) were evaluated utilizing a multivariable linear regression model and logistic model respectively, adjusting for body mass index (BMI), menopause status, depression, anxiety, low back pain within 1 year, smoking status, and current use of menopausal hormone therapy. The diagnosis of low back pain, another pain disorder, was used to test the specificity of the association of migraine and VMS. **Results:** A total of 3,308 women were included in the analysis, 895 (27%) of whom reported a history of migraine. Women were of mean age 52.8 years, white (94.5%), educated (93% with at least some college), employed (69%), partnered (84.9%) and postmenopausal (66.6%). In adjusted analysis, women with a history of migraine had significantly higher total MRS scores (estimated difference: 1.36; 95% CI 0.88, 1.85; p= <0.001), and were more likely to have severe/very severe hot flashes versus no hot flashes, OR 1.40 (1.05,1.86; p=0.021), compared to women without migraine history. The odds of reporting more severe hot flashes increased monotonically in women with a history of migraine. In addition, women with low back pain had higher MRS scores, but were no more likely to have severe/very severe hot flashes than those without back pain, confirming the specificity of the link between VMS and migraine. **Conclusion:** This large cross-sectional study confirms an association between a history of migraine and VMS presence and severity in midlife women. Neurovascular dysregulation may explain the link between migraine and VMS as well as the association of each with CVD risk in women. Given the high prevalence of migraine in women, this association may help identify women who are at risk for more severe VMS in midlife. Further study is needed to determine whether the combination of migraine history and VMS in midlife predict greater CVD risk than either alone and whether these female predominant or specific factors could be used to enhance the accuracy of CVD risk calculations for women.
Sources of Funding: EK receives funding from the NIH/National Institute on Aging Grant U54 AG044170.

S-18.
MsHEART Analysis of Palpitations During the Menopause Transition

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Objective: Palpitations occur in 20-34% of peri- and postmenopausal women. However, despite their frequency, little is known regarding etiologies and correlates of palpitations occurring during the menopause transition. The objective of this analysis was to identify demographic, clinical, biomarker and psychosocial correlates of palpitations during the menopause transition. **Design:** This was a secondary analysis from the MsHeart Study, the objective of which was to examine links between hot flashes and cardiovascular risk. A total of 304 women aged 40 to 60 years completed a protocol which included 3 days of ambulatory hot flash monitoring (skin conductance and electronic diary), phlebotomy, and completion of medical history and psychosocial questionnaires. Women reported "heart palpitations" within the previous two weeks as not at all, 1-5 days, 6-8 days, 9-13 days, or every day. Initial bivariate analyses were performed to compare demographic (age, race, ethnicity, body mass index, education, socioeconomic status), clinical (peri- versus post-menopausal status, self-reported comorbid conditions and concomitant medications), biomarker (hormonal, inflammatory, coagulation and metabolic markers) and psychosocial (health rating, stress, Pittsburgh Sleep Quality Index, anxiety measures, depressive symptoms) correlates between women who reported palpitations compared with those who did not; factors associated with the report of palpitations (any/none) at p<.05 were included in multivariable logistic regression models. **Results:** Complete palpitations data were available from 246 women (White: 71%, Black: 23%, other: 6%, Hispanic/Latina: 0.8%). Palpitations were reported by 41 (16.7%) women. Factors associated with the presence of palpitations in multivariable logistic models were history of arrhythmias [odds ratio (OR) = 14.70, 95% confidence interval (CI) 2.62-82.34, p=0.002], history of pneumonia (OR = 2.79, 95% CI 1.13-6.88, p=0.03), higher plasma estrone concentrations (OR for every increase of 5 pg/mL = 1.03, 95% CI 1.003-1.06, p=0.03), diary-reported hot flashes (any versus none; OR = 2.15, 95% CI 1.003-4.12, p=0.049), and, to a lesser extent, use of supplements other than omega-3 fatty acids and black cohosh (OR = 2.22, 95% CI 0.97-5.05, p=0.053). **Conclusion:** History of arrhythmias and pneumonia, higher plasma estrone concentrations and diary-reported hot flashes are associated with palpitations during the menopause transition. Additional research is required to identify specific arrhythmias that may underlie such palpitations and to better understand the mechanistic relationship between estrone and palpitations in peri- and postmenopausal women.
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S-19.

Validation of Novel Menopause Transition Scale in Women aged 40-65

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Objective: All women will experience the menopause transition and a majority will experience symptoms which affect quality of life. Effective care of women requires symptom tracking tools which are uncomplicated, validated, and meaningful. Current validated menopause symptom scales are time consuming, phrased in clinical language, and difficult to adopt for digital use. The first attempt to develop an instrument to address the above limitations resulted in a weak symptom correlation of all 7 questions and the failure for the loading of vaginal bleeding symptom into a factor. We performed minor changes to the survey and reperformed survey validation. **Design:** The Menopause Transition Scale© (MTS) is composed of 7 questions scored on a 3, 2, and 1 ranking with 3 being the least bothersome. The questions and scale were identified and then modified through face validation and a pilot study of patients. In this study, the MTS scale was provided to patients during a regular office visit with ages ranging from 40 to 65 who self-identified as having at least one symptom of menopause. The subjects also filled out commonly used menopause surveys (MENQOL and Greene Climacteric Scale), Decreased Sexual Desire Screener (DSDS), and Major Depressive Disorder identifier (PHQ-9). The MTS was analyzed using a Cronbach's alpha, Pearson Correlation Coefficient, Factor Analysis, and descriptive statistics. MTS was compared with the other surveys using a Pearson Correlation Coefficient. **Results:** The MTS had an error-free completion rate of 96.6% while the routinely used MENQOL completion rate without error was 59.0%. The MTS inversely correlated with the menopause symptoms scales MENQOL (-0.86, $p<0.0001$) and Greene Climatic Scale (-0.65, $p<0.0001$). Specific MTS questions correlated with other symptoms scales and subscales demonstrating construct validity. By exploratory factor analysis, the MTS questions loaded into three unique factors. The most often reported major concern was Vaginal Dryness at 45.8%. The concern with the lowest reported severity was Vaginal Bleeding with 93.8% of subjects reporting symptoms as mild. **Conclusion:** The MTS is the first menopause symptom scale, to our knowledge, to be patient-centric in wording, designed to be self-administered in a short time with accurate results, and amenable to digital use. This study validates the utility of the MTS to measure symptoms associated with menopause transition during regular office or telehealth visits, or for patient self-management. Ideally, this tool may serve to monitor symptom progression as women transition to and through menopause, and in response to a prescribed intervention or lifestyle modification. Furthermore, the brevity and accuracy could lead to scalability and ability to monitor and treat large populations of women in hopes of improving health outcomes.

Sources of Funding: Unrestricted grant from TherapeuticsMD

FRIDAY CONCURRENT SESSION #2

S-20.

The effect of an at-home ultrasound device in treating symptoms of vulvovaginal atrophy (VVA) in postmenopausal women: 1-year follow-up data from a randomized controlled trial.

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Objective: Postmenopausal women participated in this 1-year study to examine the efficacy and safety of repeated home-use therapeutic ultrasound applied to the vaginal introitus for 8 minutes/day for the treatment of VVA (Clinicaltrials.gov NCT00583-1). VVA was assessed after 3 months, 6 months, and 1 year of intervention. The initial 3-month randomized, double-blind, sham-controlled phase of this trial (results presented at the NAMS 2020 conference) was the first to demonstrate that therapeutic ultrasound increased vaginal temperature (a surrogate marker of vaginal blood flow) and significantly reduced self-reported symptoms of VVA in the treatment group compared to the sham group. The 3-month therapy also showed significant vaginal health index improvement by clinical exam for treatment compared to sham. After the double-blinded endpoint evaluation at 3 months, participants used an open-label operating device from month 3 to 1 year in both treatment (continued treatment) and sham (sham-crossover) groups. Reported here are the efficacy and safety follow-up results after 1 year of intervention. **Design:** Forty-two women (ages 48-70 years), with clinically diagnosed VVA and self-reported vaginal dryness were randomized (1:1) into treatment or sham groups. Women were excluded for use of systemic or local estrogen therapy (in the last 6 months or planned use) or any other treatment for symptomatic vaginal atrophy (in the last 4 weeks or planned use) during the study. Women were assessed after the 3-month blinded phase for participants' self-reported change (from baseline to 3 months) in VVA symptoms (vaginal dryness, soreness, irritation, dyspareunia) measured by the Vaginal Assessment Scale (VAS) with a 4-level response score ranging from none, mild, moderate, to severe. Healthcare providers evaluated change in vaginal tissue response (tissue elasticity, vaginal fluid, pH, mucosa, and vaginal moisture) assessed by the Vaginal Health Index (VHI) giving a numerical score (1-5) for each of the 5 parameters. VAS and VHI assessments were repeated at the 6-month and 1-year follow-up visits, using a Wilcoxon Signed Rank Test to assess change (paired difference) from baseline. **Results:** Month 6 follow-up results included participants (n=15) who had in-clinic visits not affected by COVID-19 closures. Change from baseline to 6 months (mean ± SD) demonstrated a 41% reduction (-0.68 ± 0.72; $p=0.005$) in symptoms of VVA on the VAS. The VHI demonstrated a 34% improvement (3.07 ± 5.32; $p=0.032$) in vaginal tissue. Change from baseline to 1 year (mean ± SD) in 13 participants with in-clinic visits demonstrated a 38% reduction (-0.74 ± 0.95; $p=0.018$) in symptoms of VVA on the VAS and a 19% improvement (1.54 ± 4.98; $p=0.352$) in vaginal tissue on the VHI. Adherence to therapy (measured via a frequency-of-use counter embedded in the ultrasound device) remained high (60-79%) from month 3 to 1 year. At study end, participants reported wanting to continue ultrasound treatment and indicated therapy preference to over-the-counter products because the device was easy to use, less messy, non-invasive, produced longer lasting results, and generated tissue moisture. No serious adverse events were recorded. **Conclusion:** For post-menopausal women experiencing symptoms of VVA, daily at-home, self-application of non-invasive therapeutic ultrasound improved VVA symptoms and vaginal health after 3 months, 6 months, and 1 year of therapy use. Treatment of VVA with repeated ultrasound could offer a new therapeutic option as it is well tolerated (no serious adverse device effects were recorded) and has demonstrated promising early signs of symptom severity relief and vaginal tissue improvement.

Sources of Funding: Madorra, Inc.

S-21.

Do Longitudinal Changes in Pituitary and Ovarian Hormones Associate with White Matter Hyperintensities in Menopausal Women after the Kronos Early Estrogen Prevention Trial?

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Objective: The effect of menopausal hormone therapy (HT) on brain structure in midlife women and how pituitary and ovarian hormones influence outcomes over time is unclear. We previously found that levels of pituitary-ovarian hormones associated with changes in white matter hyperintensity (WMH) volume, a marker of small vessel ischemic changes in the brain, in recently menopausal women using HT for 48 months. Decreases in follicle stimulating hormone (FSH) and increases in estrone (E1) slowed development of WMH in women randomized to transdermal estradiol (E2) but only increases in E1, an androstenedione (AE) metabolite, slowed development of WMH in women randomized to oral CEE. The current study objective is to detect and evaluate associations of longitudinally measured serum ovarian steroids and pituitary gonadotropins in healthy, naturally postmenopausal women studied before and 12 years after random assignment to 4 years of HT or placebo plus 8 years of observation with WMH volumes measured at the end of the 12 year period. **Design:** Cognitively healthy women aged 42-56 years within 6-36 months of their last menstrual period enrolled in the Kronos Early Estrogen Prevention Study were randomized to 4 years of 0.45 mg/d o-CEE daily or 50 μg/d tE2 weekly, plus micronized progesterone (200 mg/d x 12 d) or placebo pills and patches compliant to treatment and followed for approximately 8 years posttreatment (~12 yrs total follow-up, N=121). E2, E1, AE, testosterone (T), luteinizing hormone (LH), and FSH were measured by liquid chromatography/mass spectroscopy from serum samples collected before randomization and in follow up. Brain MRIs were performed at the same time. WMH volume was determined from 3D FLAIR MRIs using a semi-automated image segmentation algorithm. Linear regressions were run predicting log-transformed total WMH vs hormone levels (separate models for baseline, 12-yr follow-up, and slope of change from baseline to yr 12), adjusting for age and log-transformed total intracranial volume. Additional models adjusted for age, randomization arm, and cardiovascular (CV) factors potentially impacting WMH (lipids, waist to hip ratio, mean arterial blood pressure). 18 women who continued HT to follow up were excluded. **Results:** Higher baseline serum AE levels were associated with lower WMH volume after either treatment or placebo ($p=0.04$). Greater increases in AE and E1 from baseline to follow-up were associated with higher WMH volume ($p=0.04$). In the adjusted models, only the association of baseline AE and WMH volume remained significant ($p<0.05$). No statistically significant associations between other hormones at baseline, or year 12, and WMH were found. **Conclusion:** In recently postmenopausal women, higher baseline androstenedione levels, the primary steroid hormone of the postmenopausal ovary, appears to be associated with protection from WMH load years later, even after accounting for CV risk factors and randomization arm. Greater longitudinal increases in AE plus its metabolite E1 relate to greater WMH load in the long-term reflecting more small vessel ischemic changes, but these relationships were no longer significant after adjusting for CV risk factors. Investigation into the interhormonal associations and changing ratios of pituitary ovarian hormones over time for women who used HT vs placebo may further explain these relationships.

Sources of Funding: NIH RF1 AG57547, American Federation of Aging Research, research support Avid Radiopharmaceuticals, Eli Lilly

S-22.

Sexual Assault and Cerebral White Matter Hyperintensities among Midlife Women

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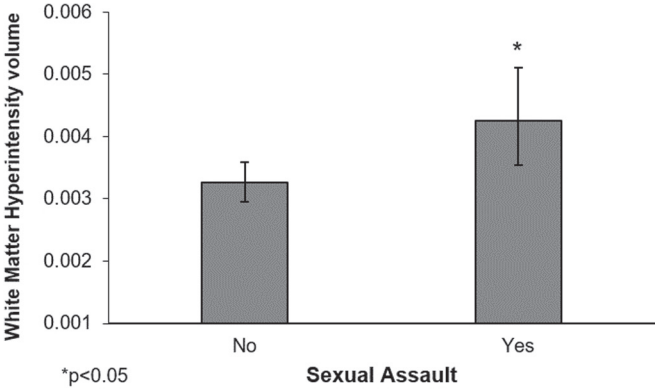
Objective: Traumatic experiences, including sexual violence, have been linked to poor mental and cardiovascular health in women as they age. However, there has been little examination of their relationship to cerebrovascular risk. White matter hyperintensities (WMHs) are markers of brain small vessel disease which can be detected decades before the onset of dementia, stroke, and other disorders and can serve as early markers for these disorders. We tested whether traumatic experiences were associated with brain WMH volume among midlife women. **Design:** In the MsBrain study, 145 midlife women (mean age=59 years) without clinical cardiovascular disease, stroke, or dementia were recruited. Women completed questionnaires [trauma checklist assessing nine trauma types, depression, post-traumatic stress measures]; physical measures [body mass index (BMI), blood pressure (BP)]; phlebotomy; actigraphy sleep measurement, and 3 Tesla magnetic resonance brain imaging for WMHs. Associations between traumatic experiences and WMH volume were assessed in linear regression models. Covariates were age, race/ethnicity, education, BMI, BP, lipids, preeclampsia, sleep, and additionally depressive and post-traumatic stress disorder symptoms. **Results:** 68% of women endorsed at least one trauma, with the most common trauma being sexual assault (23% of women). Women with trauma exposure had greater WMH volume than women without trauma [B(SE)=.24 (.09), p=.01, multivariable]. The particular trauma significantly associated with WMH was sexual assault [B(SE)=.25 (.11), p=.02, multivariable; see Figure]. Results persisted when adjusting for depressive or post-traumatic stress symptoms. **Conclusion:** A trauma history, particularly sexual assault, was associated with greater WMH volume controlling for multiple potential confounders, as well as depressive and post-traumatic symptoms. Sexual assault may place women at risk for poor brain health. Prevention of sexual assault and management of its sequalae may support stroke and dementia prevention.

Sources of Funding: NIH grants RF1AG053504 (Thurston & Maki) and K24HL123565 (Thurston)



White matter hyperintensities by sexual assault history

S-23.

Incarcerated Menopausal Women: Need for Trauma-Informed Care

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Objective: Traumatic events have both psychological and physiological effects on an individual's health. Adverse consequences from these events can range from substance abuse to mental illness. The incarcerated population is more vulnerable to trauma exposure both pre-incarceration and then, with incarceration, re-traumatization. Menopausal symptoms in the midlife and older incarcerated population can be exacerbate the effects of the trauma. This review evaluated the available data on trauma informed care in the prison population, with a focus on menopausal women. **Design:** A literature review was conducted of peer-reviewed journal articles published from 2017 to 2021. Key words included trauma-informed care, menopause and incarceration. **Results:** Six papers dealing with these topics were identified, which suggest that there is limited research on trauma-informed care for incarcerated menopausal women. The available data note, however, that trauma-informed care, although essential for improving quality of care and increasing long-term patient engagement, both inside and outside of the criminal justice system, is not universally provided. And although adverse menopausal symptoms can add to the trauma, there are no data addressing this population of incarcerated women. **Conclusion:** Women in the criminal justice system are prone to both Pre-Incarceration Trauma (PIT) and Incarceration-Based Trauma (IBT) at rates higher than incarcerated men. Furthermore, the experience of menopause during incarceration can have significant impact on a woman's overall wellbeing and contribute to IBT. Barriers to medical care and medication, as well as a lack of informational support, exacerbates the adverse effects for symptomatic menopausal incarcerated women. Given the existing prevalence of trauma for incarcerated women and the potential adverse health outcomes for menopausal women, trauma-informed care is necessary to prevent further IBT in this population. Further, to prevent victimization and re-traumatization in the clinical setting, providers may implement staff training on the impact of trauma, universal screening for past traumatic events and symptoms of menopause.

Sources of Funding: None

POSTER PRESENTATIONS

P-1.

The Impact of Team Based Learning on Confidence of Physicians' Care for Menopausal Women

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Objective: By the end of this year, more than 50 million women will be older than 51 years of age, the majority of whom will experience vasomotor symptoms. Based on a prior family medicine survey, knowledge gaps in menopause management were identified, including hesitancy to use hormonal replacement therapy in appropriate patients. Our objective is to evaluate for improvement in knowledge, attitudes and nature of menopause management during Family Medicine residency after educational intervention with team based learning (TBL). **Design:** A previous survey was collected between April and June of 2019 in the Memorial Family Medicine Residency program (MFMRP), which identified gaps in menopause knowledge. Our TBL approach utilizes a hybrid curriculum model composed of case-based experiential learning strategies along with traditional lecture-based delivery to enhance critical thinking skills and communication skills essential in clinic practice. Six weeks after a four-hour TBL discussing menopause diagnosis, treatment and management, another menopause knowledge assessment survey was implemented to MFMRP residents and faculty. Between April 19 and 29, 2021, 27 of our trainees and faculty completed the survey, which included cases and questions regarding knowledge of hormone therapy and menopause management options. **Results:** Post-didactics, there was a 22% increase in correctly identifying the diagnosis of menopause. In an uncomplicated menopausal female with hot flashes, 30% more residents were willing to use menopausal hormonal therapy (HT) as first line treatment for vasomotor symptoms. It is concerning that the majority still did not recommend appropriate and adequate HT at least until the age of natural menopause for a prematurely menopausal woman, and only a little over one-third would give HT if she was experiencing vasomotor symptoms. Nearly two-thirds of residents were unsure or disagreed about known effects of HT on gallbladder disease and dementia. Respondents were more likely to recommend resuming HRT, SSRI/SNRIs, gabapentin, weight loss and behavioral changes in patients trying to discontinue HRT than clonidine, black cohosh, soy diet, phytoestrogen supplements, acupuncture, and hypnosis. There was a 21% increase in respondents that would encourage HT for menopausal symptoms to family members. Respondents reported caring for more symptomatic menopausal women after participating in the TBL session, and 21% felt more prepared to do so. **Conclusion:** The TBL on menopause management did bridge some gaps in knowledge identified in family medicine residents. Participants had improved willingness to manage menopause, including prescribing HT, in appropriate patients and felt more prepared with menopausal management. The impact of the educational session may not have been captured in the time frame of this survey. Further didactics may address gaps that still exist.

Sources of Funding: None

P-2.

TIME FOR CHANGE: Improving the menopausal experience in the workplace for UK doctors

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Objective: NHS doctors are currently not well supported in the workplace during their menopause. A recent BMA survey revealed that very few doctors felt comfortable discussing their symptoms with their managers and many feel unable to make changes to their working lives to accommodate their menopausal symptoms. An improved menopausal experience in the workplace has been associated with increased job satisfaction, increased economic participation and reduced absenteeism. However, there is a lack of research exploring the experiences of menopausal doctors. Existing literature is composed of mostly single-sector studies and no study has considered the perspective of non-menopausal colleagues. This qualitative study aimed to explore the barriers and facilitators of an improved menopausal experience for doctors in the workplace. **Design:** We conducted a cross-sectional qualitative study using semi-structured interviews of both menopausal (n=21) and non-menopausal (n=20) doctors. Participants were recruited using purposive sampling. Interview questions were designed to capture the menopausal workplace experiences of both cohorts. Interviews were transcribed and then thematically analyzed using the Gioia method. **Results:** Our qualitative study identified a total of 8 barriers to an improved menopausal experience: taboo, the negative symptomatic effects of menopause, a lack of discussion, a lack of knowledge, a superhero mentality, unhelpful gender dynamics, the archaic culture of the NHS and a lack of support from both colleagues and the organisation. We also identified a total of 5 facilitators: Accommodating working conditions, knowledge, a supportive organisational environment, non-occupational support streams and open discussion. **Conclusion:** This study highlights that many barriers and facilitators to an improved menopausal experience for working doctors are comparable to other work sectors, however novel themes specific

to the NHS were elicited, including the superhero mentality where doctors felt they needed to just 'get on' with work and ignore their menopausal struggles and the archaic culture of the NHS whereby traditional organisational structures negatively impacted menopausal individuals. All of the themes identified must be addressed to successfully improve the menopausal experience for working doctors, and they highlight the necessity for further research in the field of menopause in working doctors.
Sources of Funding: None

P-3.

Cannabis Use in Menopause: Capturing the Experiences and Perspectives of Women

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Objective: Use of cannabis has increased in Canada since the legalization of recreational cannabis in 2018, with growing interest to manage health issues. Midlife women may be using cannabis to help with symptoms overlapping with menopause. Yet, there is a lack of evidence available on the benefits of cannabis for this, despite anecdotal reports and online promotion of cannabis products for menopause. Moreover, it is unclear how many women are currently using cannabis, specifically for medical purposes related to menopause. As part of a mixed methods study, the purpose of the survey was to characterize cannabis use patterns and perceptions in a population of midlife women living in Alberta, Canada. The overall goal of this study was to go directly to women to learn from their experiences and examine the rates of cannabis use in this population. **Design:** A cross-sectional, web-based survey was designed by the research team and hosted on Qualtrics. Survey questions included self-reported menopause status, symptoms, and questions on cannabis use, reasons for use, information resources and overall perceptions about cannabis. Inclusion criteria for participation was women, ages 35 and over, and living in Alberta. Recruitment was done between October to December 2020 through social media platforms (Facebook, Instagram, and Twitter) using post-sharing and targeted-ad campaigns. A link to the survey was publicly available and respondents first completed screening questions off inclusion criteria. Eligible participants then completed the survey, available in English-only. Free response answers underwent content analysis to depict general perceptions towards cannabis use in menopause. Descriptive statistics summarized the sample, and demographic and clinical data from current cannabis users and non-users was compared using chi-square test. **Results:** A total of 1,761 responses were collected and 1,495 were included for analysis. The median age was 49.0 years (IQR=43.0-55.0). Of the survey respondents: 272 (18%) women self-reported in pre-menopause, 486 (33%) women in perimenopause, and 522 (35%) in post-menopause. Overall, 187 (13%) had undergone a hysterectomy and 64 (4%) a bilateral oophorectomy. The respondents were predominantly white (93%) and 119 (8%) were current tobacco smokers, while 524 (35%) were past smokers. Over a third of women (33%) reported using cannabis within the last 30 days, and 65% indicated ever using cannabis. Current cannabis use rates were similar among the different menopause stages. Of the 499 current cannabis users, 374 (75%) reported use for medical purposes and 213 (43%) used at least once daily. Most common reasons for current use included: sleep issues (65%), anxiety (45%), muscle/joint achiness (33%), irritability (29%), and depression (25%). Three-quarters of current users found cannabis helpful with their symptoms. Compared to current non-users, current users were more likely to report sleep issues (73.5% vs. 62.8%, p<0.0001), depression (42.3% vs. 28.0%, p<0.0001), irritability (54.5% vs. 43.0%, p<0.0001), mood swings (44.7% vs. 32.2%, p<0.0001), anxiety (58.9% vs. 44.8%, p<0.0001), difficulty concentrating (57.7% vs. 46.0%, p<0.0001), muscle/joint achiness (52.7% vs. 39.1%, p<0.0001), and painful intercourse (14.8% vs. 10.4%, p=0.01). Edibles (52%) and oils (47%) were the most common currently used formulation. Common sources of cannabis information for medical purposes were internet searches (46%) or family/friends (34%). Analysis of comments provided by over a third of respondents identified women were seeking more information on this topic, some experienced symptom improvement with cannabis, whereas others expressed desire to relieve menopause symptoms with cannabis. **Conclusion:** Midlife women are using cannabis for symptoms which overlap with menopause. Women who currently use cannabis reported more symptoms compared to women who are not using cannabis. Information about cannabis was more frequently accessed through online searches and personal contacts rather than healthcare providers. Further research is required to assess the safety and efficacy of cannabis for menopausal symptoms, as well as develop clinical resources for women.
Sources of Funding: Canadian Institutes of Health Research (CIHR)

P-4.

Results of a patient experience survey to evaluate the effects of Relizen to treat vasomotor symptoms in women

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Objective: Menopausal women often experience vasomotor symptoms (VMS) including hot flashes and night sweats, and many desire non-hormonal treatment options. Relizen® is a unique flower pollen extract that is non-hormonal and efficacious in the treatment of hot flashes, night sweats, irritability, and fatigue. Relizen has been shown to work through a serotonergic mechanism and has no estrogenic effects. In a randomized, double-blind, placebo-controlled clinical trial, Relizen significantly reduced hot flashes compared to placebo. This national survey study was conducted to further confirm the results of controlled trials in a real-world setting and gather patient experience data on the use of Relizen for the relief of vasomotor symptoms. **Design:** Data were compiled from 4,925 Relizen customers who participated in three optional, rolling online surveys, conducted between January 2015 and April 2021. Participating women had been taking Relizen for at least three months and were given a $5-10 gift card for completing the survey. The survey results were pooled and analyzed. **Results:** Major survey findings reflecting the opinions of women taking Relizen for at least three months include: 84% responded that they saw a positive effect in one or more areas; 75% responded that they saw positive effects in three or more areas; 77% responded that Relizen reduced the frequency of hot flashes; 75% responded that Relizen reduced the intensity of hot flashes; 71% responded that Relizen reduced the frequency of night sweats; 70% responded that Relizen reduced the intensity of night sweats; 65% responded that Relizen improved their quality of life; 55% responded that Relizen improved their quality of sleep; 73% responded that they saw a positive effect within three months. In addition, 85% responded that they would continue taking Relizen and 83% responded that they would recommend Relizen to any friends or family members experiencing menopausal symptoms. **Conclusion:** The results of this survey study demonstrated that Relizen frequently improved multiple vasomotor symptoms, including hot flashes, night sweats, and quality of sleep. Furthermore, the benefits reported in women taking Relizen in an uncontrolled, at-home setting are consistent with the findings of previously published controlled clinical studies.
Sources of Funding: This study was funded by JDS Therapeutics, LLC, the parent company of Bonafide®.

P-5.

Association Between Urinary Triclosan Levels and Menopausal Status: Analyses of NHANES (2003-2016) Data

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Objective: To investigate the association between urinary levels of triclosan (TCL), a ubiquitous, putative endocrine disrupting compound, and menopausal status using Centers for Disease Control and Prevention's National Health and Nutrition Examination Survey (NHANES) 2003-2016 data. **Design:** We used data from female participants who completed the reproductive health questionnaire and provided urine for TCL measurement during NHANES collection from 2003–2016. Participants who responded "No" to "Have you had at least one period in the past 12 months?" were subsequently asked "What is the reason that you have not had a period in the past 12 months?" We classified women as postmenopausal if they answered "No" to the first question and indicated the reason to be "Menopause" or "Menopause/hysterectomy." For women who reported having gone through menopause, age at occurrence was recorded. The relationship between urinary TCL level and age at menopause as well as menopausal status was examined utilizing univariable analyses. Quartiles of urinary TCL were calculated. Multivariable ordinal logistic regression examined the association between quartiles of urinary TCL (Q1 as reference) and menopausal status after adjusting for age at menopause, race/ethnicity, smoking status, and BMI. Sensitivity analysis re-examined the relationship of urine TCL with menopausal status in women of age < 65. P-values < 0.05 were deemed statistically significant. We used Stata V 16.1 for analyses. **Results:** The mean age at time of survey for the menopausal population (n=5,664) was 64.8 years (SD 11.3). The mean age at menopause was 45.0 years (SD 8.26). Urinary TCL levels (ng/ml) did not relate to age at menopause (r=-.027, p=.316). Urinary TCL levels were not associated with age at the time of survey (r=-.0010, p=.899). Urinary TCL levels were significantly higher in the menopausal compared to premenopausal population (median 8.2, 25th-75th percentile 1.63-49.5 vs median 7.3, 25th-75th percentile 1.8-36.7, p<.001). On multivariable analysis menopausal status was a significant independent predictor of higher quartiles of urinary TCL (OR=1.15, 95% CI: 1.03-1.28) compared to the non-menopausal population. On sensitivity analyses restricting the menopausal population to age less than 65 (n=2,336) at the time of survey completion, the magnitude of association of menopausal status with greater quartiles of urinary TCL was more robust (OR=1.69, 95% CI: 1.45-1.96). **Conclusion:** Our findings identify menopausal status as an independent predictor of higher urinary TCL levels in the general U.S. population.
Sources of Funding: None

P-6.

Compounded hormones for female patients: a survey assessment of clinical practices in the U.S.

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Objective: In the U.S., millions of prescriptions are filled annually for compounded bioidentical hormone therapy (cBHT). In the light of an increasing demand and supply for a personalized and natural approach to hormonal imbalance, the clinical utility of cBHT has been recently questioned. A national-wide survey research of clinical practices was conducted with the objective to provide current evidence-based data on the safety, effectiveness and use of compounded hormones for female patients. **Design:** The survey research was developed using Google Forms and a bit.ly web link was disseminated online to a purposive sample of physicians who commonly prescribe compounded hormones for female patients in the U.S. The survey was launched on December 7th, 2020 and closed on February 15th, 2021. It was organized in 5 sections and 12 brief questions, of which 5 were required. The majority of the survey questions were multiple-choice or check-boxes and only 3 were open-ended questions. The introduction stated the objective of the research and a confidentiality disclaimer. The first section was demographic and included an eligibility question. The following section gathered data on the prescribing

habits, namely the preferred route(s) of administration and the commonly prescribed hormones. The third section addressed the physician's evaluation of the efficacy of their prescribed hormones. Physician's were asked the methods used to evaluate efficacy (open-ended). Three additional questions assessed the testing of laboratory values for hormone levels. The following section was one open-ended question regarding the safety evaluation. The last section was an invitation to enroll physicians in a retrospective and/or prospective study. The data collected was automatically stored online and entered into a spreadsheet for further analysis. **Results:** A total of 489 responses were submitted online, of which 434 met the eligibility criteria and were deemed valid. This was a national-wide survey research including physicians' data across 44 U.S. States, mainly from AZ, TX and CA. Topical and/or transdermal is the preferred route of administration of hormones, as stated by 78.1% physicians, followed by oral/sublingual/buccal (73.3%) and vaginal delivery (55.3%). Hormone pellets (implanted under the skin) are the least popular dosage form (35.5%). The top 3 most commonly prescribed hormones are, in descending order, progesterone, testosterone and Bi-Est (estradiol and estriol). Almost all physicians test laboratory values before initiating hormone therapy and repeated testing is commonly performed at 3, 6 and 12 months. Close to 90% of physicians test hormones in serum (blood). Saliva and urine testing are also popular but to a much smaller extent. Almost all physicians evaluate the safety of their prescribed hormones, mainly using mammograms, follow-up laboratory values (hormones, CBC, CMP) and pelvic exams (pap smear, transvaginal ultrasound). **Conclusion:** Compounded bioidentical hormones are currently prescribed to female patients across the U.S. Almost all physicians evaluate the efficacy and safety of the prescribed hormones on a regular and individual basis using recommended routine laboratory tests and OB/GYN exams.

Sources of Funding: Not applicable

Physicians' responses to survey question number 8: Which is your preferred testing for compounded hormones?

Serum (Blood)	89.4%
Saliva	16.6%
Urine (All)	10.4%
Blood Spot	0.5%
None or Blanks	1.4%

Survey question number 6: Do you test laboratory values before initiating hormone therapy? Physicians' responses: 'Yes' displayed in blue colour (97%) and 'No' displayed in black colour (3%).

P-7.

Impact of viewing a 10-minute educational video prior to initial consultation in Mature Women's Health and Menopause Clinic

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Objective: To assess acceptability of a 10-minute educational video about menopause, vasomotor symptoms and available treatments among women before first appointment at a menopause clinic and to determine its impact on participants' menopause knowledge and certainty about treatment choice. **Design:** This was a before-after intervention study among new patients referred with vasomotor symptoms to the Menopause Clinic at Mount Sinai Hospital, a tertiary care hospital in Toronto, Canada. Participants completed an online pre-intervention survey collecting baseline demographics (age, ethnicity, education level, household income and referring physician), prior and current menopause treatments, menopause knowledge and certainty about treatment choice. They were then prompted to view a 10-minute video on basic menopause facts as well as information about vasomotor treatment options available (lifestyle modification, natural supplements, non-hormonal prescription treatment and menopause hormone therapy). After the video, participants answered the post-intervention survey assessing menopause knowledge, certainty about treatment options and acceptability of the education video. Menopause knowledge was evaluated using a 19-item true/false questionnaire and decisional certainty and acceptability were assessed using validated instruments (Decisional Conflict Scale (DCS) and Acceptability questionnaire, respectively). Demographic information and acceptability were summarized descriptively and independent samples t-test compared knowledge and DCS total and sub-scores before and after viewing the education module. Being "sure" about treatment was defined as a DCS total score ≤ 25. Multivariable analysis was used to identify factors associated with achieving treatment certainty after watching the video. **Results:** Ninety participants were recruited with 78.8% (71/90) completing pre- and post-intervention surveys. Of those who completed the study, mean age was 51.41 years ± 6.04 years. Most participants were Caucasian (58/71, 81.7%), had a university degree (24/71, 63.3%), had a household income > $90,000 (53/71, 74.6%) and were referred by a family physician (52/71 73.1%). After watching the video, there was a significant increase in knowledge score (12.7 ± 2.15 vs 16.9 ± 1.79) and decision certainty with all DCS scores (total and all five sub-scores) decreasing between the pre- and post-video surveys ($p < .001$). There was also an increase in those who "sure" about treatment choice (3/71, 4.2% vs 21/71, 29.6%, $p < 0.001$). Acceptability of the tool was high with most participants (62/71, 87.3%) indicating it was useful in helping to make a decision about therapy. These findings were independent of level of education, annual household income, or type of referring physician. **Conclusion:** Viewing a 10-minute educational video on menopause and treatment of vasomotor symptoms was acceptable among patients, improved knowledge and increased decision certainty about treatment for vasomotor symptoms.

Sources of Funding: This project was awarded a quality improvement competitive grant from Pfizer Canada.

P-8.

The use of vaginal CO2 laser for the management of genitourinary syndrome of menopause in gynecological cancer survivors: a systematic review

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Objective: Our objective is to evaluate the published data on the effect of CO2 vaginal laser for the management of GSM in gynecological cancer patients. **Design:** Databases searched included MEDLINE, Embase, PubMed (for non-MEDLINE records only), Cochrane Central Registry of Controlled Trials, Cochrane Database of Systematic Reviews, and Google Scholar. No date, age, or geographic restrictions were applied to the searches. Databases were searched from their inception dates. Selected studies assessed the use of CO2 vaginal laser in gynecological cancer patients with GSM. **Results:** A total of 269 studies were retrieved. Three studies met the inclusion criteria. All these studies were conducted in Italy. Each study used a different type of CO2 vaginal laser for the management of gynecological cancer patients. All of the studies followed a different laser protocol, and used a vaginal probe only. None of the studies used a vulvar probe. Two studies were prospective, and one study was a retrospective chart review. There are no randomized controlled trials that assess the use of CO2 vaginal laser in gynecologic cancer patients. The number of gynecological cancer patients treated with intravaginal CO2 laser for the management of GSM is extremely limited (N<100) to recommend its use outside of the clinical setting. There are no studies that support the use of CO2 vaginal laser to manage GSM in vulvar or vaginal cancer patients. **Conclusion:** There is a lack of literature on the impact of vaginal CO2 laser use in gynecologic cancer patients to manage GSM. Research into vaginal CO2 laser use is essential, as it is frequently used to alleviate symptoms without evidence of its benefits.

Sources of Funding: None

P-9.

MsFLASH Analysis of Diurnal Salivary Cortisol and Palpitations in Peri and Postmenopausal Women

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Objective: Greater understanding of biological mechanisms associated with heart palpitations (feelings of skipped, irregular, or exaggerated heartbeats) during the menopause transition could further treatment efforts. Cortisol diurnal pattern may be an important biomarker of palpitations. Cortisol may affect the myocardial tissue directly through cardiomyocyte glucocorticoid signaling and indirectly by heightening catecholamine and renin-angiotensin effects. Using the Menopause Strategies Finding Lasting Answers to Symptoms and Health (MsFLASH) data repository, the objective was to evaluate the relationship between diurnal salivary cortisol patterns and distress from heart palpitations in peri- and postmenopausal women. **Design:** Baseline data from 293 women with vasomotor symptoms from the MsFLASH behavioral intervention trial were analyzed. "Palpitations distress" was defined as "distress from heart racing or pounding in the past two weeks". Responses of "not at all" were coded as no distress. Responses of "a little bit", "moderately", "quite a bit", and "extremely" were coded as yes. Salivary cortisol values were obtained via self-collected swabs at 4 time points on each of two days: upon awakening (wake), 30 minutes later (wake+30), early afternoon, and bedtime. Demographic, clinical, and symptom data were compared between palpitations distress groups (no, yes) using t-tests and chi-square tests. Cortisol values were log transformed and geographic means and 95% confidence intervals were graphed. Data from both days of cortisol collection were included as repeated measures in linear regression models of log cortisol values at each time point as a function of palpitation distress (yes/no), day (1st or 2nd), clinical center, and other potential confounders. Robust standard errors were calculated via generalized estimating equations to account for correlation between repeated measures from each participant. **Results:** Women were white (67%), Black (23%), or other races (10%) and peri- (16%) or postmenopausal (84%). Palpitations distress was reported by 26% of women. Palpitations distress did not vary by age, race/ethnicity, smoking, marital status, employment, body mass index, blood pressure, or menopausal status. Compared to those without palpitations distress, those with palpitations distress had significantly more VMS, perceived stress, depressive symptoms, and insomnia severity. Further, relative to their non-distressed counterparts, women with palpitations had significantly lower wake+30 cortisol that remained significant in models adjusted for multiple covariates. **Conclusion:** Distress from heart palpitations was associated with blunted morning salivary cortisol, which has been associated with increased cardiovascular mortality in some populations. The cardiovascular consequences of the relationship between menopausal palpitations and blunted morning cortisol response in women warrants further study.

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P-10.

A Systematic Review of Demographic, Clinical, and Symptom/Quality of Life Factors Associated with Palpitations in Menopausal Women

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Objective: Up to 40% of peri- and 54% of postmenopausal women report palpitations (feelings of skipped, irregular, or exaggerated heartbeats). Understanding demographic, clinical, and symptom/quality of life (QOL) factors related to palpitations can assist clinical practitioners identify women who may be at risk for these symptoms and help women who may be at high risk for severe symptoms. In addition, understanding factors can help researchers in designing descriptive studies that appropriately control for possible confounding variables and in developing interventions targeting modifiable factors. Thus, the objective of this integrative review was to summarize research documenting associations between various factors and palpitations prevalence and severity. **Design:** An integrative review was conducted of English-language, full-length, peer-reviewed, descriptive research studies pertaining to palpitations in menopausal women published prior to May 19, 2020. Articles identified from PubMed, Cumulated Index to Nursing and Allied Health Literature (CINAHL), and PsycINFO searches were de-duplicated and screened in two stages (abstract and full text) for their inclusion by independent reviewers. Data extraction was done by independent reviewers for verification of accuracy. Quality and risk of bias were assessed with the AXIS Tool for cross-sectional studies. **Results:** A total of 74 articles were included in this review. All were cross-sectional, descriptive studies. Most (n=72, 97%) were considered poor quality. Articles originated most often from China (n=10), Turkey (n=6), and the USA (n=5). Article results provided information on factors related to palpitations presence (57%, n=42), severity (35%. n=26), or both (8%, n=6). Articles included analysis of demographic factors (22%, n=16), clinical factors (81%, n=60), or symptoms/QOL (18%, n=13). Although 12 articles (16%) evaluated two categories of factors, no articles (0%) evaluated all three categories of factors in relationship to palpitations. Factors associated with higher palpitations prevalence were different from factors associated with palpitations severity. Variables associated with greater palpitations prevalence included: demographics (race/ethnicity, lower education and income); clinical factors (higher body mass index, advancing menopausal stage), greater dietary animal fat intake, hyperthyroidism (e.g., Grave's disease, low thyroid stimulating hormone, higher free thyroxine), greater parity, past smoking, hormone therapy use, Chinese herbal medicine use, low physical activity; and symptom/QOL factors (poor sleep, greater vasomotor, depressive, and anxiety/stress symptoms, poor quality of life). Variables associated with greater palpitations severity were: demographics (race/ethnicity, being divorced); clinical factors (advanced menopause stage, low bone mineral density, 1-2 pregnancies, older age at second abortion, use of aromatase inhibitors, Chinese medical diagnosis of Yang-xu constitution, and low soy intake); and symptom/QOL factors (poor sleep, poor sexual function). **Conclusion:** This review showed heterogeneity in factors that were studied and the relatively sparse and variable quality evidence for associations of any one factor to palpitations. Additional research from well-designed, prospective, and longitudinal studies is needed to understand risk and protective factors related to menopausal palpitations.

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P-11.

Childhood maltreatment, blood pressure, and arterial stiffening among midlife women

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Objective: Childhood maltreatment, i.e., abuse and neglect, is prevalent and increases risk for later life adverse health outcomes. Cardiovascular disease (CVD) is the leading cause of death in women, and arterial stiffening plays a key role in the pathophysiology of CVD. While past research demonstrated associations between childhood maltreatment and arterial stiffness, research has yet to examine this relationship specifically among midlife women. Studying midlife women is critical, as midlife and the menopause transition is a time of accelerated arterial stiffening. Further, the mechanisms underlying relationships between childhood maltreatment and CVD risk are not fully known; elucidating these mechanisms can guide efforts to reduce the cardiovascular sequalae of childhood maltreatment. This study tested whether childhood maltreatment is associated with arterial stiffening among midlife women and investigated mechanisms that may underlie this relationship. **Design:** Participants (N=170, 71% white, 25% black, 4% other ethnicity) were members of the MsHeart/MsBrain cohort of peri and postmenopausal women. At enrollment, all women were aged 40-60, without clinical CVD, non-smoking, not taking hormone therapy, and had their uterus and at least one ovary. Participants underwent two waves of data collection (baseline and follow-up) approximately 5 years apart. Childhood abuse and neglect was measured at baseline via the Child Trauma Questionnaire. At follow-up, participants self-reported demographics and completed seated heart rate and blood pressure measurement. Carotid-femoral pulse wave velocity (cfPWV) was assessed via ultrasound. Hierarchical linear regression analyses tested associations between childhood maltreatment in relation to cfPWV while adjusting for age, education, race/ethnicity, body mass index (BMI), hypertension medication, heart rate, and time between visits. Systolic blood pressure (SBP) was evaluated as a mediator by calculating the indirect effect of SBP in the association between childhood maltreatment and cfPWV using the products of coefficients method and bootstrapping. **Results:** Seventy-three women (43% of the sample) reported a history of childhood maltreatment. Women with a history of childhood maltreatment had higher cfPWV [b(SE)=.51 (.21), p=.02] controlling for age, education, race/ethnicity, BMI, heart rate, hypertension medication, and time between visits. Associations between childhood maltreatment and cfPWV were mediated by SBP [indirect effects of childhood maltreatment on cfPWV through SBP: effect (95% confidence intervals) =.23 (.07, .47)]. SBP mediated 46% of the effect of childhood maltreatment on cfPWV. **Conclusion:** In this sample of midlife women, childhood maltreatment was associated with arterial stiffness. This association was largely accounted for by SBP. These findings underscore the long-term cardiovascular implications of childhood maltreatment. Blood pressure control may mitigate the impact of childhood maltreatment on cardiovascular health.

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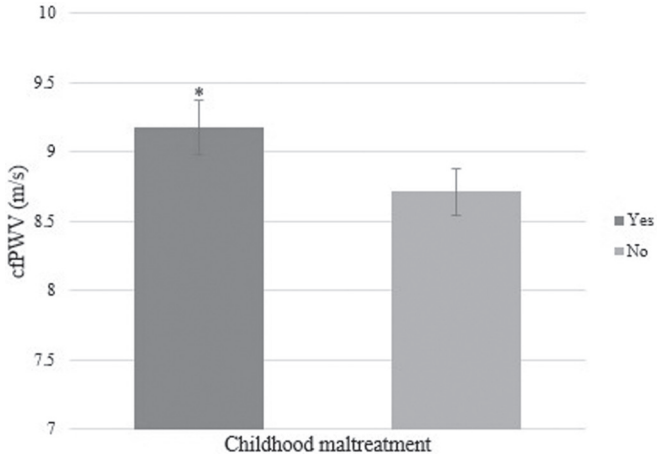

Adjusted mean cfPWV by childhood maltreatment history. Means adjusted for age, education, race/ethnicity, BMI.

P-12.

Ovarian senescence: Is there an explanation for variability in ovarian aging?

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Objective: Ovarian aging is an intricate physiologic process resulting in the age-specific, irreversible decline in the number and quality of the primordial follicle pool (PFP) to the point of infecundity and cessation of hormonal production resulting in menopause. The 12 months following the last menstrual cycle signals menopause after losing ovarian function, and its timing is affected by genetics. It is well studied that ovarian reserve decreases chronologically with age. Ovarian aging happens faster than other bodily organs, causing infertility and leading to harmful health diseases such as cardiovascular and ischemic heart disease, osteoporosis and loss of bone density, Alzheimer's disease, and weight gain and changes in the adipose deposition. Maintaining ovarian function also has a caveat associated with increased risk for breast, ovarian, and endometrial cancer. Several postulated theories on ovarian aging propose two mechanisms: either from ovarian tissue itself or dysregulation of the hypothalamic gonadotropin-releasing hormone (GnRH) production. Also, a not well-accepted theory suggests that the degradation of ovarian stem cells can cause ovarian aging, particularly in reproductive health. The rate of decline for ovarian reserve varies widely even among females of similar age. Within our Center for Specialized Women's health menopause clinic, we have witnessed several women who spontaneously had a return of ovarian function. These specific cases of return of ovarian function sparked curiosity in questioning the mechanism. Since age at menopause has been identified as a critical marker of a woman's health, research efforts to investigate the physiology of ovarian aging and factors that influence ovarian reserve are imperative. We know ovarian aging is influenced by multiple factors such

as environmental, nutrition, and genetics. Here we will conduct a retrospective study observing the effect of multiple factors (melatonin, metformin, parity, ethnicity, body mass index, age of menarche, age at first and last birth, smoking history, and diet) on ovarian aging. **Design:** This is a future study. Pending IRB approval. We will conduct a retrospective chart review of postmenopausal women to review for certain factors such as the use of metformin or melanin, age of menarche, age at first birth and age at last birth, diet, BMI, ethnicity, parity, and smoking history. **Results:** Pending results as awaiting pending IRB approval Plans to complete retrospective study by 09/2021. **Conclusion:** Pending as awaiting pending IRB approval Aim of discussion points: These specific cases of return of ovarian function sparked curiosity in questioning the mechanism. Since age at menopause has been identified as a critical marker of a woman's health, research efforts to investigate the physiology of ovarian aging and factors that influence ovarian reserve are imperative. We know ovarian aging is influenced by multiple factors such as environmental, nutrition, and genetics. Here we will conduct a retrospective study observing the effect of multiple factors (melatonin, metformin, parity, ethnicity, body mass index, age of menarche, age at first and last birth, smoking history, and diet) on ovarian aging.

Sources of Funding: none

P-13.

Impact of sleep fragmentation and estradiol withdrawal on cortisol levels in a human experimental model of menopause

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Objective: Sleep fragmentation is prevalent during the menopause transition - a reproductive stage characterized by estradiol withdrawal and hot flashes. It remains unclear if fragmented sleep and/or estradiol withdrawal perturb the hypothalamic-pituitary-adrenal (HPA) axis, which may contribute to increased cardiovascular risk after menopause. Therefore, we examined the impact of experimental sleep fragmentation and pharmacologically-induced estradiol withdrawal on the HPA axis in healthy young women. **Design:** Twenty-two premenopausal women (age 31 ±6.5 years, BMI 25.3 ±3.9 kg/m^2) completed a 5-night inpatient study during their mid-late follicular phase, a high estrogen state; a subset (n=14) completed the same inpatient protocol during leuprolide-induced estrogen deficiency. Each inpatient stay included 2 nights of undisturbed sleep with an 8-h sleep opportunity followed by 3 nights of experimental sleep fragmentation with a 9-h sleep opportunity, including ~60 min of wakefulness after sleep onset (WASO) per night. HPA axis outcomes included serum cortisol levels at bedtime, and the cortisol awakening response (CAR), calculated as the difference between cortisol values at wake and wake +30 min. Generalized linear mixed models were used to assess the effect of sleep fragmentation, estradiol withdrawal, and their interaction on HPA axis outcomes, and to quantify the magnitude of the associations between polysomnography (PSG)-derived WASO and total sleep time (TST) with HPA axis outcomes. PSG-based sleep assessment confirmed the fragmentation protocol, on average, induced 101.5 min of WASO compared to 37.7 min of spontaneous WASO on undisturbed nights ($p<0.01$), whereas, as intended, TST was no different on undisturbed and fragmented nights ($p=0.51$). **Results:** Bedtime cortisol levels were significantly higher ($p=0.03$) following nights of sleep fragmentation (adjusted mean ± standard error [SE] 3.28±1.11 μg/dL) compared to undisturbed sleep (2.60±1.07 μg/dL), and CAR was blunted ($p=0.01$) after sleep fragmentation (1.59±0.71 μg/dL) compared to undisturbed sleep (3.69±0.51 μg/dL). Bedtime cortisol was significantly higher ($p=0.02$) in the estrogenized state (3.30±1.1 μg/dL) compared to the hypoestrogenic state (2.58±1.08 μg/dL); however, CAR was similar in both estradiol conditions ($p=0.38$). The effect of sleep fragmentation on HPA axis outcomes was not modified by estradiol state (interaction $p\geq0.41$). PSG-derived WASO was significantly negatively associated with CAR (-2.2 μg/dL lower CAR for each additional hour of WASO, $p<0.01$) and positively associated with bedtime cortisol (0.21 μg/dL higher bedtime cortisol for each additional hour of WASO, $p<0.01$). However, as expected, neither HPA axis outcome was associated with PSG-derived TST (both, $p\geq0.1$). **Conclusion:** Our results show that sleep fragmentation, as seen commonly during the menopause transition, adversely impacts HPA axis activity by elevating bedtime cortisol and blunting CAR. Importantly, the magnitude of change in both bedtime cortisol and CAR after sleep fragmentation were associated with the amount of increase in objectively assessed WASO. In contrast, estradiol withdrawal did not increase bedtime cortisol or alter CAR, counter to what might be expected for menopause. These results highlight the central role of menopause-related sleep fragmentation in disrupting the HPA axis, which in turn may lead to adverse health effects in aging women. Our findings underscore the clinical importance of treating menopause-related sleep fragmentation even when women meet the recommended guidelines for sleep duration.

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P-14.

The Effect of Burdensome Ambulatory Hot Flash Monitoring on Sleep and Physical Activity

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Objective: It is essential to understand how ambulatory hot flash (HF) monitoring affects behavior, which may in turn affect HF burden. This analysis aims to evaluate the effect of ambulatory HF monitoring on physical activity (PA) and total sleep time (TST), and examine the relationship between amount of waking sedentary time (ST), light PA (LPA), and moderate-to-vigorous PA (MVPA), and number of HFs occurring in a 24-hour period. **Design:** Fifteen menopausal people with daily HFs [age (mean±SD): 54.4±4.3 yrs, BMI: 28.3±4.4 kg/m^2, 100% assigned female sex at birth, 4.0±5.8 yrs since last menstruation] who are not taking any pharmaceutical HF treatments volunteered to complete one baseline and one ambulatory HF monitoring session. In session 1 (V1) and session 2 (V2) participants wore an ActiGraph GT9X+ on the non-dominant wrist; in V2 they also wore a montage of sensors to assess vasomotor symptoms and a wrist worn digital event marker to self-report HF onset. Participants were encouraged to adhere to their usual PA and sleep habits for both sessions. Twenty four hours of HF and ActiGraph data from each session were analyzed, beginning at sleep onset on the first night. Cumulative step count (CSC) was obtained with ActiGraph's proprietary algorithm then adjusted with a regression yielding a more accurate assessment of CSC from a wrist worn monitor[1]. Time spent in ST, LPA, and MVPA was calculated using vector magnitude count cut-points[2]. TST was calculated with Cole-Kripke's sleep-wake detection algorithm. The HF count includes both participant-reported HFs and objectively identified HFs. Objective HFs were identified with UFI's FlashTrax software using an identification criteria of a ≥2.0 uMho rise in skin conductance within a 30 second window. In 5 participants the threshold was lowered to ≥1.5 uMho in 30 seconds; these participants' skin conductance peaks during participant-reported HFs consistently failed to meet the standard criteria. Cohen's *d* were calculated to examine effect size of differences in CSC, ST, LPA, MVPA, and TST between V1 and V2 and were deemed appropriate due to the small sample size of this preliminary analysis of an ongoing study. Pearson correlation coefficients were calculated to explore the relationship between ST, LPA, and MVPA and HFs in V2. **Results:** Mean CSC were 11425.0±2010.0 and 11090.0±1377.4 steps/day for V1 and V2, respectively. Participants spent 662.4±156.0 daily minutes in ST in V1 and 611.1±152.1 minutes in V2; 78.0±22.1 minutes in LPA in V1 and 98.7±28.0 minutes in V2; and 262.9±85.7 minutes in MVPA in V1 and 263.3±75.9 minutes in V2. Mean TST in V1 was 437.4±120.4 and 467.5±130.7 in V2. Effect sizes between sessions revealed a large effect size difference for the increase in LPA (d=0.82), small effect size differences in ST (d=0.33) and TST (d=0.24), and negligible effect size differences in CSC (d=0.11) and MVPA (d=0.01). On average, 9.7±4.8 HFs occurred during V2. Pearson correlation coefficients showed a statistically significant large negative association between V2 ST and HFs (r=-0.56, p=0.03) and nonsignificant moderate positive associations between V2 LPA and HFs (r=0.45, p=0.10) and V2 MVPA and HFs (r=0.50, p=0.06). **Conclusion:** The negative association between ST and HFs and the positive association between MVPA and HFs in V2 warrant further investigation as they contradict previous reporting on fitness and its positive effect on vasomotor symptoms. These trends appear to be driven by a few highly active individuals with high HF frequency; analysis of the larger sample size of our ongoing study may reveal changes in these outcomes. Differences in CSC, ST, MVPA, and TST between sessions were small to negligible, though there was a large increase in LPA from V1 to V2. The results indicate that donning cumbersome HF monitoring equipment did not have a deleterious effect on PA or TST patterns. This finding suggests that we are able to assess HF activity without negatively impacting sleep or physical activity. **1.** Park et al., *Translational Journal of the ACSM*, ahead of print, 2021. **2.** Montoye et al., *Journal of Sports Sciences*, 2020.

Sources of Funding: Massachusetts Life Sciences Center, Embr Labs

P-15.

Content Analyses of a Cognitive Behavioral Group Therapy Program for Women with Menopause Symptoms and Bipolar Disorder.

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Objective: Bipolar disorder affects millions of women, yet little is known about the impact of this disorder during the peri- and postmenopausal transition. There are three known cognitive behavioral therapy protocols to help women with problematic menopause symptoms, but these protocols do not target women on the bipolar disorder spectrum. The purpose of this qualitative study was to learn more about the group experience and treatment needs for women diagnosed on the BD spectrum with problematic menopause symptoms. **Design:** This was an analysis of qualitative data from a single group, pre-post-test of cognitive behavioral group therapy (CBGT). Narrative data from intake forms, interventionist notes, and a post-intervention evaluation survey from eight of 11 women diagnosed with bipolar disorder and with complete data were included in the content analyses. All women had provided informed consent and participated in the parent study. Ethical approval for this qualitative study was obtained from University Hospitals Cleveland Medical Center Institutional Review Board. Qualitative data were analyzed by two team members using standard content analytic procedures. The two

team members read all text units from the three qualitative sources explained above. One author then coded each relevant text unit with a label to capture the essential meaning. Similar codes were grouped together and organized into categories. Another author reviewed the coding and categorizing. Both team members reached consensus on coding and categorization through discussion. **Results:** Three themes emerged: what women wanted help with (specific symptoms and general aspects of menopause), what women liked about CBGT, (specific and general aspects of the program), and changes needed in the intervention (things wished for and barriers that interfered with the program). Most women wanted help with managing specific symptoms of menopause, such as mood, vasomotor symptoms, sleep, cognitive changes, and physical changes. Specifically related to their diagnosis, women most commonly talked about problems with worsening mood and mood instability and multiple stressors interfering with their ability to follow through with the intervention. Learning they were not alone in their feelings about menopause, hearing about other women's experiences and opinions, seeing other women going through the same thing, and being in an encouraging group setting were overall benefits. Participants wished the relaxation CD was available as an MP3 and that there was more focus on mood disorders and the effect on menopause symptoms. Participants described barriers that interfered with the intervention, such as forgetting to use the relaxation CDs and/or paced breathing, fatigue, feeling overwhelmed or stressed due to personal and interpersonal problems, caregiver roles, family, job, and financial stress. **Conclusion:** This study sought to uncover specific needs of women with bipolar disorder participating in a CBGT intervention for menopausal symptoms. These findings can help refine existing CBGT protocols for women diagnosed on the bipolar spectrum with worsening mood symptoms after menopause, problematic menopause symptoms, multiple psychosocial stressors, and other menopause-related concerns.

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P-16.

Symptom experience during the late reproductive stage versus the menopausal transition in the Spanish-language Women Living Better survey

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Objective: The late reproductive stage (LRS)**,** which precedes the menopausal transition (MT+), is characterized by subtle changes to menstrual cycle length, duration, and flow. Recent studies suggest that during the LRS women may experience symptoms typically associated with the MT+ such as hot flashes, sleep disturbances, mood changes, joint pain, and fatigue. Despite evidence of racial and ethnic differences in symptom reporting during the MT+, the majority of research on symptoms during the LRS has been conducted in English among non-Hispanic White women. The aims of the current study were to characterize and compare the symptoms women report experiencing during the LRS and MT+ in the Spanish-language Women Living Better (WLB) survey. **Design:** This is a cross-sectional analysis using data from the Spanish-language WLB survey. WLB is an evidenced-based online resource about the years leading to menopause. Women age 35 to 55 years were invited to complete an 82-item online survey to assess menstrual cycle patterns, changes, and symptoms. A link to the survey was distributed in the WLB email newsletter and social media channels. Demographic and health-related data were also collected, including age, country of residence, race/ethnicity, educational attainment, parity, smoking, and alcohol use. Data on menstrual cycle patterns were used to classify women as LRS or MT+ according to the Stages of Reproductive Aging Workshop +10 criteria. Women were excluded from the current analysis if they were using therapies or had conditions that affect their menstrual cycles (e.g., hormone therapy, endometrial ablation, hysterectomy, pregnancy). Descriptive statistics were used to characterize symptoms and chi-square tests or t-tests were used to compare symptoms between the LRS and MT+ groups. **Results:** Of 853 respondents, 358 women (267 LRS, 82 MT+) were included in the analytic sample. Women were on average age 40.2 ± 4.4 years, 40% reported difficulty paying for basics, 37% reportedly lived in Spain and 22% in Mexico. The most commonly reported symptoms in the LRS group were sleep disturbances (67%), less interest in sex/lower libido (52%), and difficulty concentrating or forgetfulness (50%). A similar proportion of women in the LRS and MT+ groups reported the following: anxiety/worried, low feelings (sad, blue, depressed); difficulty concentrating or forgetfulness; discomfort or pain with sex; urinary frequency and urgency. A greater proportion of women in the MT+ group report that symptoms interfere with their overall health (79.7% vs. 64%, p=0.02). LRS and MT+ women similarly report that symptoms interfere with personal relationships. **Conclusion:** Our findings that women in the LRS and MT+ groups experience multiple similar symptoms are consistent with earlier studies. However, the prevalence of symptoms that women reported during the LRS differed from those in analysis among English-speaking populations (e.g., sleep disturbance, less interest in sex/lower libido, difficulty concentrating or forgetfulness). A better understanding of the symptoms experienced during the LRS and MT+ among Spanish-speaking women may lead to more personalized health care management and education. Future cross-cultural research on the epidemiology of symptoms during the LRS is necessary as many women and healthcare providers do not expect symptoms associated with the MT+ to begin at this stage.

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P-17.

Menopause Management: Need for Global Perspective

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Objective: The United States of America is a melting pot of many different ethnic groups and consequently, various cultural beliefs. One's native cultural beliefs naturally inform the mindset and attitude of an individual towards the societal norms of the country in which they live. Understandably, cultural belief systems can have a significant impact on if, when and to what extent a person will engage with the healthcare system in a country that has different cultural norms. In New Jersey, Haitian immigrants are one example of a population that typically maintains their ancestral cultural practices when confronted with illness. This is particularly true when discussing women's health issues such as menopause. In Western culture, women frequently seek formal medical attention for treatment of menopausal symptoms and are counselled on the pharmacologic options, including local and systemic hormonal therapies. However, for Haitian women, pharmacologic interventions, are not the norm. Rather, these women pursue traditional folk remedies consisting of herbs or roots prepared as teas for menopausal symptoms, including hot flashes, mood swings, irritability, anxiety, depression and insomnia. In Haiti, even moderate to severe symptoms are managed with bush teas of varying formulations. Although significant strides towards inclusivity have been made in medicine, an understanding of and appreciation for health-related cultural practices, such as those that address menopause that predominate in other parts of the world, is lagging. Education of the health care team in these practices would not only improve medical care but would allow a more thorough discussion of all management options. Perhaps provider bias against culturally based therapies is a barrier to health care for women with cultural beliefs that differ from Western societal norms regarding menopause? This review discusses current understandings of cultural beliefs on menopause in Haiti and the Haitian diaspora at large. **Design:** Review of current literature exposes a dearth of recent information regarding women's health in Haiti and or Haitian cultural practices of the diaspora regarding menopause. No studies investigating the use and effectiveness of folk remedies were found despite a long history of Haitian women using bush teas to treat a variety of ailments, especially their menopausal symptoms. **Results:** Information directly from Haitian women suggest that they will use a bush tea concoction of lemon balm, rosemary and soursop to combat irritability and palpitations. Vervain tea is often used to treat depression, anxiety and sleeplessness. Knowledge of various herbs and roots are passed down between generations of Haitian women. However, formal research and data are needed to substantiate these practices to lend legitimacy to their purported therapeutic effects and elucidate their safety profile for adequate dosing. Investigating bush teas to corroborate their medicinal effects would broaden the current treatment options available to all women globally. Furthermore, it would help combat bias against non-Western approaches to managing menopause. **Conclusion:** As communities throughout the world continue to become more diverse, more research, education and amplification of legitimate non-harmful cultural practices used to treat menopause are needed. Haitian women for generations have managed their menopausal symptoms with herbal remedies successfully. When treating women of Haitian descent, providers should make the effort to ascertain all information regarding what remedies they may be using, what preparation, dosage, frequency and any side effects. When discussing cultural remedies, it is crucial to not dismiss a woman's beliefs and when safe support the woman in her continued use of natural, non-harmful medicines.

Sources of Funding: None

P-18.

Reduced Breast Cancer Incidence in Women Treated with Subcutaneous Testosterone: The Testosterone Therapy and Breast Cancer Incidence Study

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Objective: Testosterone therapy has been shown to be breast protective in both pre- and post-menopausal patients. Additionally, estradiol does not cause breast cancer in the majority of the world's literatures. This study aimed to investigate the incidence of invasive breast cancer in pre- and post-menopausal women treated with subcutaneous testosterone therapy and testosterone in combination with estradiol. **Design:** This study is a retrospective review of observational data that was collected over 9 years. Since January 2010, a total of 2,377 pre- and post-menopausal women were treated with testosterone implants or testosterone in combination with estradiol implants. Breast cancer incidence rates were reported based on newly diagnosed invasive breast cancer cases in the total study. Total cases divided by the total sample size and years in study was expressed as an incidence per 100,000 person-years. The breast cancer incidence was compared with age-specific Surveillance Epidemiology and End Results (SEER) incidence rates. **Results:** As of October 2020, 14 cases diagnosed with invasive breast cancer have been found in 9,746 person-years of follow up for an incidence of 144 cases per 100,000 person-years, substantially less than the age-specific SEER incidence rates (223/100,000), placebo arm of Women's Health Initiative Study (330/100,000), and never users of hormone therapy from the Million Women Study (312/100,000). **Conclusion:** Testosterone and/or testosterone in combination with estradiol pellet implants significantly reduced the incidence of breast cancer in pre- and post-menopausal women. The addition of estradiol did not increase the incidence over using testosterone alone. This is the second multi-year long-term study demonstrating the benefits of testosterone therapy in reducing the incidence of invasive breast cancer.

Sources of Funding: None

P-19.

Longer-term benefits of Ristela supplementation on female sexual function

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Objective: Hormonal changes associated with menopause can result in sexual problems in women, including diminished sexual arousal, orgasm, and desire. Ristela® is a hormone-free dietary supplement that combines antioxidants and amino acids to increase blood flow to the genital area and enhance the female sexual response. Ristela has been shown to improve sexual function in three randomized, controlled trials across pre, peri, and postmenopausal women. In addition, results from two open-label experience trials provide real-world evidence that Ristela improves sexual satisfaction and quality of life in women. To date, studies on Ristela reported effects up to two months. The purpose of this research is to report on the longer-term effects of Ristela over a five month time period. **Design:** Data were compiled from two open-label experience trials conducted on Ristela. Peri and postmenopausal women who completed five months of either trial and were sexually active at baseline (n=34) were included in the present analysis. In these trials, participants were recruited from gynecology or sexual medicine practices across the US. Participants were required to self-report their arousal, orgasm, or desire as "low" or "very low or none at all" at baseline and be in a monogamous relationship for at least three months prior to study enrollment. Participants were instructed to take two tablets daily of Ristela, providing the following total daily doses: 800 mg L-arginine, 800 mg L-citrulline, 200 mg rose hips extract, and 80 mg French maritime pine bark extract. Participants reported on their experience via online questionnaires after taking the product for two weeks and each month thereafter. Questionnaires contained questions from the Female Sexual Function Index (FSFI), as well as additional questions on distress related to sexual function and product satisfaction. Questions were scored on a 5 point scale, with an increase in score indicating improvement. After completion of each questionnaire, participants were compensated with a $25 gift card. Participants were allowed to remain on any preexisting medications during the study and were not precluded from social alcohol intake. **Results:** For all questions included in the present analysis, scores significantly increased from baseline at each timepoint up to five months ($p<0.05$) (Table 1). Significant changes were found in as early as two weeks and scores continued to increase over time, with the greatest improvements most often seen at month five. **Conclusion:** These data are the first to report on the longer-term benefits of Ristela on sexual function and show that women experience greater improvements with continued use.

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

Mean ± SD scores for individual questions related to distress, desire, arousal, lubrication, orgasm, emotional closeness, and pain reported at each time point.

	Baseline	Week 2	Month 1	Month 2	Month 3	Month 4	Month 5
Distress Frequency	2.2 ± 0.8	2.8 ± 0.7	3.0 ± 0.8	3.4 ± 1.0	3.4 ± 1.0	3.5 ± 1.0	3.8 ± 0.9
Degree of Desire	1.8 ± 0.8	2.5 ± 0.8	2.6 ± 0.7	2.9 ± 0.7	3.0 ± 0.9	3.1 ± 1.0	3.1 ± 0.8
Confidence in Arousal	1.9 ± 0.8	2.6 ± 0.8	2.9 ± 0.8	3.2 ± 0.9	3.1 ± 1.0	3.5 ± 0.9	3.7 ± 0.9
Lubrication Difficulty	2.9 ± 1.5	3.6 ± 1.2	3.7 ± 1.1	4.1 ± 0.9	4.2 ± 0.9	4.3 ± 0.9	4.4 ± 0.9
Lubrication Maintenance	2.4 ± 1.2	3.2 ± 1.3	3.5 ± 1.3	3.7 ± 1.3	3.9 ± 1.2	4.0 ± 1.0	4.1 ± 1.0
Orgasm Frequency	2.2 ± 1.3	3.0 ± 1.5	3.0 ± 1.5	3.4 ± 1.4	3.4 ± 1.2	3.6 ± 1.3	3.8 ± 1.2
Orgasm Difficulty	2.3 ± 1.2	3.0 ± 1.4	3.2 ± 1.3	3.5 ± 1.2	3.7 ± 1.1	3.8 ± 1.2	3.9 ± 1.0
Emotional Closeness	2.9 ± 1.4	3.8 ± 1.1	3.9 ± 1.1	4.0 ± 1.1	4.0 ± 1.1	4.2 ± 1.0	4.2 ± 1.0
Pain/Discomfort Frequency	2.8 ± 1.4	3.8 ± 1.4	3.6 ± 1.5	3.8 ± 1.4	3.8 ± 1.3	4.1 ± 1.0	3.9 ± 1.3
Degree of Pain/Discomfort	3.0 ± 1.2	3.8 ± 1.3	3.7 ± 1.3	3.8 ± 1.2	3.8 ± 1.2	4.0 ± 1.1	3.9 ± 1.2

For all questions, scores significantly increased from baseline at each timepoint up to five months ($p<0.05$). Questions were scored on a 5 point scale, with an increase in score indicating improvement.

P-20.

A National Survey Study Examining Women's Experiences with Menopause

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Objective: Women going through menopause experience a variety of physical and psychological symptoms including hot flashes, night sweats, trouble sleeping, weight gain, and brain fog. Because these symptoms can last for several years and greatly affect many women's everyday lives, it is imperative to continue research, awareness, and education around this stage of life. The following survey was conducted to better understand women's experiences with menopause today and provide additional evidence to support previously published studies on menopausal experiences. **Design:** A national survey study was conducted on 1,039 perimenopausal and postmenopausal women across the United States. A nationwide random sample of women was collected and women who met the following criteria were eligible to participate: peri or postmenopausal, 40-65 years old, experiencing menopausal symptoms, and have a household income of ≥ $50k/year. Qualified women were sent an online survey with questions focusing on their 1) symptoms and how are they treating them, 2) perceptions on Hormone Replacement Therapy (HRT), 3) knowledge about menopause and who they speak to about it, 4) perception on menopause and where they seek support, and 5) sexual experiences during menopause. Women were compensated for completing the questionnaire. **Results:** Major survey findings reflect the real-world opinions of women going through menopause. In terms of education around menopause, 45% of women did not know the distinction between perimenopause and menopause, and 29% did not seek out information prior to entering menopause. Women reported experiencing the following symptoms: hot flashes (55%), weight gain (60%), sleep difficulty (52%), night sweats (48%), bladder control issues (43%), brain fog (35%), vaginal dryness (35%), painful sex (21%), difficulty with sexual arousal or orgasm (25%), vaginal infections/odor (10%), and other (3%). In terms of opinions on HRT treatment, 73% of women were familiar with HRT treatment, but 65% of those women reported that they would not consider taking it. In terms of treating symptoms, 73% of women reported that they were not treating their symptoms. Moreover, 34% of women said that they were not formally diagnosed as menopausal by a healthcare professional (HCP) and 20% of women reported experiencing symptoms for 12+ months before being assessed by an HCP. In terms of speaking about their symptoms, 68% of women reported speaking to a HCP, 43% reported speaking to their friends, and 38% reported speaking to their significant other/partner. When speaking to their HCP and significant other/partner, 57% and 37%, respectively, reported feeling always supported and understood. Other groups women reported feeling always supported and understood by included mothers and friends (57% and 54%, respectively). In terms of the effects of menopause on respondents' sexual experiences, about half of women agreed that menopausal symptoms have affected their sex life, with 53% reporting that they have sex less often. **Conclusion:** These survey findings reveal the experiences of women currently going through menopause and support previously published literature on this area of study. Results showed that women experience various symptoms during menopause, but many do not want to use HRT and resort to not treating their symptoms. Moreover, these data shed light on a lack of education around the menopausal transition and highlighted the importance of conversations between women and their doctors and family members about their menopausal experience. Considering the significant physical and emotional impact of menopause on women's lives, these results emphasize the need to provide more communication and education around menopause, as well as alternative treatment options, in order to support women and improve their quality of life during their menopause journey.

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

P-21.

A Systematic Literature Review of Published Clinical Trials on Bonafide Cytoplasmic Extract

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Objective: Hormonal changes during menopause can result in various symptoms that interfere with women's quality of life including hot flashes, night sweats, and sleep disturbances. While hormone therapy is an effective treatment option for menopausal symptoms, many women cannot or choose not to use hormonal treatments. Bonafide Cytoplasmic Extract (BCE1;Relizen®) is a unique, non-hormonal pollen extract that is clinically shown and commonly used by women to relieve hot flashes and night sweats. The purpose of this paper is to review all controlled and observational clinical trials investigating the efficacy and safety of BCE1. **Design:** A literature search was conducted using Google Scholar and PubMed to identify all articles describing clinical trials on BCE1. In reviewing relevant articles, additional citations were found. All available and accessible articles were included in the present analysis. **Results:** We identified three (3) randomized controlled trials (n=216 women), seven (7) prospective observational studies (n=1,151 women), and one (1) survey report (n= 2,304) investigating the safety and efficacy of BCE1. Findings from randomized controlled trials showed that BCE1 significantly improved menopausal and premenstrual symptoms compared to placebo in as early as two months. BCE1 was well-tolerated, and no clinically significant adverse effects were attributed to BCE1. No significant changes in blood pressure, heart rate, and hematology, liver, and kidney function parameters were found. Data from observational studies demonstrated that women report significant improvements in their menopausal symptoms, including sleep quality and the severity and frequency of their hot flashes, with BCE1 use. Novel findings from recently published studies showed that BCE1 effectiveness improves over time (up to 6 months), is more effective than soy isoflavones in improving menopausal symptoms (including daily hot flashes) and sleep quality, and is a safe and effective option for treatment in breast cancer patients experiencing menopausal symptoms. Across all observational studies, BCE1 was well-tolerated and no clinically significant adverse events were reported. Data from surveys provided real-world evidence to further support findings from controlled trials. **Conclusion:** The safety and efficacy of Bonafide Cytoplasmic Extract (BCE1) has been demonstrated across 10 clinical studies and in over 3,000 women, including breast cancer patients. Taken together, these studies demonstrate that BCE1 is a safe and effective non-hormonal treatment option for menopausal symptoms including sleep problems, hot flashes, and night sweats.

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P-22.

Associations between hormone replacement therapy and cardiorespiratory fitness with verbal and visual memory performance in post-menopausal women

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Objective: Hormone replacement therapy (HRT) and cardiorespiratory fitness (CRF) influence cognitive performance in older women. A small human study showed an interaction between HRT duration and CRF on brain outcomes and several animal studies have indicated that effects of exercise on brain-derived neurotrophic factor might be augmented by estrogen supplementation. However, there have been few studies examining whether HRT and CRF interact to modulate cognitive functioning among post-menopausal older women. The goal of this study was to examine whether an association between CRF and verbal and visual memory would be moderated by current or prior HRT use in post-menopausal women. We expected that women with higher CRF and with a history of HRT use would exhibit higher verbal and visual memory performance. **Design:** The sample included 352 women, 65-80 years old (age *M*=69.40±3.501*)*, who were recruited for a 12-month exercise intervention. Prior to randomization, baseline cognitive and fitness assessments were conducted, and information about HRT use was collected. HRT use was coded as present (1) or absent (0). Participants completed the Hopkins Verbal Learning Test-Revised (HVLT-R), Brief Visual Memory Test (BVMT), Logical Memory Test, and Paired Associates Test, immediate and delayed recall trials. CRF was assessed using a maximal graded exercise test. Main and interaction effects were evaluated using linear regression. **Results:** Participants who reported HRT use (current or past) represented 43.75% of the entire sample. HRT use was associated with higher performance on HVLT-R Total (β=.105, *p*=.048). Duration of HRT use did not relate to cognitive performance (*p*>.220), though initiation of HRT during the postmenopausal period (as opposed to before or during menopause) was associated with higher HVLT and Paired Associates performance (β range=.218-.279; all *p*<.05). Higher CRF was associated with higher performance on numerous outcomes including HVLT-R, Logical Memory, and Paired Associates (β range=.110-.159; all *p*<.05). There were no significant interactions between CRF and HRT use on any cognitive outcome (*p*>.102). **Conclusion:** Current or prior use of HRT and higher CRF were correlated with higher episodic memory performance among post-menopausal women. However, there was no evidence of a moderating effect of HRT on the association between CRF and memory performance. Though no interaction was observed, the independent benefits of HRT use and CRF suggest that HRT and CRF-enhancing interventions may slow cognitive decline among post-menopausal women. Further research is needed to explore additional cognitive outcomes as well as other parameters of HRT use (e.g., type of HRT) on cognition.

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P-23.

Physical Activity Intensity Predicts Objective But Not Subjective Hot Flash Experience

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Objective: Hot flashes (HFs) are a menopausal symptom experienced by about 80% of women and can last for over 7 years. The cause of HFs is still unknown; however, some data suggest self-reported physical activity (PA) may influence the HF experience. As skin conductance allows HFs to be objectively measured, questions arise as to whether objectively-measured PA impacts HF physiology (objective measure) or a woman's perception of HFs (subjective measure). Examination of the relation between objectively-measured PA and HFs could improve the quality of information provided to women and influence lifestyle and treatment decisions. The goal of this project was to determine whether the HF experience was altered by objectively-measured PA. **Design:** Women aged 45-55 years, who were not taking hormone therapy or other medications that may reduce HF frequency or severity (e.g., SSRI's, clonidine, gabapentin, or black cohosh), were recruited for this study. We targeted women with irregular menstrual periods or a last menstrual period within the past two years. Ambulatory HF experience and objective PA were recorded simultaneously for 24 hours. Objective HF experience was recorded via sternal skin conductance (Biolog, UFI, Morrow Bay, CA). Participants were instructed to press a button on the Biolog monitor when they felt a HF - a measure of subjective HF experience. The Actigraph GT3X+ PA monitor (Pensacola, FL) was worn on the wrist for 24 hours. Biolog data were manually examined for each HF type. Objective HFs were defined by an increase in skin conductance > 2 μmhos over 30 seconds and/or by a distinctive pattern (sudden spike followed by a slow descent). Subjective HFs were marked at the time of a button push or by entries on a hot flash diary. Hot flashes were deemed concordant when an objective HF and subjective HF occurred within 20 minutes of one another. Frequency of HFs per hour were calculated for each HF type. Physical activity data were analyzed using Actilife software (v6.13.4) and broken down by intensity into four categories: light, moderate, vigorous, and moderate-to-vigorous (MVPA). Bivariate analyses and hierarchical methods predicting HF frequency by type were run in SPSS (v.21). Models including MVPA were run separately from other models. **Results:** At this time, sixty-six participants (mean age 50.9 ± 2.8 years; mean BMI 28.3 ± 6.1 kg/m^2) have been included in our analysis; 13 (19.7%) were pre-menopausal, 29 (43.9%) peri-menopausal, and 24 (36.4%) were post-menopausal. Mean (± SD) objective HF frequency (HFs/hour) was 0.254 ± 0.34, mean subjective HF frequency was 0.252 ± 0.62, and mean concordant HF frequency was 0.09 ± 0.16. Only concordant HF frequency was associated with menopausal stage (ANOVA, p = .017). In bivariate analyses, objective HF frequency was positively correlated with duration of moderate PA (r = 0.285, p = .020) and duration of MVPA (r = 0.303, p = .013). Concordant HF frequency was positively correlated with time in vigorous PA (r = 0.376, p = .002) and time in MVPA (r = 0.286, p = .020). All hierarchical models adjusted for menopausal stage and monitor wear time. Models without MVPA adjusted for sedentary time. Objective HF frequency was predicted to increase by .280 per minute of MVPA (95% Confidence Interval: [.000, .002], p = .032). MVPA explained 6.8% of variation. Alone, moderate and vigorous PA were not significantly associated with objective HF frequency. Concordant HF frequency was predicted to increase by 0.283 per minute of vigorous PA (CI: [.000, .006], p =.035) and by .261 per minute of MVPA (CI: [.000, .001], p = .041). Vigorous PA explained 5.9% of the variation. Subjective HF frequency was not associated with any form of PA, nor did any PA explain more than .1% of variation. **Conclusion:** Overall, our data suggest greater amounts of time in moderate and vigorous PA predicts increases in objective and concordant HFs in women aged 45-55. Understanding the role of PA on HF experience can advance efforts to provide accurate information to women undergoing menopause and optimize therapies.

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P-24.

Comparing the impact of hormone replacement therapy versus estrogen containing oral contraceptive pills on bone outcomes in women with Premature Ovarian Insufficiency: A systematic review

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Objective: Premature ovarian insufficiency (POI) affects up to 3.7% of women and is associated with the loss of ovarian function before the age of forty. POI is characterized by low levels of estrogen, which leads to a range of health consequences, including decreased bone mineral density (BMD) and increased risk of osteoporosis and subsequent fractures. The current standard of care to mitigate low BMD is estrogen-containing hormone therapy. Both hormone replacement therapy (HRT) and oral contraceptive pills (OCP) are recommended by clinical practice guidelines though there are important differences between them. There is limited evidence regarding the preferred formulation of hormone therapy for optimizing bone health in women with POI. The objective of this systematic review is to critically evaluate the evidence regarding optimal estrogen-containing hormone therapy on bone outcomes in women with POI. **Design:** We conducted a systematic review that adhered to the Preferred Reporting Items for Systematic Review and Meta-analysis (PRISMA). The protocol was registered in the International Prospective Register of Systematic Reviews (PROSPERO). We searched Ovid MEDLINE, EMBASE, Cochrane Library and Web of Science databases from inception until December 2020 for randomized controlled trials (RCTs) and observational studies. Studies met criteria for inclusion if the study population was women under age 40 at the time of POI diagnosis, if both the primary exposure and comparator were estrogen-containing hormone therapy (either OCP or HRT), and if the primary outcome was difference in bone mineral density and/or change in bone turnover markers. Studies were assessed for risk of bias using the Newcastle-Ottawa Scale and the Cochrane Risk of Bias Tool according to study design. **Results:** Our initial search results identified 1563 abstracts. A total of 38 full-text articles were assessed for eligibility by two reviewers, and 5 studies were ultimately included in our review: 3 RCTs and 2 observational cohort studies. Both observational studies were rated as having a low risk of bias. Out of the 3 RCT's, 1 study was found to be at high risk of bias, while the other 2 raised some concerns of bias. Studies varied in type of hormone therapy formulations, doses, and regimens used as well as cause of POI. Across all studies, women with Turner Syndrome (n = 625) were the most common etiology for POI, followed by idiopathic (n = 146), cancer treatment (n = 8), autoimmune (n = 3), and one study did not differentiate between surgical and idiopathic etiologies (n = 17). Of the 4 studies that assessed changes in BMD, two studies reported a significantly increased BMD at the lumbar spine with HRT as compared to OCP (+0.050 g/cm^2, p<0.025; +0.019 g/cm^2, p<0.01), one study found similar improvement in lumbar spine BMD comparing OCP and high-dose HRT (HRT -0.003 g/cm^2, p = 0.824), and one study did not directly compare OCP and HRT treatments. Results for effect of different hormone therapy on bone turnover markers were inconsistent among 3 studies that evaluated this outcome. **Conclusion:** To our knowledge, this is the first systematic review to directly compare studies that evaluate the effects of different estrogen-based hormone therapy on bone outcomes in women with POI. While we found that 2 studies reported higher BMD scores at the lumbar spine with HRT versus OCP, these results were not consistent across studies. Furthermore, studies had important differences in terms of etiology of POI, treatment regimen and formulation, and risk of bias. Further studies are required to better understand the ideal hormonal treatment for optimizing bone outcomes in POI.

Sources of Funding: None

Authors	Country of study	Design	Etiology of POI	Total N	Mean age (SD) [age range]	Duration of HT	Intervention (OCP)	Comparator (HRT)	Variables adjusted for	Secondary outcomes
Cartwright et al.	United Kingdom	Open-label randomized controlled trial	Idiopathic, autoimmune	59	38.8 [18-44]	24 months	EE + LNG	E2 + LNG	Baseline lumbar spine BMD, smoking, alcohol, parity	ND
Gazarra et al.	Brazil	Retrospective cohort	Idiopathic	119	30.34 (9.24)	Variable	EE + LNG	Low-dose/high-dose EE + MPA	Age, BMI, HT duration	ND
Guttmann et al.	Israel	Randomized controlled trial (crossover)	Turner Syndrome	17	24 [17-35]	6 months OCP + 6 months HRT	EE + GD	EE + MPA	ND	Gonadotrophins, glucose, insulin, liver function, lipids, calcium metabolism, uterine parameters, cardiac variables
Crofton et al.	United Kingdom	Randomized controlled trial (crossover)	Turner Syndrome, chemotherapy/radiotherapy, surgery, idiopathic	34	27 [19-39]	12 months OCP + 12 months HRT	EE + NE	TE + P (vaginal)/P (oral)	ND	ND
Cameron-Pimblett et al.	United Kingdom	Retrospective cohort	Turner Syndrome	599	32.9 [18.1-70.3]	Variable	Variable	Variable	Age, BMI, height	Effect of timing of puberty induction on adult health outcomes (liver function, diabetes risk, dyslipidemia, cardiovascular outcomes)

EE = ethinylestradiol, LNG = levonorgestrel, MPA = medroxyprogesterone acetate, E2 = estradiol, EE = conjugated equine estrogen, GD = gestodene, TE = transdermal estrogen, NE = norethisterone, P = progesterone

P-25.

A Systematic Literature Review of Published Intimate Partner Violence Curricula for Medical Trainees

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Objective: In the United States, over a third of women have been victims of intimate partner violence (IPV) in their lifetime. Midlife women are also at risk and clinically significant symptoms of posttraumatic stress disorder have been found to be associated with menopause symptoms. Victims of IPV have an increased risk for adverse physical health outcomes. Healthcare provides a safe space for IPV victims, but physicians cite lack of time, lack of IPV specific education and patients' perceived unresponsiveness as barriers to IPV screening. Despite the rates of IPV rising 46% higher in 2015 over the previous year, the Liaison Committee on Medical Education (LCME) removed violence and abuse as an example of a societal problem that should be covered in medical school curricula. The objective of this study was to complete a comprehensive review of published curricula on IPV in medical school, residency training, and post-residency training and provide a summary of the findings to guide future curricular work in standardizing the optimal curriculum for medical students. **Design:** A literature search of Ovid MEDLINE, Ovid EMBASE, and Scopus was conducted by a medical librarian in May 2020. Three researchers independently reviewed each title and abstract to determine whether it met inclusion or exclusion criteria. Each article was evaluated for the following curriculum content and structure items; (1) year introduced; (2) method of delivery; (3) the type of curriculum; (4) curriculum content; (5) effectiveness of the curriculum; (6) barriers experienced in implementing the curriculum. **Results:** A total of 56 articles met criteria, most were for medical school learners (32/56) and short-term (41/56). For residency training, the IPV curricula were most frequently taught in family medicine, pediatrics, internal medicine, emergency medicine, psychiatry, and obstetrics and gynecology programs. Formal lecture and use of standardized patients were the most popular methods of curricular delivery. Most curriculum taught risk factors for and the identification of victims of IPV. The most cited barrier to implementation was time, followed by inability to measure the effectiveness of the curriculum, scalability, cost/resources, lack of engagement, advocacy, and interest and lack of faculty support or perceived relevance. There was great variation in the methods of assessing effectiveness of IPV curricula. **Conclusion:** IPV curriculum exists in medical training, but it is highly variable and not consistently following evidence-based best practice for medical education. Standardizing a curriculum and raising the importance of this curriculum to the level of the LCME during medical school, early on in a physician's training, will ideally improve the rates of physician screening, identification and resource sharing for victims of this highly prevalent condition, including amongst menopausal women. Future initiatives to establish a standard of competency for medical students regarding IPV, including a standard curriculum, may ensure physicians are capable of identifying and caring for victims of IPV.

Sources of Funding: None.

P-26.

What Midlife Women Value Most When It Comes to Digital Health and Menopause: Findings from the Elektra Health User Survey

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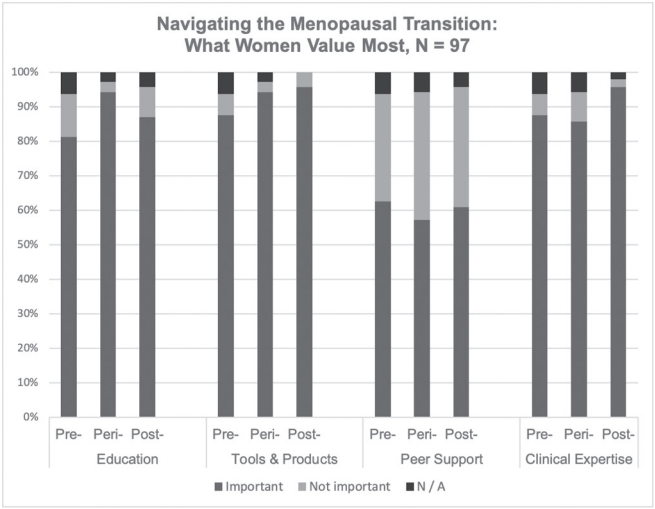
Objective: Elektra Health is a women's health company that offers a digital solution for integrated menopause care. The aim of this survey was to assess the digital preferences among members of Elektra Health's free online community. **Design:** On Sept 16, 2020, a survey was sent by email to Elektra's members, eliciting information on demographics and preference for type of help regarding menopause. The 4 elicited domains are shown in the figure and the data was divided into pre-, peri- and post-menopausal status based on respondents' self-identification. The responses were "very," "somewhat," or "not" important. For the purpose of the analyses, "very" and "somewhat" were grouped together as important. Chi-square and ANOVA analyses defined statistical significance as $p<0.05$. **Results:** Of the 5,481 members sampled, 877 opened the email and 113 (13%) completed the survey. Of these, 97 offered their menopausal status; all met eligibility criteria of having Internet access and fluency in English. Half of the respondents (50.5%) were over the age of 50 and their menopausal status was pre- (n = 16, 14%), peri- (n = 35, 31%), or post- (n = 46, 41%). Of the 4 domains, peer network was considered the least important ($F= 21.0$, $p<0.0001$). Menopausal status did not appear to influence preference for types of help (Chi-square, all, $p>0.05$). Surprisingly, respondents did not favor clinical expertise over education or tools and products (ANOVA, $F = 0.57$, $p = 0.56$). Limitations are that the Elektra Health community is self-selected and there was a low sample response. **Conclusion:** The respondents' preferences were not influenced by menopausal status. They valued education as well as tools and products on an equal footing with clinical expertise. This data, if confirmed by larger studies, suggests that women want more help than what clinical experts alone can provide. This validates Elektra Health's hypothesis that a multifaceted digital approach to menopause can provide an effective solution to meet the needs of midlife women.

Sources of Funding: Elektra Health.



P-27.

Sex Differences in Predictors of White Matter Abnormalities among Older People Living with HIV

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Objective: One of the trademark features of aging in the human brain is the deterioration of cerebral white matter. The progression of white matter loss, while strongly related to aging and neurodegeneration, has also been linked with vascular risk factors and sex hormones. Additionally, human immunodeficiency virus (HIV) has been found to be associated with abnormalities in white matter structure; however, not much is known about sex-specific differences in the brain among people living with HIV (PLWH). While postmenopausal estrogen decline is believed to contribute to reduced white matter volume among aging females, few studies have outlined sex differences in predictors of white matter abnormalities within the context of HIV infection. We compared vascular and HIV risk factors, sex hormone levels, cognitive domain scores, and measures of white matter pathologies between older females and males living with HIV. We also investigated whether biological sex mediated any relationships between white matter abnormalities and neurocognition scores with risk factors and hormone levels. **Design:** 85 participants age 50 or older and living with HIV participated in a cross-sectional study and completed a neuropsychological assessment, a blood draw, a demographic survey, and a magnetic resonance imaging (MRI) scan. Participant demographic data, vascular risk factors, and history of CD4 count and viral load were self-reported on the

questionnaire and verified by chart review. Single measures of plasma FSH, sex steroids, and DHEA-S were obtained by immunoassay of collected blood and total white matter volume, white matter hyperintensity volume, and white matter hypointensity volume measures were processed from MRI data. After excluding exogenous hormone users, we analyzed data from 44 females and 35 males living with HIV. We used chi-squared and Mann-Whitney tests to compare risk factors and biomarkers between females and males. To assess if sex moderated the relationship between white matter abnormalities and predictor variables, we compared the results of Spearman correlation and Mann-Whitney tests conducted separately for female and male groups. **Results:** Older males living with HIV demonstrated greater white matter volume compared to females ($p<0.001$), although no difference was observed in white matter hyperintensity volume, white matter hyperintensity volume percentage, or white matter hypointensity volume between both sexes. White matter volume was positively correlated with DHEA-S hormone levels among females living with HIV ($p<0.01$), but not among males. Similarly, verbal learning memory scores were positively associated with white matter volume and DHEA-S levels among older females ($p<0.05$), but not among males. No other sex hormones were associated with measures of white matter abnormalities in either sex. Age and dyslipidemia were both significantly associated with total white matter hyperintensity volume ($p<0.05$) and white matter hyperintensity volume percentage ($p<0.05$) among HIV-infected females; however, this relationship was not observed among HIV-infected males. Age was associated with white matter hypointensity volume among both females and males ($p<0.01$) White matter hypointensity volume was positively associated with CD4 count, episodic verbal memory score, and motor processing score among HIV-infected males ($p<0.05$), but this relationship was not found among females. **Conclusion:** Findings from this study show that female sex may mediate the relationship between white matter hyperintensity volume and predictive risk factors like age and dyslipidemia among older PLWH. Among older females living with HIV, DHEA-S levels may also be positively associated with white matter volume and neurocognitive performance.
Sources of Funding: National Institutes of Health [R01NR015737]

P-28.
A Postmarketing Noninterventional Study Evaluating the Risk of Endometrial Cancer in Women Who Have Been Prescribed Imvexxy® - Study Design

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Objective: Prescribing information for all estrogen products, regardless of route of administration, state that "Generally, when estrogen is prescribed for a postmenopausal woman with a uterus, a progestin should also be considered to reduce the risk of endometrial cancer." However, a comprehensive literature review evaluating low-dose vaginal estrogens (LDVE) did not support an increased risk of endometrial hyperplasia or cancer (EC).[1] Studies to date have been of relatively short duration and may have been underpowered for the detection of potential EC. Longer-term studies are evaluating the endometrial safety profile of LDVE. The objectives of this study are to: (1) estimate the risk of EC in women who have been prescribed Imvexxy (a very-LDVE, defined as ≤10 µg estradiol as the recommended daily dose [RDD]), (2) describe the duration and patterns of use of Imvexxy and other vaginal estrogen products, and (3) to estimate the risk of EC in women who have been prescribed any very-LDVE product (defined as ≤10 µg estradiol or ≤0.3 conjugated estrogens as RDD, including Imvexxy). **Design:** This cohort study will be conducted using existing insurance claims data sources in the US. A feasibility assessment explored the capability of several data sources to validate EC cases and identify the data elements that are critical to this study. Two data sources were selected. Yearly monitoring reports will provide counts of Imvexxy-exposed patients and person-time in the data sources. A validation study with medical record review will be implemented to validate an electronic algorithm to identify EC (using ICD-10-CM codes), which will be used in the safety study. The final report will include results of the drug utilization study (Objective 2) and safety study (Objectives 1 and 3). Inclusion and exclusion criteria are shown below. Each exclusion criterion will be assessed using all available information in each data source before the start of observation in the safety study. The study outcome is defined clinically as the first EC after cohort entry and will be ascertained using the previously validated algorithm. Exposure will be identified in electronic data based on dispensed prescriptions for Imvexxy 4 µg or 10 µg (Objective 1) or any very-LDVE product (Objective 3). Variables to describe the study population and variables that may confound the association between the use of very-LDVE and EC will be collected. Safety analyses will compare users of Imvexxy (Objective 1) or of any very-LDVE (Objective 3) with comparable women who do not use vaginal estrogen products using regression models. Confounding control will be implemented through propensity-score matching. The target study size, based on background rates of EC in postmenopausal women, for the analyses of very-LDVE, to exclude a hazard ratio of 2, is 109,200 person-years (36,400 exposed person-years and 72,800 unexposed person-years with a 1:2 ratio of exposed to unexposed, or, equivalently, a total of 81 EC cases). **Results:** Monitoring counts will be produced yearly, starting in December 2021. The EC validation study is projected to be completed in 2022 and the safety study will be completed in 2025. **Conclusion:** Results from this large observational study of the use of very-LDVE will provide additional information on the long-term endometrial safety of LDVE products. 1. Constantine G, et al. *Menopause*. 2019;26(7):800-807.
Sources of Funding: TherapeuticsMD

Inclusion Criteria	Exclusion Criteria
Age 50 years or older	Documented hysterectomy (partial or total)
Continuous enrollment of at least 12 months in a health plan with complete medical and pharmacy benefits	History of endometrial cancer, endometrial hyperplasia, or endometrial ablation (to ensure that any case of endometrial cancer is an incident case)
Routine visits to a gynecologist or to a primary care physician for gynecological exams	Prior use of any vaginal estrogen product
	Additional Exclusion Criteria for Objective 1
	History of estrogen-dependent cancers listed in Imvexxy's label (breast or ovarian cancer)

P-29.
Cimicifuga racemosa extract Ze 450 re-balances cellular energy metabolism and promotes longevity in *C. elegans*

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Objective: Climacteric complaints are caused by hormonal changes in the female body. Extracts prepared from the rhizome of *Cimicifuga racemosa* have been shown to effectively treat menopausal complaints such as hot flushes. Recent studies revealed *Cimicifuga racemosa* extract Ze 450 also plays a role in regulating energy metabolism [1]; among others by the activation of AMPK a key modulator of fatty acid and glucose metabolism. In particular, Ze 450 exerted a metabolic shift from mitochondrial oxidative phosphorylation to glycolysis and prevented neuronal cells from oxidative damage [2]. **Design:** The aim of this study was to investigate the molecular mechanisms underlying the metabolic role of mitochondria under conditions of oxidative stress. We investigated whether Ze 450 targets the respiratory chain function of isolated cortical mitochondria directly, thereby increasing resilience of neuronal cells against oxidative cell death, induced by erastin in vitro, and in the nematode C. elegans exposed to mitochondrial poisons in vivo. The effects of Ze 450 on mitochondrial respiration and its protection against oxidative cell death were further compared to metformin and estrogen receptor stimulation. **Results:** High-resolution respirometry and extracellular flux analysis revealed that Ze 450 mediated a direct effect on mitochondria by enhancing the metabolic shift towards glycolysis, and this was associated with cMyc and HIF1α regulation. These effects of Ze 450 were mediated independently of estrogen receptor activation and distinct from effects exerted by metformin. Furthermore, Ze 450 increased survival of *C. elegans* challenged with mitochondrial toxins. **Conclusion:** These findings shed light on metabolic mechanisms promoted through a metabolic shift to glycolysis via direct effects on mitochondria, which enhances neuronal resilience against ferroptosis *in vitro* and promotes longevity *in vivo*.
Sources of Funding: The study was sponsored by the funding of the Max Zeller Soehne AG to TransMIT Project Division for "Mitochondrial Mechanisms of Neuronal Processes" of Prof. Dr. Carsten Culmsee.

P-30.
Feasibility and Effectiveness of Utilizing Personalized Thermal Interventions for Improving Quality of Life in Women with Symptomatic Hot Flashes

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Objective: At menopause, 70-80% of women report bothersome hot flashes or vasomotor symptoms (VMS), often having a negative impact on quality of life. Research supports hormone therapy (HT) as the preferred treatment for relieving vasomotor symptoms and night sweats. However, this treatment is not appealing to all symptomatic women, and is contraindicated in some. Surveys suggest that 50% to 80% of midlife women seek out and use nonhormonal therapies for hot flashes, demonstrating the need for other treatment modalities. Thus, there is a compelling need for safe, effective, and non-iatrogenic approaches to hot flashes. We evaluated the commercially available Embr Wave device for menopausal symptom reduction in women with VMS. This pilot study aimed to investigate the feasibility of using a personalized thermal intervention, delivered by the wearable Embr Wave device, in reducing bothersome VMS. Secondarily, we evaluated the preliminary effectiveness of the Embr Wave device on its ability to improve either the frequency or severity of VMS, sleep disruption, as well as its impact on self-reported mood and cognition changes. **Design:** Willing participants were screened through telephone calls. Eligibility included experiencing more than 28 bothersome hot flashes per a week, a willingness to wear the device for at least 8 hours a day, and the presence of VMS for greater than 30 days. Participants were ineligible if they were on hormone therapy or if they had made any changes to prescription medications 30 days prior to the study. Three validated scales were used to collect weekly data on menopausal symptoms: the Menopause Quality of Life (MENQOL), the Hot Flash Related Daily Interference Scale (HFRDIS), and the Patient-Reported Outcomes Measurement Information System (PROMIS). Baseline data was collected for two weeks, and then participants completed weekly surveys for four weeks while wearing the device. At the end of the study, participants were given renumeration for completion of all study requirements. Average composite scores for each scale from baseline weeks (weeks 1-2) and intervention weeks (weeks 3-6) were compared using linear mixed-effects models with a random intercept for each participant (fitted by restricted maximum likelihood) to determine if the use of the Embr Wave was associated with relief from menopausal symptoms while taking into account the within-participant correlation. **Results:** Of the ten participants, the average age of the women was 59.6 years and average time since menopause was 13.4 years,

and 90% fully completed data collection. Baseline scores showed significantly reduced quality of life, mild daily interference, and sleep disturbance indicated by high average composite scores for each scale as shown in the Table. Average composite scores for all three scales were lower during the intervention weeks compared to baseline weeks. The MENQOL average composite score was lower by 0.55 (95 % CI 0.20 to 0.90, P = 0.003), the HFRDIS lower by 1.03 (95% CI 0.38 to 1.68, P = 0.004), and the PROMIS lower by 0.24 (95% CI 0 to 0.48, P = 0.053), compared to the baseline weeks (Table 1). **Conclusion:** Use of the Embr Wave resulted in improved composite scores in all three scales which assessed for quality of life, changes in hot flash severity and/or frequency, and sleep. Future directions include expanding the sample size and comparing the efficacy of the device to other non-medical or non-hormonal treatment modalities for menopause related symptoms.

Sources of Funding: Embr wave

Table 1. Average Composite Change for MENQOL, HFRDIS, and PROMIS Scales

Scale	Average Baseline Score	Average Intervention Score	Crude Change in Average Score (Baseline-Intervention)	Mixed-effects model estimated change in score (95% CI) # (Baseline – Intervention)	P Values
MENQOL	3.51	2.96	0.55	0.55 (0.20-0.90)	0.003
HFRDIS	3.75	2.79	0.96	1.03 (0.38-1.68)	0.004
PROMIS	2.56	2.42	0.14	0.24 (0.00- 0.48)	0.053

***The mixed-effects model estimated change in score and takes into account the within-participant correlation (participant with higher/lower baseline score may tend to have higher/lower intervention score), whereas the crude change in average score does not.**

P-31.

Family Building: An Essential Part of Menopausal Counseling

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Objective: Counseling of menopausal women usually centers on the topics of vasomotor symptoms and genitourinary syndrome of menopause. However, with average life expectancy increasing into the ninth decade for women in many countries and advanced reproductive technologies now available, childless years beyond the menopause may no longer be the norm. **Design:** A literature search using PubMed and Google Scholar with use of English language literature was retrieved and reviewed. **Results:** Natural menopause, which can occur as early as 40 years of age, usually heralds the end of reproductive capability. Yet, many women can expect to live an additional 40 to 50 years beyond their cessation of menses. This longevity coupled with advanced reproductive technologies is allowing women to build their family during these perimenopause and postmenopausal years not only through adoption, but also through both natural and assisted conception. Birth rate data support that the fact that older women are indeed pursuing childbirth. For example, the birth rate in 1990 for women 40-44 years was ~5/1,000 females. This number jumped to ~11/1,000 females in 2016 and 12/1,000 females in 2019. For women 45-49 years (which includes women aged 50 years and older) the birth rate was 0.9/1,000 females in 2018 and 2019.* **Conclusion:** These data suggest that family building is still wanted in the peri and post-menopausal years. Practitioners should consider including this topic in the counseling that they provide to midlife and older women. Early referral for "third-party reproduction" is helpful.

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P-32.

Menopause Mobile Health Applications: An Innovative Educational Modality

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Objective: A large number of mobile applications are available that address topics of menstruation, maternal and infant health, and reproductive health. Mobile health applications allow users to track symptoms and gain educational resources. Certain health apps also allow users to chat with experts and link health records to the app. The utility of mobile health apps is growing and most are geared to significantly helping the individual manage their own health. However, there appears to be a stark difference in the number of applications available for the aforementioned areas of health vs the topic of menopause. Increasing the number of menopause tracking mobile apps should be considered in order to not only help individuals track symptoms and find resources, but also to empower menopausal individuals. **Design:** A review on current menopause applications available on mobile app stores was conducted to assess the number of menopause mobile applications on the market. To determine the utility of menopause apps, the features of certain menopause apps were reviewed. As well, comparisons of menopause and other health mobile applications were made to determine the differences in the number of these apps on the market. **Results:** Data suggests that there is a limited number of mobile applications focused on menopause that are currently available. In researching different menopausal apps, a common feature present in most apps is the ability to input data and track symptoms. Menopausal apps differ based on intended purpose. A few of the more commonly used menopausal apps include Menopause View, Caria: Menopause & Midlife, and My Luna. The app Menopause View provides a calendar feature and daily journal to allow users to record symptoms and schedule times to take medication. Caria: Menopause & Midlife helps users find educational resources, chat with experts, and connect with other users in an online community. My Luna allows users to track their health and generates predictions that can be shown to a health care provider. However, in comparison to menstruation and maternal health apps, the number of menopause apps were significantly less than the other health apps. **Conclusion:** The need for more mobile health applications directed towards menopause is apparent, given the limited number of menopause apps on the market. Some of the current menopause apps allow the users the ability to communicate with other individuals/health care providers. An ideal menopausal app should include features present in Menopause View, Caria: Menopause & Midlife, and My Luna. Another component that may be useful to both users and physicians is a HIPAA-secure platform. The app Mahmee utilizes a HIPAA-secure platform that allows a mother to link her and her infant's health records to the app. Health care providers can use the app to help create personalized care plans for mothers and infants. Incorporating a HIPAA-secure platform in menopausal apps can provide additional support to menopausal individuals. Given the current COVID-19 pandemic, individuals are physically isolated from each other and menopause mobile health apps would allow individuals to connect with others who are experiencing similar experiences. Overall, menopause health apps appear to have a role in the education and management of menopause for midlife and older women.

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P-33.

Mindfulness Techniques for Amelioration of Menopausal Symptoms

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Objective: Mindfulness practices were inspired by Buddhist teachings and are present-focused awareness. It obliges persons to use all of their senses to focus on the current moment. Women have known Mindfulness to be a natural alternative to treat both the physical and psychological symptoms of menopause. However, there are few women who utilize this for menopausal symptom relief. A review of mindfulness effectiveness for menopausal issues is reported. Works Cited Health, Lisa. "Mindfulness: A Natural Way to Manage Menopause Symptoms." Lisa Health Blog, Lisa Health Blog, 14 Feb. 2021, https://blog.lisahealth.com/blog/2021/1/19/mindfulness-a-natural-way-to-manage-menopause-symptoms **Design:** A Google Scholar search was done of the English literature exploring mindfulness and menopausal symptoms. **Results:** Data is minimal in this area. Research from a British 2018 evaluated the outcome of persons who practiced mindfulness-focused therapy and how it does appear to help with hot flashes and menopausal symptoms. It explored the results for symptoms of depression, anxiety and sleep problems. Further, since the pandemic, a number of people have experienced heightened stress, anxiety, and depression. From the literature, it appears that there are four mindfulness techniques for women experiencing menopausal symptoms. The techniques include yoga, meditation, breathing techniques and body scanning. For example, yoga is a great exercise to ameliorate menopausal and psychological symptoms. mData suggest that yoga lessens pain, which has positive implications for menopausal symptoms such as on headaches, joint pain, sleep and mood. Meditation is another technique in reducing menopausal symptoms, persons can meditate while lying down on the floor, sitting in a chair, or sitting on the floor. Breathing techniques such as, Paced-respiration, is a slow, deep breathing approach, that has shown to be effective in reducing the impact of hot flashes and managing stress and anxiety. For instance, sitting or lying down in a comfortable position while breathing in deeply through the nose and holding your breath for four counts; and slowly exhale through the mouth. Women who are experiencing hot flashes are instructed to practice this exercise daily for 15 minutes to lessen hot flashes, reduce stress as well as anxiety. Body Scan has proven to be an essential form in healing in meditation. This technique allows an individual to focus on each part of their body; starting at the toes and slowly moving to each part of the foot; then scan the whole leg, and lastly ending scanning the face and head. It can be done by laying down, sitting, or even standing up. The purpose is to draw attention to the different sensations one experiences when focused on one specific body part. Works Cited Health, Lisa. "Mindfulness: A Natural Way to Manage Menopause Symptoms." Lisa Health Blog, Lisa Health Blog, 14 Feb. 2021, https://blog.lisahealth.com/blog/2021/1/19/mindfulness-a-natural-way-to-manage-menopause-symptoms **Conclusion:** Despite scan literature, use of mindfulness may ameliorate menopausal symptoms. Perhaps focused literature in this practice should be offered to all menopausal women.

Sources of Funding: Robert Wood Johnson Medical School Women's Health Institute

P-34.

Menopause in Women with Polycystic Ovarian Syndrome (PCOS)

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Objective: Polycystic ovarian syndrome (PCOS) is the most common endocrinopathy affecting women. It is well known that women diagnosed with PCOS are at an increased risk of obesity, heart disease, insulin resistance, and psychiatric disorders (anxiety and depression). Menopause has also been associated with increased risk of these conditions, however, only limited research exists evaluating how PCOS may affect the prevalence and severity of menopausal symptoms and chronic disease. Although it is not included in the diagnostic criteria, women with PCOS are known to have elevated anti-mullerian hormone (AMH) levels. Prior studies have shown that AMH may be predictive of time to menopause, with higher AMH levels being suggestive of later time to natural menopause. Conversely, studies have also shown that increasing BMI and other medical comorbidities classically associated with PCOS may be inversely related to time to natural menopause. Furthermore, menstrual irregularities make it difficult to determine the age of natural menopause in midlife women with PCOS. The age at menopause is an important marker of a woman's health. Later onset of menopause has been associated with prolonged life longevity, lower risk for osteoporosis, decreased cardiovascular

disease, and decreased all-cause mortality. Late menopause may also increase risk for breast, endometrial, and ovarian cancers. Few studies have looked at PCOS and how the endocrinopathy may affect the diagnosis, timing, and severity of menopause. **Design:** This study aims to increase research efforts to investigate the implications of menopause for women diagnosed with PCOS. This study is a retrospective cohort study conducted via chart review aimed at evaluating the effect of PCOS on the timing of menopause and severity of menopausal symptoms, when controlling for demographics and relevant influential clinical factors and comorbidities. **Results:** The goal for completion of this research is September 2021. **Conclusion:** N/A

Sources of Funding: None

P-35.

Psychosocial Impacts of the COVID-19 Pandemic on Women with Trauma Histories: Study of Women's Health Across the Nation (SWAN)

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Objective: Older adults and those with trauma histories may be vulnerable to adverse psychosocial outcomes during the COVID-19 pandemic, due in part to vast changes in social behavior and daily life (e.g., social distancing). We tested whether pre-pandemic histories of childhood abuse or adult intimate partner violence (IPV) were related to elevated depression, anxiety, conflict, or sleep problems during the pandemic in a well-characterized, longitudinal sample of aging women. **Design:** Between June 2020-March 2021, women from Pittsburgh, Boston, and Newark, New Jersey, sites of the Study of Women's Health Across the Nation (SWAN) received a survey on the impact of COVID-19 on their lives. 644 women (72%) returned the survey; 582 women comprised the final analytic sample (63% White, 25% Black, 12% Hispanic; mean age=70). Items queried sleep problems, conflict with household members and non-household family, and household size. Depressive and anxiety symptoms were assessed via Patient Health Questionnaire (PHQ)-2 and Generalized Anxiety Disorder (GAD)-2 scales; we considered PHQ-2 and GAD-2 scores ≥2 elevated. Pre-pandemic depression (Center for Epidemiological Studies-Depression), anxiety (GAD-7), childhood trauma (Child Trauma Questionnaire), and sleep (frequency of nighttime awakenings) were drawn from SWAN Visit 15 (2015-2017). Physical and emotional IPV was assessed at Visits 12, 13, 15 (2009-2017). Longitudinal relations of childhood trauma (any/none) or IPV (any/none) with higher COVID-19 depressive or anxiety symptoms (total 0-1 vs. ≥2), conflict (yes/no), and sleep problems (yes/no) were examined in separate logistic regression models, adjusted for age, site, race/ethnicity, and education. Secondary models further adjusted for pre-pandemic depressive, anxiety, or sleep symptoms, respectively; however, there were no pre-pandemic measures of conflict. **Results:** 48% and 35% of women reported childhood trauma or IPV (largely emotional IPV), respectively. Elevated COVID-19 depressive, anxiety, and sleep symptoms were reported by 27%, 32%, and 46% of women, respectively. 29% and 17% of women reported elevated conflict with household members and non-household family, respectively. Childhood trauma and IPV were related to elevated depressive symptoms, sleep problems, and household conflict (Table). Childhood trauma also related to elevated anxiety symptoms and conflict with non-household family. Significant associations persisted after adjustment for pre-pandemic anxiety (for childhood trauma only) and sleep symptoms, but not after adjustment for pre-pandemic depressive symptoms, in respective models. **Conclusion:** Aging women with childhood abuse or IPV histories reported worse mental health, sleep, and conflict during the COVID-19 pandemic than women without these histories. Trauma survivors were more vulnerable to elevated anxiety and sleep problems beyond their pre-pandemic symptoms. Women's trauma histories and prior symptomatology are critical to understand psychosocial impacts of the pandemic.

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	Depressive symptoms OR (95% CI)	Anxiety symptoms OR (95% CI)	Sleep problems OR (95% CI)	Conflict (household)[a] OR (95%CI)	Conflict (family outside household) OR (95% CI)
Childhood trauma	**1.67 (1.11-2.52)**	**2.00 (1.35-2.97)#**	**1.50 (1.04-2.16)#**	**2.36 (1.45-3.87)**	**2.30 (1.40-3.77)**
Intimate partner violence	**1.58 (1.03-2.43)**	1.35 (0.89-2.04)	**1.71 (1.15-2.54)#**	**1.97 (1.23-3.15)**	1.33 (0.81-2.16)

Referent: PHQ-2 [GAD-2] <2, no sleep problems, no conflict, respectively. Covariates: age, race/ethnicity, site, education. Bold text=p<0.05. OR (95%CI)=odds ratio (95% confidence interval).
[a]Analysis excluded women living alone and further adjusted for household size.
#Association persisted beyond pre-pandemic depressive, anxiety, or sleep symptoms, respectively; pre-pandemic conflict was not measured.

P-36.

Comparison of mammography findings and breast pathologies in postmenopausal women treated with compounded "bioidentical" hormone therapy versus FDA-approved hormone therapy

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Objective: We aim to compare mammography findings and breast pathologies after initiation of Custom compounded "bioidentical" hormone therapy (cBHT) vs. FDA-approved hormone therapy (FHT) in postmenopausal women. **Design:** We performed a retrospective cohort study of 280 postmenopausal women on hormone therapy (HT), including 127 on pellet hormone therapy (PHT) and 153 on FHT. A total of 700 patients (450 on PHT, 250 on FHT) were initially retrieved from electronic medical record with 420 being excluded due to duplicate records, no mammogram or breast ultrasound readings available after HT initiation, personal history of breast cancer prior to HT, sequentially receiving both PHT and FHT. Incidence of noninvasive and invasive breast cancer, including ductal carcinoma in situ, invasive ductal carcinoma, invasive lobular carcinoma, and other types of invasive breast cancer), was analyzed as a primary outcome. **Results:** Mean (SD) of treatment duration (4.3[3.0] vs. 6.9[5.1] years, p<0.001) and length of follow-up (7.8[1.3] vs. 10.1[4.4] years, p<0.001) were significantly shorter in PHT compared to FHT. Mean (SD) age at HT initiation was significantly younger in women on PHT than those on FHT (51.2[8.1] vs. 57.5[11.7] years, P<0.001). Significantly higher number of women on PHT had breast tenderness compared to those on FHT (41[33.1%] vs. 24[16.1%], p=0.001). There were no significant differences between PHT vs. FHT in the number of BIRADS ≥4 based on the worst BIRADS reading (21[16.5%] vs. 24[15.7%]), the number of women undergoing a breast biopsy (28[21.9%] vs. 25[16.2%]), and the incidence of noninvasive and invasive breast cancers (9[7.1%] vs. 5[3.3%]) during the follow-up. In logistic regression model with HT type, treatment duration, length of follow-up, and risk factors considered (table 1), a family history of breast cancer (odds ratio[95%CI]=17.6[1.6-188.9], p=0.018) and length of follow-up (odds ratio[95%CI]=1.4[1.02-2.0], p=0.036) significantly predict the future risk of breast cancer. Interestingly, many women in both HT groups had a family history of breast cancer (PHT 49[38.6%] vs. FHT 65[42.5%], p=0.51). **Conclusion:** A null finding of the study does not provide reassuring evidence supporting the breast safety of pellet use in postmenopausal women, due to a likelihood of type 2 error. Women with a family history of breast cancer should be intensively counseled on the increased risk of breast cancer prior to HT initiation.

Sources of Funding: None

Table 1. Baseline comparison of demographic characteristics, breast cancer risk factors, and incidence of breast cancer between PHT and FHT

	PHT (n=127)	FHT (n=153)	P Value
Age at HT initiation (Mean [SD], years)	51.2 (8.1)	57.5 (11.7)	<.001
BMI (N [%], kg/m2)	29.5 (6.5)	28.4 (7.2)	ns
Ethnicity – White (N [%])	118 (92.9)	142 [92.8]	ns
Marital status - Married (N [%])	94 (74.0)	8 (64.1)	ns
Family history of breast cancer (N [%])	49 (38.6)	65 (42.5)	ns
History of diabetes (N [%])	12 (9.6)	23 (15.1)	ns
History of smoking (N [%])	57 (44.9)	55 (36.2)	ns
Alcohol use (N [%])	15 (11.8)	4 (2.6)	.002
HT duration (Mean [SD], years)	4.3 (3.0)	6.9 (5.1)	<.001
Length of follow-up (Mean [SD], years)	7.8 (1.3)	10.1 (4.4)	<.001
Hysterectomy before or during HT (N [%])	78 (61.4)	104 (68)	ns
Progesterone use (N [%]) *	57 (44.9)	45 (29.4)	.007
Breast tenderness during HT (N [%])	41 (33.1)	24 (16.1)	.001
BIRADS ≥4 based on the worst mammogram reading (N [%])	21 (16.5)	24 (15.7)	ns
Breast biopsy during or after HT (N [%])	28 (22.0)	25 (16.3)	ns
Breast cancer (noninvasive and invasive) (N [%])	9 (7.1)	5 (3.3)	ns
Age at breast cancer diagnosis (Mean [SD], years)	60.4 (7.7)	65 (5.7)	ns

ns: non-significant (P > 0.05)
***Most women were not on progesterone because they had undergone a hysterectomy.**

P-37.

Women's Health Initiative Clinical Trials: The Effect of Menopausal Hormone Therapy on Blood Pressure in Postmenopausal Women with Hypertension

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Objective: The objective of this study was to assess the effect of menopausal hormone therapy (MHT) on blood pressure control in postmenopausal women with hypertension. **Design:** The Women's Health Initiative MHT clinical trials were double-blinded, randomized, placebo-controlled studies of women aged 50-79 years testing the effects of MHT (conjugated equine estrogens [CEE, 0.625 mg/day] or CEE + medroxyprogesterone acetate [MPA, 2.5 mg/day]) on risks for coronary heart disease and invasive breast cancer, the primary outcomes for efficacy and safety, respectively. This secondary analysis of the WHI MHT trials examined a of 9,332 women with hypertension (reported ever taking pills to treat hypertension or were taking antihypertensive medication) at baseline. Blood pressure was measured at baseline and up to ten annual follow-up visits during the planned study phase. Antihypertensive medications were inventoried at baseline and years 1, 3, 6 and 9 during the study, and self-reported during extended follow-up; 2009–2010 and 2012–2013 that occurred median of 13 and 16 years after randomization, respectively. The intervention effect was estimated through year-6. Cumulative follow-up included all visits. **Results:** Compared to placebo, CEE-alone had significantly ($P = 0.02$) higher systolic blood pressure (SBP) by mean (95%CI) = 0.9 (0.2, 1.5) mmHg during the intervention phase. For cumulative follow-up, the CEE arm was associated with increased SBP by mean (95%CI) = 0.8 (0.1, 1.4) mm Hg ($P = 0.02$). Furthermore, CEE+MPA relative to placebo was associated with increased SBP by mean (95%CI) = 1.8 (1.2, 2.5) mmHg during the intervention phase ($P < 0.001$). For cumulative follow-up, the CEE+MPA arm was associated with increased SBP by mean (95%CI) = 1.6 (1.0, 2.3) mm Hg ($P < 0.001$). The mean number of antihypertensive medications taken at each follow-up visit did not differ between randomization groups during the intervention or long-term extended follow-up of 16 years. **Conclusion:** There was a small but statistically significant increase in SBP in both CEE-alone and CEE+MPA arms compared to placebo, during both the intervention and cumulative follow-up phases among postmenopausal women with hypertension at baseline. However, this increase in SBP was not associated with an increased antihypertensive medication use over time among women randomized to MHT compared to placebo.

Sources of Funding: The Women's Health Initiative (WHI) program is funded by the National Heart, Lung, and Blood Institute, National Institutes of Health, U.S. Department of Health and Human Services through contracts 75N92021D00001, 75N92021D00002, 75N92021D00003, 75N92021D00004, and 75N92021D00005.

P-38.

Addressing Menopausal Symptoms in Primary Care: An Opportunity for Improvement? The Results from a Registry of Midlife Women in US Tertiary Care

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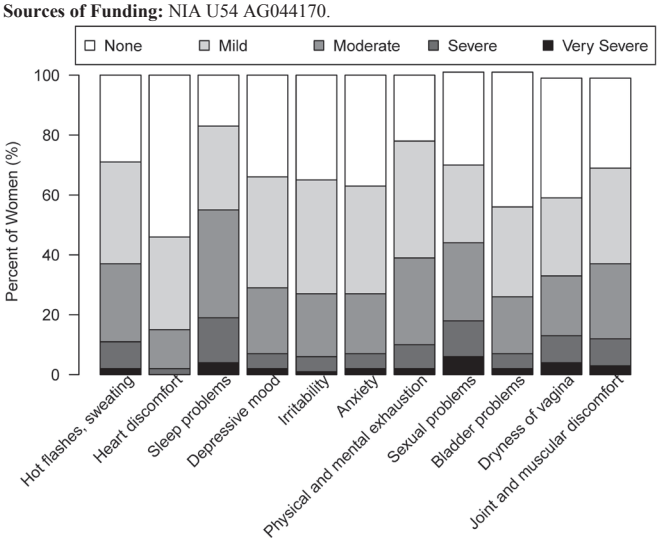
Objective: Menopause symptoms affect most midlife women. Despite the significant health and economic burdens faced by untreated menopausal women, many do not receive adequate care for menopausal symptoms. It is not well understood whether this is a result of women's hesitancy to report their symptoms and seek treatment, reluctance of their providers to treat these symptoms, or both. The study's objective was to assess the burden of menopausal symptoms and to evaluate potential barriers to menopausal care in women receiving primary care at a tertiary medical center in the US. **Design:** This cross-sectional study included participants in the Mayo Clinic registry of midlife women (Hormones and ExpeRiences of Aging, HERA). The registry includes women aged 45-60 years who receive primary care at one of 4 Mayo Clinic sites- Rochester, MN; Scottsdale, AZ; Jacksonville, FL; and Mayo Clinic Health System, NW WI. From March-June 2021, women were sent a questionnaire that included the Menopause Rating Scale, and questions about the impact of menopause symptoms on their personal and professional lives. They were also asked whether they received care for these symptoms and their perception of the quality of care received. Reasons for not seeking or receiving care were also queried. **Results:** As of June 1, 2021, 22,125 surveys had been sent, and 3036 (13.7%) responses received. The mean age of the respondents was 54.2 years. Most were white (95.2%), educated (college or higher, 93.4%), and non-smokers (94.4%). Thirty-four percent reported menopausal symptoms that were moderate, severe or very severe (Figure). The most common symptoms rated as severe or very severe were sleep and sexual problems. About 80% of women did not seek medical care for menopausal symptoms, with most of them reporting being too busy or a lack of awareness about effective treatment options. **Conclusion:** This large cross-sectional study reveals a significant symptom burden among menopausal women. Given the availability of safe and effective treatments to manage menopause symptoms, there is a need for additional education of women and their primary care providers. Future steps may include building algorithms in primary care practice that enable providers to identify and counsel women with bothersome menopause symptoms.

Sources of Funding: NIA U54 AG044170.



P-39.

Trajectories of Metabolic Parameters after Bilateral Oophorectomy in Premenopausal Women

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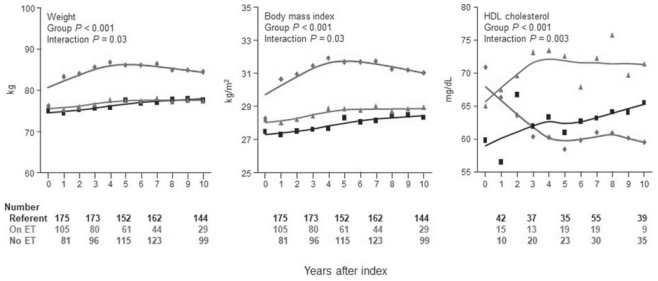
Objective: To study the trajectories of change for blood pressure, hemoglobin, weight, and lipids over 10 years after premenopausal bilateral oophorectomy. **Design:** This population-based cohort study included a random sample of all premenopausal women who underwent bilateral oophorectomy at or before age 45 years between January 1, 1988 and December 31, 2007 in Olmsted County, Minnesota, and age-matched (±1 year) referent women who did not undergo bilateral oophorectomy. The medical records of all women were reviewed to collect data on blood pressure, hemoglobin, height, weight, fasting lipid profiles, and estrogen therapy use over a 10-year period. We compared the trends using generalized estimating equation models for three groups of women: 1) referent women, 2) women who underwent bilateral oophorectomy and received estrogen therapy, and 3) women who underwent bilateral oophorectomy and did not receive estrogen therapy. The models were adjusted for race, household income, and smoking status. **Results:** There were 1,031 women who underwent bilateral oophorectomy at age ≤45 years and 1,031 age-matched referent women. A weighted random sample of 270 women who underwent bilateral oophorectomy was selected, among whom 163 (60%) used estrogen therapy at some point after oophorectomy and 107 (40%) did not. The corresponding 270 age-matched referent women were also selected. When compared to the referent women, women who underwent oophorectomy had significantly higher systolic blood pressure, weight, body mass index (BMI), and triglycerides at the time of oophorectomy. The trajectories of change over 10 years were significant for weight, BMI, and HDL-cholesterol (Figure), and suggestive for total cholesterol. Women who underwent bilateral oophorectomy and were not taking estrogen therapy at the specific time points of measurement during follow-up had higher weight and BMI, whereas women who took estrogen therapy had modest increases over time like the referent women. Women who took estrogen therapy after oophorectomy experienced an increase over time in HDL-cholesterol, whereas women who did not take estrogen experienced a decrease over time. Significant group differences were also found for diastolic blood pressure, hemoglobin, total cholesterol, and triglycerides, however, the interactions between group and years after oophorectomy were not significant. **Conclusion:** Women who underwent bilateral oophorectomy before menopause experienced significant adverse changes in some metabolic parameters.

Sources of Funding: NIH Grants: R01 AG034676, R01 AG052425, U54 AG044170



Smoothed curves of predicted mean values for weight, body mass index, and HDL cholesterol over ten years after bilateral oophorectomy or index date (for referent women)

P-40.

Efficacy of sequential treatment with bisphosphonate compared to prolonged denosumab treatment after discontinuation of denosumab in postmenopausal osteoporosis

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Objective: Denosumab, a recently developed receptor activator of nuclear factor-kBligand (RANKL) inhibitor, has been widely used as the primary treatment for osteoporosis. In Korea, the National Health Insurance limits the administration of denosumab in patients diagnosed with osteoporosis to up to one year, and can only be re-dosed if osteoporosis persists afterward. If bone mineral density (BMD) improves in subsequent bone densitometry and is not diagnosed with osteoporosis denosumab is not covered by the insurance. However, sequential treatment should be considered because of the severe rebound-associated vertebral fractures after denosumab discontinuation. In this study, we aimed to compare the changes in BMD between women sequentially treated with bisphosphonate and those who continued treatment with denosumab after completion of denosumab treatment postmenopausal women with osteoporosis. **Design:** A retrospective cohort study was conducted on postmenopausal patients diagnosed with osteoporosis who initiated treatment with denosumab at Seoul National University Hospital from 2017, when the insurance support for denosumab in patients with osteoporosis began in Korea. We reviewed patient records by April 2021. We compared the changes in BMD between women sequentially treated with bisphosphonate and those who continued treatment with denosumab after denosumab treatment. Bone density of the spine, femur neck, and femur total regions were compared based on the T-score of DXA. The Mann-Whitney method was used to evaluate the significant differences on bone density change between groups. **Results:** Since 2017, a total of 57 women diagnosed with postmenopausal osteoporosis were included in the study. Of these, 19 were patients who continued treatment by changing to bisphosphonate after treatment of denosumab, and 38 continued treatment with denosumab. The average follow-up period for patients who administered only denosumab was 18.58 months, and 25.09 months for patients who administered denosumab followed by bisphosphonate. The baseline BMD before treatment also had no difference between the two groups. The BMD changes before and after treatment were 8.61% for spine, 5.65% for femur neck and 6.12% for femur total in the group that changed the medication to bisphosphonate. In Denosumab-persistence group, spine for 18.76%, total hip for -4.55%, and femur neck for -4.35%, there was no difference between the two groups (p=0.472, p=0.364, p=0.133, respectively). **Conclusion:** In postmenopausal osteoporosis women, there is no significant difference in bone density change between patients treated by switching to bisphosphonate to prevent rebounding after denosumab treatment and those who continued denosumab treatment. In the denosumab-persistence group, the treatment effect was stable in spine and femur, while the change to bisposphonate tended to vary greatly depending on the site. Although it was not a statistically significant difference, it can be inferred that bone density can be maintained stably in the denosumab dose group, and follow-up studies are needed. The BMD difference between the two groups was not significant with insufficient periods of follow-up, as DXA is often follow-up every one year. Due to increased compliance due to ease of administration and side effects lower than bisphosphonate administration, denosumab prescription is expected to increase gradually, and further research will be conducted on whether it will be scalable in osteopenia patients through long-term follow up.

Sources of Funding: None

Baseline characteristics

	Denosumab (n=38)	Denosumab followed by bisphosphonate (n=19)	P-value
Age	66.71	67.64	0.665
Body Mass Index (BMI)	21.9747	24.2862	0.047
Follow up period (month)	18.58	25.09	0.130
Baseline DXA			
Spine (L1-4)	-2.787	-2.291	0.101
Femur neck	-1.642	-1.727	0.673
Femur total	-1.711	-1.736	0.912

BMD during f/u period

	Denosumab (n=38)	Denosumab followed by bisphosphonate (n=19)	P-value
Mean change (%)			
Spine (L1-4)	8.61	18.76	0.472
Femur neck	5.65	-4.55	0.364
Femur total	6.12	-4.35	0.133

P-41.

Consumer Acceptance and In-Use Study Evaluating a Vulvar Moisturizer

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Objective: There is a limited number of peer-reviewed medical publications concerning non-invasive topically genital cosmetic products that could act as a frontline treatment for aesthetic concerns. The vulvar area has received limited research and attention in the cosmetic and skincare industry. Many topical creams exist primarily for medical conditions; however, topical cosmetic products are an unmet consumer need in that they have less risk than surgical intervention when seeking enhancement or improvement of the female genital appearance. The unmet consumer need can be realized with a non-invasive vulvar moisturizer developed to improve vulvar aesthetics. This prospective study was conducted to assess consumer acceptance and tolerability of a vulvar moisturizer product (VMP) when used by healthy women twice-daily over the course of four weeks. **Design:** This was an institutional review board (IRB)-approved single-center consumer in-use study that was performed at a sexual medicine center by a trained sexual medicine physician. Twenty-five female subjects, 18-85 years old, and in good medical and gynecological health with no active untreated medical conditions were recruited in the study. Subjects applied the VMP on both the left and right sides of the external vulvar tissue twice daily for four weeks. At the end of the study, subjective tolerability measurements and self-assessment were completed. A binomial exact test was performed on responses to each question. The null hypothesis was that the responses (positive, negative, neutral) were evenly distributed (33%, 33%, 33%) among the 25 subjects. The goal was to disprove the null hypothesis at a statistical significance of $*p < 0.05$. **Results:** Twenty-five, female subjects, with an average age of 39 +/- 10 years completed the consumer in-use study. Female subjects were primarily Caucasian (48%) and 44% Hispanic or Latino completed the study. Self-assessment results indicated highly statistically ($***p < 0.001$) favorable responses for each category: vulva perception, product characteristics, product package, and overall satisfaction. Specifically, after 4 weeks: 100% of subjects responded favorably to “After product use, my vulva feels soft.” 100% of subjects responded favorably to “This product nourishes vulvar skin.” 96% of subjects responded favorably to “After product use, my vulva feels overall healthy and beautiful.” 96% of subjects responded favorably to “This product maintained and improved my natural healthy vulvar skin.” Overall, subjects felt confident and valued that the VMP was formulated with high-quality ingredients and appreciated that it did not contain hormones. Results from subjective tolerability evaluation showed the VMP yielded no vulvar burning, itching, or stinging, or other adverse events for any subject by the end of the study. **Conclusion:** This single-center consumer in-use study supports the hypothesis that the VMP when used twice daily for four weeks achieved consumer acceptance and was tolerable. Consumer acceptance was demonstrated in all self-assessment categories, vulva perception, product characteristics, packaging, and overall satisfaction. Further research is currently being conducted with the VMP for a post shave utilization use.

Sources of Funding: Revision Skincare®

P-42.

Knowledge Gaps in Women’s Health: Results of a Survey of Primary Care Providers

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Objective: To better understand the knowledge gaps and educational interests in women’s health among primary care clinicians, a survey was conducted to measure clinician knowledge and interest in several women’s health topics. We report on the topics of menopause and sexual health. **Design:** A survey was distributed via email on 3/16/21 to 5916 primary care clinicians who had participated in a Pri-Med in-person or online activity within the past 24 months. The sponsor (Pri-Med), topic (Women’s Health), survey length (~4 minutes), and incentive (4 x $100 Amazon Gift card drawing for completers) were revealed in the survey invitation. Two-hundred eighteen clinicians (response rate 3.7%) completed the survey. Clinicians with no female patients or not identifying as primary care were excluded from the analysis. Analysis was conducted on 150 completed surveys including 48 physicians (MDDOs) and 102 nurse practitioners or physician assistants (NPPAs). **Results:** When responding to options about which health conditions they manage, 65% indicated menopause, 63% indicated perimenopause and 53% indicated sexual complaints. MDDOs were significantly more likely to manage menopause symptoms than NPPAs (81% vs 57%, $p<0.05$) and, although not significantly different, MDDOs were also more likely to manage perimenopause symptoms (75% vs 57%). When provided a list of barriers to managing women’s health conditions, the most common were: other health issues take priority (42%); office visits are too short (36%); treatment options are sometimes controversial (36%); lack of training in women’s health (35%); data on treatment options is sometimes ambiguous (26%). MDDOs were significantly more likely than NPPAs to indicate treatment options are sometimes controversial (53% vs 28%, $p<0.05$). When asked how frequently they ask about

symptoms of perimenopause or menopause in patients between the ages of 45 and 64, only 53% reported asking more than 50% of the time. MDDOs were more likely to ask than NPPAs (71% vs 44%, p<0.10). Only 39% of total respondents report they ask about sexual health more than 50% of the time. 50% of MDDOs ask more than half the time vs 33% for NP/PAs, although the difference is not significant. When asked about familiarity with NAMS or ACOG guidelines for prescribing menopausal hormone therapy (HT), 9% reported being very familiar, and 39% reported being not at all familiar. NPPAs were less familiar than MDDOs and over half reported being not at all familiar (51% vs 13%, p<0.05). Level of familiarity with guidelines appears to correspond to clinician age, with older clinicians being more familiar than younger ones. When asked about comfort with prescribing FDA approved HT for menopause symptoms, a small percentage of clinicians (9%) reported they are very comfortable, and the level of comfort corresponded with increasing age. Similarly, when asked about comfort prescribing FDA approved and off-label non-HT for menopause symptoms, only a small percentage of all clinicians (15%) reported being very comfortable. MDDOs were more comfortable than NPPAs (29% vs 9% are very comfortable, p<0.05). When asked about comfort addressing sexual complaints, only 14% of clinicians reported being very comfortable, while 15% of all clinicians reported being not at all comfortable. When asked about comfort in treating genitourinary syndrome of menopause only 13% of all clinicians reported being very comfortable. A very small percentage of clinicians (5%) reported being very familiar with FDA approved medications for low sexual desire while 53% of all clinicians reported not being at all familiar with these medications. Seventy-two percent of all clinicians are very interested in learning more about women's health. **Conclusion:** Although most respondents report they ask about and treat menopausal and sexual symptoms in women between the ages of 45 and 64, many are unfamiliar with treatment guidelines, feel they lack training and are unfamiliar or uncomfortable with HT, FDA approved and off-label non-HT, and FDA approved treatments for low sexual desire. However, the vast majority are interested in learning more about women's health.
Sources of Funding: None

P-43.

Associations of antimullerian hormone levels among women in their mid-30s with menopausal symptoms ~15 years later

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Objective: Circulating antimullerian hormone (AMH) levels correlate with antral follicle counts and can predict menopause age of onset. However, it is unknown whether AMH levels in fertile women during their reproductive years, within a few years of a pregnancy, are associated with menopausal symptoms in mid-life. Our objective was to examine the associations of AMH levels in reproductive aged women with menopausal symptoms ~15 years later, and with age at menopause onset. **Design:** We studied 430 women enrolled in Project Viva, a prospective, longitudinal cohort of women enrolled during pregnancy between 1999-2002 and followed since. We measured AMH levels at a 3-year postpartum visit and participants completed the 11-item Menopause Rating Scale (MRS) ~15 years later. Outcomes included total score and individual item responses on the MRS, and self-reported age at menopause. We used linear and logistic regression, and survival analyses, adjusted for race/ethnicity, education, household income, parity, age at menarche, and age and BMI at time of AMH measurement. **Results:** 75% of participants were white and 80% had a college degree at recruitment. Mean (SD) age at AMH measurement was 37.8 (3.8) years and at follow-up 52.2 (3.8) years. Mean (SD) AMH level was 2.84 (2.81) ng/mL and mid-life total MRS score was 8.1 (5.8). At time of MRS completion, 51% of the participants had reached menopause by median age 50 years. AMH in the lowest quartile (mean [SD] 0.31 [0.21] ng/mL) was associated with higher odds of moderate to severe vaginal dryness (Odds Ratio: 2.81; 95% CI: 1.05, 7.50) and greater risk of earlier attainment of menopause (Hazard Ratio 13.3; 95% CI 6.0, 29.9) compared to AMH in the highest quartile (mean [SD] 7.04 [2.11] ng/mL). We did not find associations of AMH levels with total MRS score. **Conclusion:** Very low AMH in the mid-thirties was associated with earlier menopause, and higher likelihood of vaginal dryness ~15 years later in this longitudinal cohort. Higher level of AMH, a proxy for greater ovarian reserve, in fertile women following a pregnancy appears to protect against early menopause and the experience of moderate to severe vaginal dryness.
Sources of Funding: Viva Moms: R01HD096032 SCORE: 1U54AG062322-01A1 Viva Obesity R01 034568

P-44.

"It just makes me feel a little less alone": A qualitative exploration of the podcast 'menopause: unmuted' on women's perceptions of menopause

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Objective: Many women report inadequate information and support during the menopause transition. Podcasts have been found to be an accessible method for increasing knowledge and challenging perceptions of stigmatized topics. The current research aimed to understand the impact of the podcast 'menopause: unmuted' on women's menopause-related knowledge, understanding, and communication practices. 'menopause: unmuted', is a five-episode podcast series using immersive storytelling to share the experiences of US women. Alongside these first-hand accounts, a women's health professional provides a medical perspective to contextualize the women's stories, offer evidence-based lifestyle advice and address menopause myths. The podcast was funded by Pfizer Inc Women's Health Team. **Design:** A diverse sample of 30 women in the United States, aged 40-60 years listened to the podcast series, which focused on menopause stories, before taking part in semi-structured interviews to discuss the impact of the podcast on how they understood and communicated about menopause. The interviews were analyzed thematically. **Results:** Two overarching themes were identified in the data. A 'journey of knowledge gain' explores participants' understanding of menopause before listening to the podcast and reflects on how this is deepened by hearing and connecting with women's stories. 'Reframing menopause' describes the impact of the podcast, where women reflect on the value of communication amongst women, challenge and re-evaluate the stigmatization of menopause, and discuss ways to make positive behavioral changes in their lives. **Conclusion:** The podcast 'menopause: unmuted' helped women to learn about the menopause experience, have a greater sense of belonging to a community of women, and feel empowered to make changes in their own lives. Sharing stories via podcasts has potential as an accessible and impactful medium to educate women and reduce the widespread stigma associated with menopause.
Sources of Funding: Pfizer Inc

P-45.

Efficacy of Topical Sinecatechins Ointment for Significant to Severe Secondary Provoked Vestibulodynia in Sexually Active Post-Menopausal Women: A Randomized Double-blind Placebo-Controlled Clinical Trial

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Objective: The objective of this clinical research was to evaluate the efficacy of 5% and 10 % topical sinecatechins ointment, a botanical drug derived from green tea, in significantly reducing provoked vestibulodynia in sexually active postmenopausal women, and without affecting the vaginal mucosa. **Design:** Inclusion criteria: 32 postmenopausal sexually active women with a chief complaint of secondary provoked vestibulodynia. Vaginal pH was tested at each of three office visits with the gynecologist to confirm that topical sinecatechins ointment, a botanical drug derived from green tea, does not affect the maturation of the vaginal mucosa. . Localization and severity of pain was documented by standardized Q-Tip testing. At least one or more of seven points on the vulvar vestibule had to have a pain score of 7 or above (significant to severe) to be included. Subjects indicated their overall subjective vulvar vestibular pain on the same 0-10 point Numerical Rating Scale where 0 no pain; (1-3) mild pain; (4-6) moderate pain; (7-9) significant pain; (10) severe pain. Subjects were asked to comment on any subjective sexual sensations. Subjects were asked to apply ½ inch of ointment once daily (5% sinecatechins, 10% sinecatechins or placebo) to the vulvar vestibule, avoiding the urethral introitus. Subjects were told to immediately report any irritation, and if that occurred, to reduce use to three times per week. Subjects were seen initially and in two subsequent office visits 2 to 3 weeks apart for evaluation of their vestibulodynia. **Results:** There was no significant difference in the average vestibular pain between the placebo, 5% and 10% at baseline. There were no significant changes in the vaginal pH of the placebo, 5% or 10% sinecatechins groups. There was a significant decrease in vestibulodynia when comparing the placebo to the 5% sinecatechins group by the first follow-up office visit, but less of a decrease in pain when comparing placebo to 10% sinecatechins at the first follow-up office visit. It was observed that several subjects experienced irritation with daily use of the 10% sinecatechins which resolved with reducing the frequency of application to no more than three times per week. There was a significant decrease in vestibulodynia by the third and final office visit in both the 5% sinecatechins group with daily use and 10% sinecatechins group with reduced frequency of application. With reduced frequency to three times per week, the 10% group subjectively reported an increase in pleasurable sexual sensations in addition to a significant reduction in their vestibulodynia. **Conclusion:** Topical 5% sinecatechins ointment applied once daily, or 10% sinecatechins ointment applied three times a week, significantly reduced provoked secondary vestibulodynia. Daily use of 5% sinecatechins ointment was not irritating, but daily use of 10% sinecatechins can be. Unmyelinated afferent C-fibers innervating the vulvar vestibule transmit both sensations of pain and sexual pleasure. The novel finding that topical sinecatechins both significantly reduce vestibulodynia and increase sexual sensations of arousal has a neurological basis. We propose that topical sinecatechins may be used adjunctively to alleviate persistent vulvar vestibular pain in women using estrogens to treat vaginal atrophy. Women who are unwilling to use estrogenic compounds, or for whom estrogens are contraindicated because of estrogen sensitive malignancies, may safely use topical sinecatechins ointment to significantly reduce their vestibulodynia because topical sinecatechins do not cause proliferation of the vaginal mucosa. Post-menopausal women with or without provoked vestibulodynia may elect to use topical sinecatechins ointment to increase overall sexual function, including sexual arousal. Based on this preliminary research we hope to see larger clinical trials in both pre and post-menopausal women with provoked vestibulodynia.
Sources of Funding: GTO Pharmaceutical, LLC

P-46.

Associations of the premenopausal Life's Simple 7 components and high-density lipoprotein metrics later in life: The SWAN HDL Study

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Objective: Higher level of high-density lipoprotein cholesterol (HDL-C) in midlife women is not always cardioprotective, suggesting a potential dysfunction of HDL. Novel metrics of HDL may provide further information on its protective cardiovascular effects. The American Heart Association developed the Life's Simple 7 (LS7) score based on 7 lifestyle components [4 health behaviors (body mass index, physical activity, diet and smoking) and 3 health factors (cholesterol, glucose and blood pressure)] as a measure of cardiovascular health. A higher LS7 indicates a healthier lifestyle. We aimed to assess if higher LS7 score and individual health behavior components before menopause were associated with a cardioprotective HDL metrics profile [higher HDL cholesterol efflux capacity (HDL-CEC), HDL-phospholipids (HDL-PL) levels, and large HDL-particles (HDL-P), lower small HDL-P and HDL-triglycerides (HDL-Tg) levels, and larger HDL size] later in life. **Design:** We included 529 women [baseline age 46.4 (2.6) years, 57% White] from the Study of Women's Health Across the Nation (SWAN) HDL ancillary study who had premenopausal LS7 components and repeated HDL metrics at later visits [mean duration between LS7 and first HDL metric measure: 3.9 (1.4) years]. The LS7 score and each health behavior component were categorized as ideal, intermediate or poor. Multivariable linear mixed models were used to analyze the independent associations between each component and each HDL metric. Final models were adjusted for race, education, and baseline age, menopause status, economic hardship, and log C-reactive protein. **Results:** In final models (Table), ideal LS7 score was associated with lower levels of HDL-Tg, higher levels of HDL-PL, large HDL-P and HDL-C and larger HDL size, all P <0.05. Ideal BMI status was associated with higher HDL-CEC, HDL-PL, large HDL-P, and HDL-C, and with lower HDL-Tg, small HDL-P and larger HDL size, all P <0.05. Increased physical activity was associated with higher HDL-PL, total HDL-P, and HDL-C, and lower medium HDL-P, all P <0.05. Ideal smoking status was associated with lower HDL-Tg. Diet was not associated with any HDL metrics. **Conclusion:** Ideal premenopausal cardiovascular health behaviors, particularly BMI and physical activity, were related to favorable HDL metrics, such as contents and subclasses, later in life. This indicates that a better premenopausal lifestyle may contribute to a better HDL profile later in life.

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Associations between AHA LS7 Score and health behaviors with HDL Metrics^

		HDL-CEC (%)	Log HDL-Tg	HDL-PL (mg/dL)	Total HDL-P (μmol/L)	Large HDL-P (μmol/L)	Medium HDL-P (μmol/L)	Small HDL-P (μmol/L)	HDL Size (nm)	HDL-C (mg/dL)
LS7	Poor	5.82 (0.06)	2.93 (0.02)*	4.88 (0.07)	5.60 (0.06)	2.12 (0.07)	1.78 (0.06)	2.36 (0.06)	17.43 (0.07)*	3.84 (0.07)*
	Intermediate	5.84 (0.07)	2.85 (0.02)	5.06 (0.07)	5.65 (0.07)	2.38 (0.07)	1.81 (0.07)	2.34 (0.07)	17.75 (0.08)	4.17 (0.07)
	Ideal	5.81 (0.10)	2.82 (0.03)	5.10 (0.10)	5.85 (0.10)	2.42 (0.11)	1.98 (0.10)	2.25 (0.10)	17.75 (0.11)	4.20 (0.11)
	p-trend	0.98	0.0005	0.04	0.06	0.005	0.11	0.24	0.002	0.0005
BMI	Poor	5.60 (0.09)*	2.95 (0.02)*	4.70 (0.09)*	5.51 (0.09)	1.99 (0.09)*	1.75 (0.08)	2.39 (0.09)	17.32 (0.09)*	3.66 (0.09)*
	Intermediate	5.83 (0.08)	2.90 (0.02)	4.91 (0.08)*	5.69 (0.08)	2.08 (0.08)*	1.91 (0.06)	2.49 (0.08)*	17.38 (0.08)*	3.91 (0.08)*
	Ideal	5.96 (0.07)	2.84 (0.02)	5.17 (0.07)	5.73 (0.07)	2.50 (0.07)	1.73 (0.08)	2.16 (0.07)	17.85 (0.07)	4.25 (0.07)
	p-trend	0.002	0.0005	<0.0001	0.06	<0.0001	0.07	0.02	<0.0001	<0.0001
Physical Activity	Poor	5.81 (0.05)	3.28 (0.05)	4.94 (0.05)*	5.59 (0.05)*	2.23 (0.05)	1.78 (0.05)	2.29 (0.05)	17.57 (0.05)	3.97 (0.05)*
	Intermediate	5.90 (0.18)	3.27 (0.18)	4.88 (0.18)	5.61 (0.18)	2.20 (0.19)	1.85 (0.17)	2.25 (0.18)	17.50 (0.19)	3.88 (0.19)
	Ideal	5.89 (0.10)	3.18 (0.10)	5.21 (0.10)	6.05 (0.10)	2.44 (0.10)	2.02 (0.10)	2.39 (0.10)	17.71 (0.11)	4.26 (0.10)
	p-trend	0.44	0.32	0.02	<0.0001	0.06	0.02	0.37	0.25	0.01
Smoking	Poor	5.89 (0.12)	3.64 (0.11)*	4.98 (0.12)	5.57 (0.12)	2.21 (0.12)	1.80 (0.11)	2.27 (0.12)	17.58 (0.12)	3.88 (0.12)
	Intermediate	5.96 (0.39)	3.14 (0.37)	5.10 (0.39)	5.75 (0.38)	2.33 (0.40)	2.02 (0.37)	2.19 (0.39)	17.70 (0.41)	4.15 (0.40)
	Ideal	5.82 (0.05)	3.22 (0.05)	4.98 (0.05)	5.67 (0.05)	2.67 (0.05)	1.83 (0.05)	2.31 (0.05)	17.59 (0.05)	4.02 (0.05)
	p-trend	0.54	0.0003	0.92	0.41	0.64	0.93	0.70	0.96	0.25

Data presented as standardized HDL metrics. Bonferroni's adjustment for multiple comparisons applied

^ Diet not included since it was not related to any HDL metrics

*** Different than Ideal**

P-47.

Utilizing Telehealth to Reinforce Patient Comprehension in Complex Vulvovaginal And Gynecologic Disorders

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Objective: Studies have shown that up to 50 % of patients leave their health care provider appointment either not understanding what was told to them, not remembering their instructions or misunderstanding the use of prescribed medications. The Rutgers Center for Vulvovaginal Health (CVVH) assess and treats complex vulvovaginal disorders such as vulvodynia, vaginismus and the genitourinary syndrome of menopause. Sexual function and dysfunction, including dyspareunia are also addressed, as are non-vulvar menopausal symptoms and treatment with menopausal hormone therapy. As a referral center, many women have already seen multiple providers and often present frustrated or disheartened because of lack of diagnosis or previous unsuccessful treatments. Their initial visit is a comprehensive history and directed physical exam with a detailed explanation of findings, including a vulvar diagram (when appropriate) and an outline of both suspected diagnosis and treatment strategies. The women are provided with both a copy of the diagram and written instructions prior to leaving the office. Despite this, many return 6 – 12 weeks later without having appropriately initiated treatment due to misunderstanding, inability to schedule testing or incorrect use of medications. Our objective was to determine if, in these patients with complex vulvovaginal or gynecologic disorders, the introduction of a telemedicine follow-up shortly after an initial visit may improve the level of comprehension and increase patient compliance and satisfaction. **Design:** Women who present to the Rutgers Center for Vulvovaginal Health for an initial visit are scheduled for a 2-3 week follow up telehealth visit to review their understanding and satisfaction with their initial visit, ability to obtain medications or other required testing and initial response or side effect to any prescribed therapy. **Results:** Women have expressed a positive response to this short-term follow up appointment. They have appreciated an opportunity ask questions after knowing and, in many cases, researching their diagnosis. Medication side effects or concerns that may have prevented initiation or continuation of therapy may be addressed. Additionally, as Covid restricts in-person appointment to just the patient, women have appreciated the ability of a support person to attend the telehealth appointment. **Conclusion:** Telehealth may be an effective short interval follow up opportunity for assessing patient comprehension and compliance in women with complex vulvovaginal or gynecologic problems. Trials looking at the impact on this short term follow up on patient satisfaction, compliance and short- and long-term outcomes should be considered.

Sources of Funding: nine

P-48.

Design of OASIS-1 and -2: Phase 3 trials to assess the efficacy and safety of elinzanetant for the treatment of vasomotor symptoms related to menopause

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Objective: Vasomotor symptoms (VMS) are one of the most common and distressing symptoms associated with menopause and there is an unmet need for additional safe and effective treatment options. Elinzanetant (NT-814) is a first-in-class dual NK-1,3 receptor antagonist which has previously shown efficacy in reducing the frequency and severity of VMS as well as improving patient-reported outcomes (PROs) of sleep, mood, and quality of life. The OASIS (Overall Assessment of efficacy and Safety of elinzanetant In patients with vasomotor Symptoms) clinical trial program currently consists of 3 studies in over 20 countries. OASIS-1 and -2 will assess efficacy and OASIS-3 will evaluate long-term safety of elinzanetant 120 mg for the treatment of VMS. The 120 mg dose was selected for evaluation in the Phase 3 program as it has previously been shown to be optimal with respect to efficacy, safety, and receptor pharmacology. **Design:** OASIS-1 and -2 are Phase 3, multi-center, multi-country, placebo-controlled, double-blind, randomized, parallel group intervention studies in postmenopausal women with moderate to severe VMS. Postmenopausal women between 40–65 years of age who experience at least 50 moderate or severe VMS over 7 days will be included. The aim of OASIS-1 and -2 is to evaluate the efficacy and safety of elinzanetant 120 mg for the treatment of VMS associated with the menopause as well as sleep quality, mood-related symptoms, and menopause-related quality of life. The total study duration is 32–34 weeks including 2 to 4-week screening period, 26-week treatment period and 4-week follow-up. A washout period may also be required prior to screening. In each study, 370 participants will be randomized to one of two study arms to give an estimated 332 eligible for primary efficacy evaluation, with 166 per study arm. Participants will receive either elinzanetant 120 mg for 26 weeks or placebo for 12 weeks followed by elinzanetant 120 mg for 14 weeks. Treatment will be taken orally once daily in both arms. **Results:** Efficacy endpoints will use PROs such as the hot flash daily diary, which will be collected using an electronic hand-held device on pre-defined days. The primary efficacy endpoints are the mean change in frequency and severity of moderate to severe hot flashes from baseline to Week 4 and to Week 12. Key secondary endpoints will assess the onset of efficacy and impact on sleep, mood and quality of life, and include mean change in frequency of moderate to severe hot flashes from baseline to Week 1, mean change in PROMIS SD SF 8b (Patient-reported Outcomes Measurement Information System Sleep Disturbance Short Form 8b) total score from baseline to Week 12, mean change in BDI-II (Beck Depression Inventory) total score from baseline to Week 12

and to Week 26, as well as mean change in MENQOL (Menopause Specific Quality of Life Scale) total score from baseline to Week 12. Primary endpoints and key secondary endpoints will be analyzed using a mixed model with repeated measures on the change from baseline scores at Weeks 1, 4 and 12. Adverse events will be reported throughout treatment and follow-up to evaluate the safety of elinzanetant 120 mg. Safety endpoints include the number of participants with treatment-emergent adverse events. **Conclusion:** OASIS-1 and -2 will assess whether elinzanetant is an effective and safe treatment for VMS in postmenopausal women and examine its impact on sleep, mood and quality of life. OASIS-3 will further evaluate the safety of elinzanetant.
Sources of Funding: The OASIS study program is being funded by Bayer AG.

P-49.

Adverse Sexual Affects after Gynecologic and Breast Cancers

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Objective: To understand the effect of gynecologic and breast cancers and their treatments on long-term sexual function. **Design:** This was a prospective cohort study. In June, 2021, Qualtrics, a cloud-based platform for creating and distributing web-based surveys, was utilized to recruit community research participants from Ohio, Pennsylvania and Michigan to complete an anonymous survey. Data collected included baseline sexual function, cancer history and participants perceptions about the effects of their cancer and treatments on the quality of their sexual life. **Results:** The results reported here are analyzed from the 123 women of the 1,052 who responded to the survey who indicated that they had or have survived some form of cancer. Ten of these had ovarian cancer, 4 had endometrial cancer and 44 had breast cancer. Sixteen women had used tamoxifen, raloxifene, or another estrogen modulating treatment. Fifty seven percent responded that they had a satisfactory sex life prior to cancer (n=70) and 51.2% (n=63) were not told about changes to their sex life that cancer or treatment for cancer might cause. Eighty-one percent (n=100) did not consider sexual function in any treatment decision making. Forty-six percent (n=57) experienced negative changes in their sexual function since having cancer, but very few used any treatments or therapies for improving sexual quality. Invited comments from respondents on what they would tell someone preparing to go through cancer treatments range from: “Be prepared for changes that will affect you and your partner negatively,” and, “Make sure you speak to your doctor,” “Think positive[ly],” “Sex sucks after chemo,” and, “If having ovaries removed is part of the process and cannot use/take estrogen, be prepared for this change,” and, “Sex hurts!” Others said they would, “Warn them about possible urinary incontinence,” and “Stay strong.” **Conclusion:** The results of this community-based survey of women covering a wide population of women from 3 states in the Mid-West and Northeast provide additional evidence of the negative impact of cancer treatments, particularly surgical menopause and adjuvant chemotherapy and the pervasive lack of communication, education or sexual health treatments by healthcare professionals.
Sources of Funding: None

P-50.

Impact of sleep fragmentation on perceived sleep quality and daytime sleepiness in an experimental model of menopausal sleep fragmentation with normative sleep duration.

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Objective: The menopausal transition is associated with greater difficulty maintaining sleep and poor subjective sleep quality. Polysomnographic (PSG) sleep analysis confirms increased middle-of-the-night wakefulness after sleep-onset (WASO), more N1 (light) sleep, but not a reduction in total sleep time (TST) during the menopausal transition. The impact of WASO, independent of a reduced TST, and of estradiol withdrawal, on subjective sleep quality and daytime sleepiness is not well characterized. Therefore, we experimentally induced sleep fragmentation without reduction in TST in women before and after medically induced menopause to evaluate the impact of these objective sleep changes and estradiol withdrawal on subjective sleep quality and daytime sleepiness. **Design:** Twenty-three healthy premenopausal women (mean age 30.7 years) completed 5-night inpatient studies during the mid/late follicular phase of the menstrual cycle [mean (SE) serum estradiol 81.3 (12.2) pg/ml]. A subset (n=17) completed the same 5-night inpatient study under a hypo-estrogenic state following leuprolide administration [serum estradiol 7.8 (1.7) pg/ml]. Each inpatient study was comprised of 2 nights of 8-h undisturbed time in bed (TIB) followed by 3 nights of 9-h TIB that included ~1 h of experimentally induced WASO using a 2-min acoustic stimulus repeated every 15 min throughout the sleep episode (34 total interruptions), allowing up to ~8 h of TST. Sleep was assessed by PSG, first-morning subjective sleep quality on a scale (range 1-7, lower score worse), and sleepiness on the self-rated Karolinska Sleepiness Scale (KSS). Associations were tested using repeated measures linear mixed models; correlation strengths were estimated with Pearson’s *r*. **Results:** The fragmentation protocol, on average (SE), induced 99.3 (5.9) min of WASO as compared to 36.9 (6.3) min of spontaneous WASO on undisturbed nights ($p<0.01$), without reducing TST [424.7 (6.7) min vs. 426.6 (7.0) min, $p=0.72$, respectively]. Fragmentation also increased light N1 sleep [74.9 (3.4) min vs. 50.6 (3.5) min, $p<0.01$] and decreased deep N3 sleep [42.6 (5.5) min vs. 69.9 (5.6) min, $p<0.01$]. Following fragmentation, participants reported significantly poorer sleep quality [2.5 (0.2)] and more daytime sleepiness [5.2 (0.2)] compared to undisturbed nights [4.3 (0.2) and 4.5 (0.2), respectively, $p<0.01$]. Worse subjective sleep quality correlated with more WASO ($r=-0.46$, $p<0.01$), more N1 sleep ($r=-0.34$, $p<0.01$), less N3 sleep ($r=0.34$, $p<0.01$) but only weakly with TST ($r=0.1$, $p=0.03$). More subjective daytime sleepiness (KSS) correlated with more WASO ($r=0.25$, $p<0.01$) but not with TST ($r=0.07$, $p=0.76$). Estradiol withdrawal did not affect WASO or TST (both $p\geq0.28$) and was not associated with subjective sleep quality or sleepiness (both $p\geq0.74$). **Conclusion:** In an experimental model of menopausal sleep fragmentation, more PSG-assessed WASO distributed across the sleep episode correlated with poorer subjective sleep quality and increased daytime sleepiness even when PSG-assessed TST was maintained within the recommended range. Poorer sleep quality and increased daytime sleepiness induced by fragmentation are likely explained by the dispersed WASO and shift toward lighter sleep. Estradiol withdrawal, however, did not affect these outcomes. Our results have important implications for understanding the impact of menopausal sleep fragmentation on perceived sleep quality and daytime sleepiness even when women meet the recommended guidelines for sleep duration.
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P-51.

Long-term Efficacy of a Nutraceutical Supplement for Promoting Hair Growth in Perimenopausal, Menopausal and Postmenopausal Women with Self-Perceived Thinning Hair.

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Objective: Hair loss in women increases with age and menopause. The most common diagnosis is female pattern hair loss, also known as androgenetic alopecia, which affects an estimated 40% of women over 60. Hormonal changes of menopause are associated with decreased hair growth rate as well as percentage of hairs and time spent in anagen phase. Here, we present results of a 12-month study assessing the efficacy of a nutraceutical supplement in promoting and improving growth of hairs in perimenopausal, menopausal and postmenopausal women with self-perceived thinning hair. **Design:** This was a 6-month randomized, double-blind, placebo-controlled trial with a 6-month open label extension phase, whereupon placebo subjects were crossed over to active treatment. The interim 6-month results were previously reported showing statistically significant improvements in hair growth and shedding compared to placebo. The full 12-month study period, including the extension phase, consisted of six clinic visits at baseline, Day 90, 180, 270 and 360. Phototrichograms were obtained of the target area during each visit via macrophotography for hair count analysis. Hair wash shed count was also conducted at each visit. During each clinic visit, 2-dimensional standardized global photographs were obtained of the entire head, hair and target region. Two-D images were used to assist a blinded investigator in grading general hair growth and hair quality (texture, shine, dryness, scalp coverage, hair brittleness and overall appearance) improvement from baseline. **Results:** Sixty (33 active and 27 placebo) per protocol population completed both the randomized and the open-label extension phase. Subjects had an overall mean age of 55.2 (+/- 6.6) years with no significant differences between groups. Among subjects in the active treatment group for 12 consecutive months, mean total hair counts increased significantly and progressively from Day 0 to 360, culminating in a mean increase of 11.7% ($F=15.39$; $p<0.0001$). Blinded investigator global hair assessments also showed progressive improvements throughout the study duration. Global hair growth improvement ratings increased significantly 43% from Day 90 to 180 ($p<0.001$) and 25% from Day 90 to 360 ($p<0.05$). Global hair quality improvement ratings significantly increased by 24% from Day 90 to 180 ($p<0.05$) and by 37% from Day 90 to 360 ($p<0.005$). A 13% increase was noted from Day 180 to 360 but was not statistically significant. Subjects who were initially in the placebo group had a 5.1% increase in hair growth ($p<0.001$) and a 39% decrease in shedding ($p<0.0001$) from day 180 to 360 when they were switched over to the active treatment. Global hair growth improvement ratings across 6-month of active treatment for this group increased by 30% ($p<0.05$) versus 11% when they were taking placebo ($p>0.05$). Global hair quality improvement ratings significantly increased by 40% ($p<0.001$) versus 11% when they were taking placebo ($p>0.05$). Daily administration of the nutraceutical supplement was well-tolerated. **Conclusion:** With progressive aging of society and the fact that women now spend approximately one-third of their lives in the postmenopausal period, research into interventions for menopausal symptoms including hair thinning are needed, especially since therapeutic options are so limited. The results of this study showed significant and progressive improvements in hair growth during 6 and 12 months, demonstrating the ability of a nutraceutical supplement to effectively improve hair growth and quality in peri-, menopausal and postmenopausal women with thinning hair.
Sources of Funding: Nutraceutical Wellness

P-52.

Seeking Healthcare for Perimenopausal Symptoms a Mixed Experience: Findings from the Women Living Better Survey

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Objective: Objective: The aim of this research is to evaluate the experience of women ages 35-55 who consulted a healthcare provider (HCP) about their most bothersome of an exhaustive list of possibly perimenopausal symptoms. We explore the factors which contributed to making interactions with clinicians satisfying or unsatisfying. **Design: Methods:** The Women Living Better Survey collected data from women ages 35-55 via an 82-question online survey from March to August 2020. After they reported current menstrual patterns, participants were queried about symptoms, their frequency and degree of bother. Respondents then identified their most bothersome symptom and whether they had consulted a HCP about it. Those who responded positively were invited to answer the open-ended question "How did that go"? We used conventional content analysis as described by Hseih et al. to identify themes in the responses. We divided the responses into three groups and each of the investigators reviewed two of these. Using an open coding approach, each investigator suggested codes reflecting participant's descriptions of their experiences. In the first round of coding, we evaluated whether the comment was positive or negative then created categories reflecting components of responses and defined these.. Content that was neutral or had insufficient information was coded as "not enough information" and excluded from further analysis. Investigators completed iterative reviews of the responses until consensus on the final scheme was reached. Then we analyzed a third set of responses we had not previously seen to determine whether saturation had been reached, and to identify overarching themes in the data. **Results: Results:** Of the 2407 women who initiated responding to the survey, 890 said they did not consult a HCP about their most bothersome symptom, while 1024 had, and 493 did not answer the question. Of the 1024 who answered "Yes", 966 responded to the open-ended question "how did that go?" 57 consulted a provider but provided no additional information. Of the respondents who gave input, 49% shared what we judged negative experiences. 18% of experiences seemed positive and 32% did not provide enough content to code. Responses reflecting a positive affect were collapsed into four themes; 1.) **Validating Experiences**: being heard and supported, an indication that symptom(s) were "normal", typical for age and perimenopause status; 2.) **Matching Explanatory Models**: a shared view between provider and patient of the cause of symptom and rationale for addressing; 3.) **Supported by a Team**: having multiple providers involved in care and 4.) **Shared Decision Making**: engaging in shared treatment-planning or decision-making with their HCP. We identified 4 negative themes: 1.) **Invalidating Experiences:** having concerns dismissed, being told they couldn't be having symptoms related to perimenopause because of age or cycle regularity or being told "that's just how it is;" **2.) A Mismatch in Expectations:** inconsistency between patients' expectations or their explanatory model of their experiences and those of the HCPs, seeking but not receiving an explanation of the root cause of their symptoms, receiving what they perceived to be incorrect information about a remedy offered or receiving conflicting information from different providers; **3.) Barriers to treatment:** the need to see multiple providers, treatment perceived as too expensive. 4.) **Not feeling helped:** received no helpful advice, told that nothing could be done, had testing but results were not helpful, offered a treatment that wasn't helpful. **Conclusion: Conclusions:** Women consulting healthcare providers for bothersome symptoms during perimenopause responded with both positive and negative comments in the WLB Survey. Negative experiences were more frequent but both positive and negative comments could be classified into a small number of patient-provider interaction types. Awareness of the character of experiences that contribute to satisfactory or unsatisfactory patient provider interactions could reveal opportunities for both HCPs and patients to improve health care visits related to perimenopause.

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P-53.

Comparing Urinary Estrogen Profiles of Women on Transdermal Estradiol Patches, Gels, or Creams

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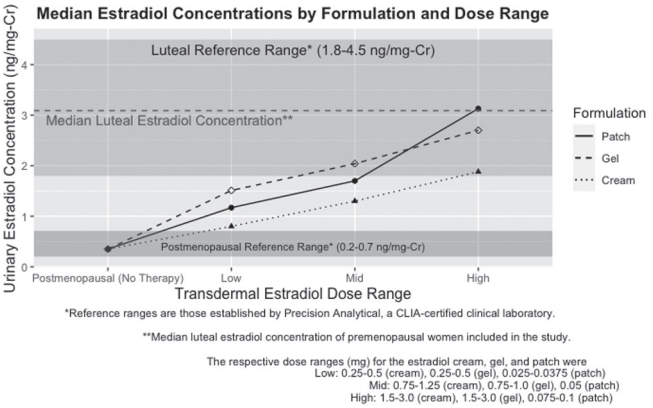
Objective: Transdermal (TD) E2 patches and gels are the most commonly used types of TD E2; however, some providers choose to treat select patients with compounded E2 creams. A need exists to understand the comparative effects of these 3 different TD delivery systems given their complex and differing pharmacokinetics and the lack of data to support the efficacy of compounded E2 products. E2 levels are most often measured in serum, but these values may not be the most accurate, especially since creams and gels show significant variation in E2 levels throughout the day, and serum only represents 1 moment in time. In contrast, urinary E2 levels may provide a representation of serum E2 concentrations over a 24-hour period. The aim of this study was to compare the effects of increasing doses of TD E2 patches, gels, and creams on urinary E2 in postmenopausal women. **Design:** This study utilized data from a retrospective observational study, Precision Analytical Retrospective Data Correlation (NCT04305093). The dataset from this larger study contained multiple urinary markers obtained via a 4-spot dried urine sampling method measured using gas chromatography/tandem mass spectrometry (GC-MS/MS) with a lower limit of quantification of 0.092 ng/mL for E2. For this analysis, we used a subset of the dataset that included only the urinary E2 profiles of premenopausal women, postmenopausal women not on MHT, and postmenopausal women using TD E2 patches, gels, or creams, which were divided into 3 dose range categories to facilitate comparison. Comparisons between groups were made by Kruskal-Wallis 1-way ANOVA and the nonparametric Jonckheere-Terpstra (JT) trend test. **Results:** Analysis of the data demonstrated that for patients in the patch and gel groups, E2 concentrations were similar within the defined dose ranges and the E2 concentrations for each of the 2 formulations showed an ordered trend with dose-proportional increases (P<0.0001 for patches and P=0.001 for gels). E2 concentrations for patients using creams also showed an ordered trend for dose-proportional increases (P<0.0001); however, the concentrations were lower than those observed with patches and gels in the same dose ranges. **Conclusion:** Our results demonstrated the differences in urinary E2 profile changes in response to increasing doses of E2 patches, gels, and creams. These results suggest that the validated dried urine assay used in this study may provide an attractive alternative or complement to serum when monitoring TD E2 therapy. Future studies utilizing this assay may help illuminate the degree to which these measurements correlate with clinical improvement, which could lead to improved precision and personalization of MHT.

Sources of Funding: Precision Analytical



P-54.

Monitoring Estradiol Patch Therapy with a Validated Dried Urine Assay

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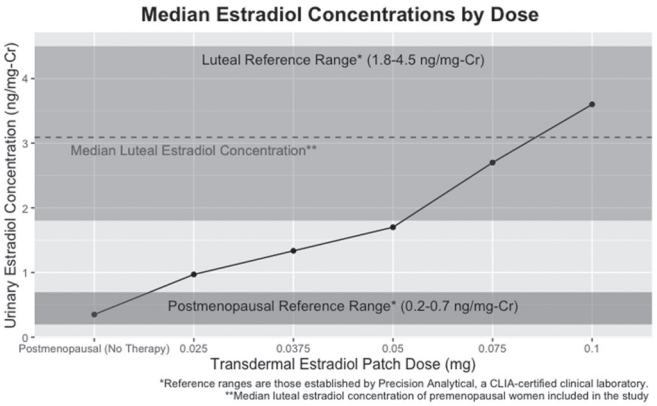
Objective: Estradiol (E2) patches are one of the most commonly used menopausal hormone therapy (MHT) formulations, and, as a result, are also one of the most studied. Many of these studies use serum testing, the most common tool for monitoring therapy in both research and clinical practice; however, a great deal of intra- and inter-subject variability exists in serum levels. Urine may provide a representation of serum E2 levels over a 24-hour period while being non-invasive and easier to collect. The aim of this study was to evaluate a multi-spot, dried urine assay to determine if it may be a viable option for monitoring MHT administered via transdermal (TD) E2 patch. **Design:** This study utilized data from a retrospective observational study, Precision Analytical Retrospective Data Correlation (NCT04305093). The dataset from this larger study contained measures of multiple urinary markers obtained via a 4-spot dried urine sampling method. For this analysis, we used a subset of the data that included only the urinary E2 profiles of premenopausal women (n = 16308), postmenopausal women not on MHT (n = 17827), or postmenopausal women using TD E2 patches (n = 1350). Urinary E2 was measured using gas chromatography/tandem mass spectrometry (GC-MS/MS) with a lower limit of quantification of 0.092 ng/mL. The nonparametric Jonckheere-Terpstra (JT) trend test was used to assess for ordered differences across groups to determine if expected dose-proportional increases in urinary E2 excretion were seen with increasing doses of TD E2 patches. **Results:** Increasing doses of E2 patches resulted in dose-proportional increases of median (IQR) E2 concentrations, which were 0.35 ng/mg-Cr (0.20, 0.73) for postmenopausal women on no therapy, 0.97 ng/mg-Cr (0.65, 1.50) for women on a 0.025 mg patch, 1.34 ng/mg-Cr (0.88, 1.90) for women on a 0.0375 mg patch, 1.70 ng/mg-Cr (1.11, 2.52) for women on a 0.05 mg patch, 2.70 ng/mg-Cr (1.55, 4.15) for women on a 0.075 mg patch, and 3.60 ng/mg-Cr (2.06, 5.36) for women on a 0.1 mg patch. A stepwise, dose-proportional, ordered trend existed for E2 with each increase in dose of the E2 patch (JT trend test all with p<0.0001). **Conclusion:** This study demonstrated that a validated dried urine assay is a viable method of monitoring changes in women's urinary E2 profiles in response to MHT with differing doses of TD E2 patches. Because the urine collection process is simpler and urinary E2 potentially represents serum E2 levels over a 24-hour period, the dried urine assay used in this study may provide an attractive alternative or complement to serum for exploring not only the changes in the urinary estrogen profile but also the efficacy and effectiveness of TD E2 patches.

Sources of Funding: Precision Analytical, Inc.



P-55.

Monitoring Transdermal Estradiol Gel Therapy with a Validated Dried Urine Assay

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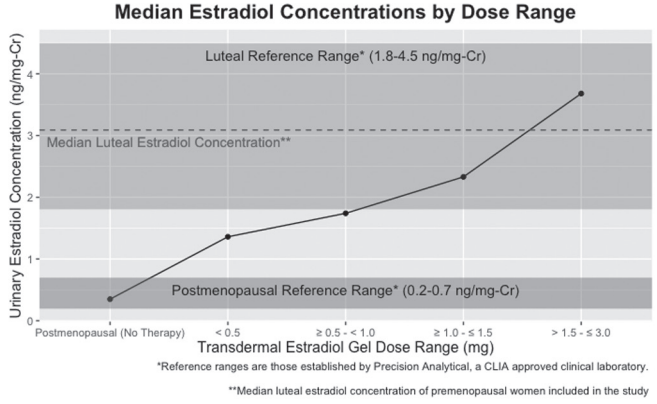
Objective: Transdermal (TD) estradiol (E2) gel is a commonly used menopausal hormone therapy (MHT). In research studies investigating gels, serum is often used to measure E2 levels, but the results only represent a moment in time during phlebotomy. In contrast, urine may provide a representation of serum E2 levels over a 24-hour period, and it is non-invasive and easier to collect. The aim of this study was to evaluate a dried urine sampling method to determine if it may be a viable option for monitoring MHT administered via TD E2 gel. **Design:** This study utilized data from a retrospective observational study, Precision Analytical Retrospective Data Correlation (NCT04305093). The dataset from this larger study contained measures of multiple urinary markers obtained via a 4-spot dried urine sampling method. For this analysis, we used a subset of the data that included only the urinary E2 profiles of premenopausal women (n = 16308), postmenopausal women not on menopausal hormone therapy (n = 17827), and postmenopausal women using TD E2 gel (n = 261). Urinary E2 was measured using gas chromatography/tandem mass spectrometry (GC-MS/MS) with a lower limit of quantification of 0.092 ng/mL. Doses were divided into 3 ranges: low dose (0.25 mg, 0.26 mg, 0.375 mg, 0.5 mg, and 0.52 mg), mid-dose (0.75 mg and 1 mg), and high dose (1.5 mg, 2.0 mg, 2.25 mg, and 3 mg). The nonparametric Jonckheere-Terpstra (JT) trend test was used to assess for ordered differences across groups to determine if dose-proportional increases in urinary E2 were seen with increasing dose ranges of TD E2 gel. **Results:** Increasing dose ranges of TD E2 gel resulted in dose-proportional increases of median (IQR) concentrations of E2 which were 0.35 ng/mg-Cr (0.20, 0.73) for women on no therapy 1.51 ng/mg-Cr (0.71, 2.49) for women on low dose TD E2 gel, 2.04 ng/mg-Cr (1.12, 3.63) for women on mid dose TD E2 gel, and 2.70 ng/mg-Cr (1.15, 5.20) for women on high dose TD E2 gel. A stepwise, dose-proportional, ordered trend existed for urinary E2 with each increase in dose of TD E2 gel ($p = 0.001$). **Conclusion:** This large population-based study conducted using real-world data demonstrated that an assay performed with dried urine samples is a viable method of monitoring changes in women's urinary E2 profiles in response to MHT with differing dose ranges of TD E2 gel. These results suggest that the validated dried urine assay used in this study may provide an attractive alternative to serum for exploring not only the changes in the urinary E2 profile but also the efficacy and effectiveness of TD E2 gels.

Sources of Funding: Precision Analytical



P-56.

The association between a history of childhood maltreatment and depression in midlife women

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Objective: The objective of the current study was to characterize the influence of early life childhood maltreatment and incident depression among women experiencing bothersome menopausal symptoms. **Design:** Women were prospectively recruited from two university-affiliated specialty menopause clinics. In addition to basic demographics, participants were asked to complete the Childhood Trauma Questionnaire (CTQ), the Center for Epidemiological Studies – Depression (CES-D) scale and the Greene Climacteric Scale. A general linear model (GLM) was used to evaluate the impact of childhood trauma (as measured by the CTQ) and other clinical variables on current depressive symptoms (CES-D scores) and climacteric symptoms (GCS scores). Secondary analyses were done to evaluate the impact of the CTQ scores on the frequency of daytime VMS and night sweats. **Results:** Findings from this cross-sectional study indicate that adverse childhood experiences, as measured using the CTQ, were highly prevalent among women seeking care for bothersome menopausal symptoms (66%). Further, a greater score on the CTQ was significantly associated with higher CES-D scores, as well as with a greater burden of menopausal symptoms, after adjusting for confounding. **Conclusion:** Our findings lend support to the growing body of literature suggesting that early life stress affects mental health well into adulthood.

Sources of Funding: not applicable

P-57.

Effect of Menopausal Symptom Treatment Options on Palpitations: A Systematic Review

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Objective: Menopausal palpitations are reported by 20% to 42% of perimenopausal women and 16% to 54% of postmenopausal women as sensations of skipped, missed, or exaggerated heartbeats. Menopausal palpitations distress has been associated with more severe insomnia, and worse depressive symptoms and menopausal quality of life. Similar to untreated vasomotor symptoms, untreated palpitations may lead to poorer health, lower work productivity, and greater healthcare utilization and costs. To date, evidence about the effect of menopausal symptom treatment options on palpitations have not been reviewed and summarized to create recommendations for practice. The objective of this systematic review was to provide an overview of the effects of menopausal symptom treatment options on menopausal palpitations. **Design:** A systematic review was carried out to identify articles that were full-length, peer-reviewed, English-language, randomized, non-randomized, controlled, and uncontrolled trials of menopausal symptom therapies that included data on palpitations as an outcome or adverse effect. Searches were conducted in PubMed, CINAHL, and PsycINFO in May 2020 to identify articles meeting pre-specified inclusion criteria. **Results:** Of the 670 unique articles identified, 37 were included in the review. Palpitations were studied as an outcome in 89% of articles and an adverse effect in 11% of articles. Articles were mostly grade II/III evidence due to their design and/or small sample sizes. Treatments included (1) drug therapies (hormone therapy (n=14), SSRI/SSNRI (n=3), antihypertensives (n=1), or steroids (n=1)) and (2) non-drug therapies (supplements – isoflavones and other phytoestrogens (n=5), *Rheum rhaponticum* (n=3), *Salvia officinalis* or sage (n=3), or other (n=4); psychological intervention (n=2), and auricular acupressure (n=1)). There was no level I efficacy/effectiveness data for any intervention and level II evidence was sometimes equivocal or negative. **Conclusion:** Based on available evidence, no therapy can be recommended in clinical practice, only hormone therapy can be recommended with caution, and all other treatments from the reviewed articles cannot be recommended at this time. Additional well-designed randomized controlled trials focusing on menopausal palpitations as the outcome are needed to advance the field.

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P-58.

Review of Menopausal Palpitations Measures

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Objective: Palpitations are reported commonly by women during the menopause transition as skipped, missed, irregular and/or exaggerated heartbeats or heart pounding. However, much less is known about palpitations than other menopausal symptoms, such as vasomotor symptoms. It is unclear whether and to what degree various symptom

dimensions of palpitations are being assessed and reported. The objective of this review was to integrate evidence on menopausal palpitations measures. **Design:** An integrative review was conducted of English-language, full-length, peer-reviewed, descriptive research studies pertaining to palpitations in menopausal women published prior to May 19, 2020. Articles were de-duplicated and scanned in two stages for their inclusion by independent reviewers. Data extraction was also conducted by independent reviewers for verification of accuracy. **Results:** Of 1574 identified citations, 670 unique records were identified, and of these, 110 met criteria for the review. Palpitations were measured with standardized instruments (76%) or other methods (24%), such as unspecified self-administered questionnaires or interviews. Measures included the Menopause Rating Scale (n= 69), unspecified self-administered questionaries (n=14), interviews (n=10), the Blatt Kupperman Menopause Index (n=8), Kaczmarek menopause-specific questionnaire (n=2), Simplified Menopause Index (n=2), unspecified (n=2), Cardiovascular Symptom Index for Midlife Women (n=1), Menopausal-specific Quality of Life (n=1), Survey adapted from menopause symptom list (n=1), or Women's Health Questionnaire (n=1). All measures used a single item to assess palpitations. In all articles, palpitations were measured along with other menopausal symptoms. Heterogeneity and inconsistencies in the wording of measurement items, recall periods, and response options were observed even when standardized measures were used. For example, the Menopausal Rating Scale item varied (e.g., "heart discomfort," "palpitations," "cardiac discomfort," or "cardiac symptoms (palpitations, racing heartbeat, irregular beats, tightness in chest)" and response options varied from yes/no to various Likert-response options. In addition, only 10% (7/69) of articles reported recall periods and these varied from 1 week to 1 month. Different response options measured different concepts, such as discomfort, heart rate sensations, and heartbeat sensations. Most articles used uni- or bi-dimensional measures (presence and/or severity). Only seven (6.4%) articles measured other palpitations symptom dimensions, such as distress of bother, frequency, or interference/impact. No articles addressed temporal pattern, duration, quality, degree of unpredictability, perceived control over, symptom representations, or electrocardiogram findings. **Conclusion:** Although palpitations have been assessed in menopausal women, nearly all assessments have been limited to a single item. There was a lack of consistency in item wordings and response options, limited information on recall periods, and a limited number and type of symptom dimensions measured. Findings suggest that efforts should be undertaken to (1) standardize conceptual and operational definitions of menopausal palpitations and (2) develop a user-friendly, conceptually clear, and psychometrically sound measure of menopausal palpitations.

Sources of Funding: Funded by an Indiana University Ethel Clarke Fellowship and a Collaboration in Translational Research Pilot Grant (Carpenter/Tisdale, MPI) from the Indiana Clinical and Translational Sciences Institute and Grant Number UL1TR002529 from the National Institutes of Health, National Center for Advancing Translational Sciences, Clinical and Translational Sciences Award. Dr. Sheng is supported as a postdoctoral fellow under 5T32CA117865 (V. Champion, PI). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

P-59.

A Comparison of Stress, Symptoms, Physical Activity, and Adiposity Before and During the Pandemic

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Objective: This study of hot flashes began in October 2019 and was brought to a halt by the COVID pandemic in March 2020. The study started again in October 2020 and is ongoing. Anecdotally, participants described how their eating habits, exercise patterns, levels of stress, and social interactions changed due to COVID precautions. The purpose of this study was to empirically test health-related effects associated with those observations. We hypothesized that women would report higher levels of stress and depressed mood, more general symptoms, lower levels of physical activity, and a higher level of adiposity during the pandemic compared to before the pandemic. We divided the sample into three groups: pre-pandemic (n=36), early pandemic (n=39), and later pandemic (n=46). **Design:** Women aged 45 to 55 years were drawn from western Massachusetts for this cross-sectional study. Exclusion criteria included use of hormone therapy or other medications that dampen hot flashes. A semi-structured questionnaire was administered in person (pre-pandemic) or by Zoom (during the pandemic). In the laboratory, we collected height, weight, circumferences, and skinfolds, and calculated percent body fat from bioelectrical impedance. We asked women to fill out the Perceived Stress Scale (PSS-10). The Patient Health Questionnaire (PHQ-9) was used to measure depression. Physical activity was assessed with the International Physical Activity Questionnaire (IPAQ Short Form). Starting in December 2020, we added two open-ended questions: Do you think the pandemic has influenced your health? How? Do you think the pandemic has influenced your experience of menopausal symptoms, like hot flashes? How? Comparisons across pre-, early, and later pandemic categories for stress, depressed mood, symptoms (aches/stiffness in joints, difficulty concentrating, feeling depressed, headaches, hot flashes, irritability, lack of energy, mood swings, nervous tension, and trouble sleeping), physical activity, and adiposity (body mass index (BMI), percent body fat) were carried out by ANOVA and Chi-square analyses. The Levene test for homogeneity of variances was examined prior to each ANOVA. Open-ended questions were analyzed for yes/no responses and general themes. **Results:** Across pre-, early- and later-pandemic categories, stress scores (PSS-10) remained remarkably consistent (15.47 vs. 15.58 vs. 15.41). PHQ-9 scores also did not significantly differ (5.03 vs. 5.21 vs. 4.75). More women were classified as moderately to severely depressed during the COVID pandemic (PHQ-9 score ≥10; 8.3% vs. 11.1% vs. 13.6%) but the differences were not significant. Aches/stiffness in joints (84%), irritability (74%), and hot flashes (71%) were the most frequently reported symptoms. There were no significant differences in symptoms across the pandemic categories. From the IPAQ, sitting increased from 6.04 to 6.49 to 7.68 hours per day across the pre-, early-, and later-pandemic categories, but the differences were not significant (p=.07). Neither were there significant differences in mean BMI (kg/m^2) or percent body fat across the pandemic categories. Open-ended answers reveal a bi-modal distribution of responses among women with regard to the pandemic and their health. Some women found extra time for self-care, while others described more stress working from home, overeating, and caring for children. The majority of women (65%) said they did not think the pandemic influenced their experience of menopausal symptoms. **Conclusion:** To date, our hypotheses have not been supported. Although some women expressed concern about gaining weight, exercising less, and having higher stress levels during the pandemic, simple comparisons across pre-, early-, and later-pandemic categories do not reveal higher levels of stress, depression, symptoms, sedentary behavior, or adiposity associated with the life changes brought about by COVID-19. While the means did not change during the pandemic, women differed in their ability to cope with the lifestyle changes engendered by the pandemic (e.g., stress versus self-help).

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P-60.

Onset of Flibanserin Treatment Effect in Postmenopausal Women Assessed by Subdomain Scores of the Female Sexual Function Index (FSFI)

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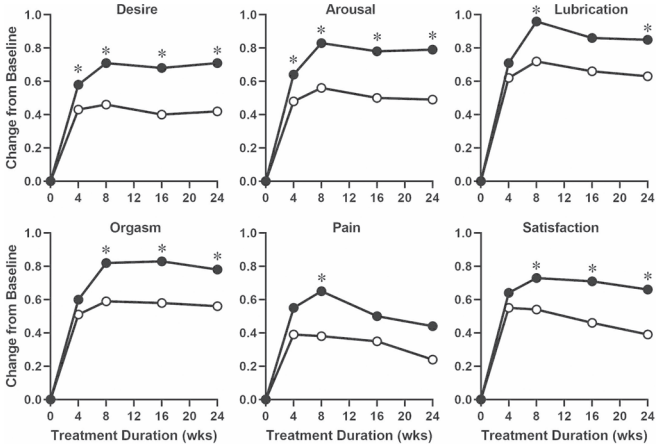
Objective: Flibanserin, a treatment for acquired, generalized hypoactive sexual desire disorder (HSDD), is approved in the US for use in certain premenopausal women and in Canada for use in both premenopausal and naturally postmenopausal women ≤60 years of age. Improvement in symptoms following initiation of flibanserin may take several weeks to emerge and it is important to set realistic expectations of treatment onset. The primary objective of this analysis is to evaluate the onset of flibanserin's treatment effect in naturally postmenopausal women with HSDD across the 6 subdomains of the FSFI. **Design:** A post-hoc analysis was conducted using FSFI data from a randomized, controlled, double-blind trial of flibanserin in 895 naturally postmenopausal women with HSDD (flibanserin, n=432; placebo, n=463) who had at least one on-treatment efficacy assessment. The FSFI is a validated, 19-item self-report questionnaire comprising 6 subdomains of sexual functioning: desire, arousal, lubrication, orgasm, satisfaction, and pain. Each subdomain has a maximum score of 6 and higher scores indicate better sexual functioning. For each subdomain, change from baseline at each assessment visit (4, 8, 16, and 24 weeks) was calculated as the least squares mean difference. Comparisons between flibanserin and placebo groups were performed using analysis of covariance. **Results:** Postmenopausal patients treated with flibanserin had significantly greater sexual desire and arousal scores than those treated with placebo at Week 4 and at every assessment timepoint thereafter. By Week 8, patients in the flibanserin group had significantly higher scores for all FSFI subdomains compared to the placebo group. This treatment effect was maintained at Week 24 for all subdomains except for pain. **Conclusion:** Results from this post-hoc analysis indicates that postmenopausal women treated with flibanserin experienced improved sexual function compared to those treated with placebo with regard to sexual desire, arousal, lubrication, orgasm and satisfaction. This improvement was maintained over the entire course of treatment. These findings are consistent with those from a previous FSFI post-hoc analysis of clinical trial data from premenopausal women and suggest that flibanserin treatment of postmenopausal women was associated with improvement of multiple aspects of sexual function in addition to sexual desire.

Sources of Funding: Sprout Pharmaceuticals



P-61.

Treatment Rates and Healthcare Costs of Osteoporosis and Fragility Fracture Patients by Physician Specialty: A Real-World Data Analysis

Andrea Singer[9,2], Michael McClung[6,8], Steven Goldstein[3], Risa Kagan[4,5], Oth Tran[7], Cynthia D. Morrow[7], Michele McDermott[1], Alon Yehoshua[1]. [1]Amgen Inc, Thousand Oaks, CA; [2]Georgetown University Medical Center, Washington, DC; [3]NYU Grossman School of Medicine, New York, NY; [4]University of California San Francisco, San Francisco, CA; [5]Sutter East Bay Medical Foundation, Berkeley, CA; [6]Oregon Osteoporosis Center, Portland, OR; [7]IBM Watson Health, Cambridge, MA; [8]Australian Catholic University, Melbourne, VIC, Australia; [9]MedStar Georgetown University Hospital, Washington, DC

Objective: To characterize osteoporosis (OP)-related treatment rates and healthcare costs of patients with OP or fragility fracture by physician specialty making their initial OP or fracture diagnosis. **Design:** Two samples were identified in the IBM Marketscan Commercial and Medicare Databases among women 50 years of age or older; women with newly diagnosed OP (index date = first diagnosis) without prior OP-related treatment in the preceding year and women with a fragility fracture between 1/1/2013 and 6/30/2018. Patients were categorized based on the physician specialty making the initial diagnosis of OP or fracture. OP-related treatment rates and OP-related and all-cause healthcare costs during the 12-month follow-up were reported. **Results:** 216,988 patients (mean age 67) with OP and 108,965 patients (mean age 69) with fragility fracture met the inclusion criteria. For OP patients, the initial diagnosis was made most often by family practice (25%) and internal medicine (25%) specialties. Orthopedic (37%), family medicine (17%), and emergency medicine (12%) physicians most often made the initial diagnosis of the fragility fracture. The proportion of patients receiving OP-related treatment varied by physician specialty from 15% to 44% for OP patients and from 14% to 34% for fragility fracture patients (Table). For patients diagnosed with OP, rheumatologists, endocrinologists, and obstetrics & gynecology (OB/GYNs) had the highest treatment rates, while emergency medicine physicians had the lowest rate. Patients whose initial fragility fracture was diagnosed by orthopedics had the lowest OP-related treatment rate. Annual healthcare costs were lowest for OP patients whose initial diagnosis was made by OB/GYN and for fragility fracture patients whose diagnosis was made by orthopedics. **Conclusion:** The initial diagnosis of OP and fragility fracture tended to be made by different physician specialties. Both OP-related treatment rates and healthcare costs of patients differed based on the specialty where the first diagnosis of OP or fracture was made. Though there was a lot of heterogeneity between physician specialties, fewer than half of patients were treated during the 1 year follow-up. Further studies are needed to determine whether these differences reflect differences in attitude or knowledge about OP-related treatment or the assigned roles of different specialties in the medical management of OP.

Sources of Funding: Funding supplied by Amgen, Inc.

	OP Dx (N=216,988)				Fragility Fx (N=108,965)			
Specialty Categories	Specialty on Index (%)	OP-Related Treatment Rate (%)	OP-Related Cost (mean $USD)	All-Cause Total Cost (mean $USD)	Specialty on Index (%)	OP-Related Treatment Rate (%)	OP-Related Cost (mean $USD)	All-Cause Total Cost (mean $USD)
Family medicine	25.42	29.77	1,750	15,192	16.90	25.21	9,569	44,817
Internal medicine	24.83	27.29	1,963	17,933	11.90	27.12	12,626	74,580
Obstetrics & Gynecology	8.19	34.18	1,203	12,649	0.07	24.36	9,309	50,802
Orthopedics	2.08	24.16	6,804	34,217	37.35	13.79	7,690	30,538
Geriatrics	0.32	17.91	2,703	24,677	0.04	34.04	16,078	85,519
Rheumatology	6.36	44.27	2,347	27,928	0.02	N/A	N/A	N/A
Endocrinology	4.69	34.62	2,093	19,969	0.04	29.55	16,397	69,226
Emergency medicine	0.97	15.45	9,543	38,868	11.59	21.01	12,093	54,133
Mean		30.11	2,276	18,881		14.10	9,784	44,311

OP = osteoporosis; N/A=non-applicable

P-62.

Treatment Rates and Healthcare Costs of Osteoporosis and Fragility Fracture Patients by Site of Care: A Real-World Data Analysis

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Objective: To characterize osteoporosis (OP)-related treatment rates and healthcare costs of patients with OP or fragility fractures by clinical site of care for their initial OP or fracture diagnosis. **Design:** Two samples were identified in the IBM MarketScan Commercial and Medicare Databases among women 50 years of age or older; women with newly diagnosed OP (index date = first diagnosis) without prior OP-related treatment in the preceding year and women with a fragility fracture between 1/1/2013 and 6/30/2018. Patients were categorized based on the site of care for their initial diagnosis of OP or fracture. Treatment rates, and OP-related and all-cause healthcare costs during the 12-month follow-up were reported. **Results:** 216,988 patients (mean age 67) with OP and 108,965 patients (mean age 69) with fragility fractures met the inclusion criteria. For OP patients, the initial diagnosis was most often made at an outpatient office visit (78%). For fragility fracture patients, an inpatient setting (43%), followed by an outpatient office visit (32%) and outpatient hospital without inpatient admission (24%) were the most common sites for the initial diagnosis. The proportion of patients receiving OP-related treatment varied by clinical site of care from 5% to 32% for OP patients and from 9% to17% for fragility fracture patients (Table). Annual healthcare costs were lowest for patients whose initial diagnosis of OP or fragility fracture was made at an outpatient office visit. Annual healthcare costs were highest for patients whose initial diagnosis of OP or fragility fracture was made at an inpatient setting. **Conclusion:** The clinical site of care for the initial diagnosis of OP or fragility fracture affected treatment and healthcare cost. Though there was a lot of heterogeneity between groups, in all settings, less than a third of patients were treated during the 1 year follow-up. Further studies are needed to determine whether these differences reflect differences in attitude or knowledge about OP treatment or healthcare experiences at various clinical sites of care in the medical management of OP.

Sources of Funding: Funding supplied by Amgen, Inc.

Table

	OP Dx (N=216,988)				Fragility Fx (N=108,965)			
Sites of Care	Site of Care on Index (%)	OP-Related Treatment Rate (%)	OP-Related Cost (mean $USD)	All-Cause Total Cost (mean $USD)	Site of Care on Index (%)	OP-Related Treatment Rate (%)	OP-Related Cost (mean $USD)	All-Cause Total Cost (mean $USD)
Inpatient Setting	3.16	15.91	14,819	56,093	42.68	17.22	12,137	71,561
Outpatient Office Visit	78.27	32.09	1,590	16,838	31.93	10.91	4,280	20,867
Outpatient Hospital	14.51	27.64	2,975	19,710	23.98	12.91	12,922	28,236
Emergency Room	0.13	14.39	3,540	19,129	1.26	10.92	10,438	23,193
Federally Qualified Health Center	0.1	26.32	1,001	10,632	0	N/A	N/A	N/A
Rehabilitation Facility	0.05	5.36	5,185	27,311	0	N/A	N/A	N/A
Nursing Facility	1.86	6.41	4,358	31,836	0.01	N/A	N/A	N/A
Urgent Care	0.03	30.77	1,114	24,007	0.11	8.62	4,048	26,380
Patient Home	0.89	9.89	2,963	30,041	0.01	N/A	N/A	N/A
Rural Health Clinic	0.40	30.90	1,291	11,974	0.01	N/A	N/A	N/A
Assisted Living	0.07	4.61	2,009	17,935	0	N/A	N/A	N/A
All Patients Mean		30.11	2,276	18,881		14.1	9,784	44,311

OP = osteoporosis; N/A = non-applicable

P-63.

Polycystic ovary syndrome and female sexual dysfunction: Is there an association?

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Objective: Female sexual function is complex and can be influenced by multiple determinants including physical and emotional health, hormonal status, medication use, and relationship factors. While female sexual dysfunction (FSD) is prevalent and a source of significant distress in affected women, it is often underdiagnosed and undertreated. Women with polycystic ovary syndrome (PCOS) may be at greater risk of FSD as they are often affected by conditions that can negatively influence sexual function, including greater odds of having obesity, body-image related concerns and mood disorders. Moreover, treatments used for PCOS such as oral contraceptives can have a negative impact on sexual function. Limited data exist regarding associations between PCOS and sexual function, and it is unknown if PCOS has a direct effect on female sexual function. We sought to investigate associations between self-reported history of PCOS and female sexual function in pre-, peri- and postmenopausal women. **Design:** This cross-sectional study utilizing the Data Registry on Experiences of Aging, Menopause and Sexuality (DREAMS) was performed in women over the age of 20 years who presented to women's clinics at Mayo Clinic in Minnesota, Arizona and Florida between May 2015 and December 2019. Women self-reported history of PCOS and completed the Female Sexual Function Index (FSFI) and Female Sexual Distress Scale-Revised (FSDS-R) for assessment of sexual function as part of their clinic visits; only women who reported being sexually active in the prior 4 weeks were included. The association between a prior diagnosis of PCOS and the presence of FSD, defined by the combined diagnostic thresholds defined for the FSFI and FSDS-R questionnaires, was assessed using logistic regression. The results were adjusted for multiple variables known to impact female sexual function including age, body mass index, partner satisfaction, menopause status, depression, anxiety, and current use of menopausal hormone therapy. **Results:** Responses from 5,294 women with a mean age of 51.4 years were included in the analysis. The majority were white (95.2 %), partnered (85.5%), educated (92.6% with some college education) and postmenopausal (61.7%). A history of PCOS was reported by 254 (4.8%) women. Women with PCOS were more likely than women without PCOS to have obesity (40.8% vs 20.4%, p<0.001) and to report anxiety (48.5% vs 31.4%, p<0.001), depression (57.7% vs 36.2%, p<0.001), relationship distress (32.1% vs 25.3%, p=0.019) and FSD (FSFI < 26 and FSDS >11) (62.6% vs 55.9%, p=0.036). After multivariable analysis, factors associated with a higher risk of FSD included postmenopausal status (OR 2.03, 95% CI 1.58-2.62; p<0.001), anxiety (OR 1.60, 95% CI 1.36-1.88; p<0.001), depression (OR 1.73, 95% CI 1.48-2.03; p<0.001) and relationship distress (OR 2.12, 95% CI 1.82-2.47; p<0.001). However, self-reported history of PCOS was no longer associated with a significant risk for FSD in multivariable analysis (OR 1.07, 95% CI 0.78-1.46; p=0.68). **Conclusion:** Women who self-reported PCOS were

more likely to have sexual dysfunction. However, on multivariable analysis, this was explained by moderating factors including depression, anxiety, postmenopausal status, and relationship satisfaction. While clinicians should query all women about sexual function, they should be aware that women with PCOS may have multiple contributing factors to FSD which should be considered and addressed.

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P-64.

Clinical effect and Metabolic Safety of Medically- Supervised Ketogenic Therapy in Midlife Women with Major Depressive Disorder – A protocol for a pilot open-label study

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Objective: To investigate the efficacy of Medically-Supervised Ketogenic Therapy (MSKT) in reducing severity of depressive and vasomotor symptoms in midlife women suffering from Major Depressive Disorder (MDD) and to evaluate the metabolic safety of this intervention. **Design:** Proof-of-concept, open-label single arm clinical trial. *Sample***:** Thirty women aged 45-55 years in menopause transition or early postmenopausal years (stages -2 to 1+c, STRAW + 10 criteria); experiencing a Major Depressive Disorder (MDD, DSM-5 criteria) will be enrolled into a 16-week (4-week induction phase + 12-week maintenance phase) study. Participants might be considered eligible despite being on antidepressant medications if receiving a stable dosing for at least 6 weeks prior to study entry. *Intervention***:** Patients will be assessed for maintaining weight during this trial and meal prescription will be developed based on this assessment. A registered dietitian (RD) will assess diet history, anthropometrics and prescribe a MS-KT intervention that will begin at low ketogenic ratio and slowly titrate to a tolerable isocaloric ketogenic diet prescription. Titration will involve gradual reduction in carbohydrate with concurrent increase in fat intake that will be offered in a calorie prescribed meal plan with goal to offer calories to support weight maintenance during the study. Meal plans, food exchange lists and recipes will be provided to patient along with regular RD support & KetoSuite software support. Meal plans will be adjusted to support flexibility for patient food preferences, budget and cooking ability. Food diaries will be used to register daily intake of solid and fluids throughout the study. The adherence to the intervention and proper achievement of ketotic state will be checked weekly through a food diary and capillary blood and urine ketone assessment. Only those showing adherence to the MSKT and testing positive for ketones during the run-in phase will be further enrolled in the maintenance phase. Most procedures will take place virtually due to the COVID-19 pandemic. *Outcomes***:** *Primary outcome measure:* Changes in depressive symptom severity evaluated by the Montgomery-Asberg Depression Rating Scale (MADRS) total scores. *Secondary outcome measures* include changes in anhedonia symptom severity (SHAPS and DARS scores), quality of life (MENQoL) and menopause-related symptoms (Greene Climacteric Scale) from baseline to endpoint. Ketonuria will be weekly assessed. Clinical assessments will occur at baseline (week 0) and at weeks 2, 4, 8, 12 and 16; metabolic profile (serum fasting glucose and serum lipids), serum electrolytes, vitamins and uric acid levels, bone density biomarkers (CTX-1 and PINP - procollagen type I N propeptide) and hormone profile (Follicle-stimulating hormone [FSH] and estradiol [E2] levels) will be evaluated at baseline and at the endpoint. Treatment will be discontinued in case of 1) unacceptable weight loss; 2) serious treatment-emergent symptoms; 3) severe worsening of depression; 4) protocol non-adherence. **Results:** The study has been approved by the Queen's University Institutional Review Board and the project has received funds from the Canadian Menopause Society (2020 Canadian Menopause Society/Pfizer Research Award) and the Brain and Behavior Research Foundation (2020 BBRF Early Investigator Award). Recruitment is ongoing. **Conclusion:** This pilot study has the potential to open new avenues for research on the efficacy and safety of dietary interventions for the treatment of symptomatic midlife women with depression.

Sources of Funding: Canadian Menopause Society/Pfizer and BBRF Early Investigator Award

P-65.

Nutritional approaches and their impact on depressive symptoms in midlife women: a systematic review.

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Objective: To evaluate the effects of dietetic or nutraceutical interventions on depressive symptoms among women during the menopause transition and postmenopausal years. **Design:** A systematic review registered with the International Prospective Register of Ongoing Systematic Reviews (Systematic review registration – PROSPERO 2021: CRD42021231479), reported according to the PRISMA statement guidelines. We conducted a systematic review of databases (PubMed, Cochrane and Embase), searching for articles indexed from inception until January 31st, 2021; primary focus was on randomized controlled trials documenting the effects of diet or nutritional supplements on depressive symptoms among women in perimenopause or during postmenopausal years. The review included studies on depressive symptoms as well as major depressive disorder (MDD) based on DSM-IV, DSM-IV-TR or DSM 5 criteria. Effects on depressive symptoms were assessed through changes in depressive scores from baseline (study entry) to endpoint, based on standardized depressive rating scales. **Results:** From 923 studies initially identified, this systematic review yielded 35 studies (1 triple-blind, randomized, controlled trial; 17 double-blind, placebo- controlled, randomized trials; and 17 randomized, controlled trials) with a total of 19,039 participants receiving active treatments and 27,237 participants in the placebo group. We identified 3 studies with dietary interventions (low sodium-DASH diet, caloric restriction, and low-fat diet) and 32 studies with nutraceuticals (nutritional supplements, natural extract, herbal products and vitamins). Of those, all dietary interventions and 85.7% of the nutraceuticals showed positive outcomes (i.e., improvements in depressive symptoms) when compared to placebo or control intervention. Moreover, there were favorable outcomes among women with diagnosis of MDD, as 2 out of 3 studies showed improvement compared to control conditions. There was significant heterogeneity among studies with respect to sample sizes, duration of intervention and rating scales used as outcome measures. **Conclusion:** Several nutritional approaches have been investigated for the management of symptomatic, midlife women. Preliminary results are promising, with most studies indicating favorable outcomes; yet, they should be interpreted with caution given the heterogeneity of interventions and methodologies applied to date.

Sources of Funding: Partially funded by grants/awards from the Canadian Menopause Society and the Brain and Behavior Research Foundation.

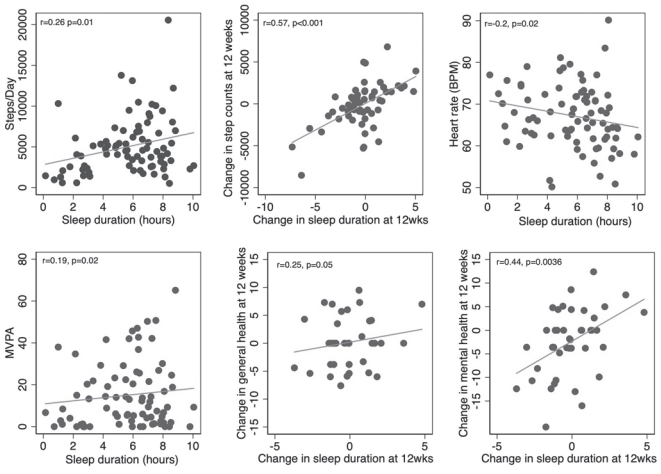
P-66.

Correlation of Remotely Monitored Sleep, Exercise and Heart Rate by Fitbit and Patient-Reported Psychometric Outcomes in Menopausal Women with Stable Ischemic Heart Disease

Benita Tjoe, MD[1], Gillian Gresham[2], Sandy Joung[2], Corey Arnold[3], Garth Fuller[2], William Speier[3], Mitra Mastali[2], Irene van den Broek[2], Janet Wei[1], Brennan Spiegel[2], Jennifer Van Eyk[2], Noel Bairey Merz[1], Chrisandra Shufelt[1]. [1]Barbra Streisand Women's Heart Center, Cedars-Sinai Medical Center, Los Angeles, CA; [2]Cedars-Sinai Medical Center, Los Angeles, CA; [3]Computational Diagnostics Lab, University of California Los Angeles, Los Angeles, CA

Objective: Cardiovascular disease remains the leading cause of death in women and risk increases at menopause. Patients with ischemic heart disease (IHD) may have angina, sleep disturbance and depression that limit quality of life. Remote patient monitoring with consumer-grade biosensors is increasingly utilized, but the clinical implications of collected data are poorly understood. The study aims to evaluate associations between biosensor indices with patient-reported outcomes (PROs) in a cohort of menopausal women with IHD. **Design:** Women age ≥55 years with stable IHD were followed for 12 weeks. Biometric (steps, resting heart rate (HR), moderate-to-vigorous activity [MVPA], sleep duration) and PROs (global health, mental health, depression, anxiety, fatigue, physical function, and sleep disturbance) were obtained via Fitbit and weekly smartphone NIH-PROMIS surveys, respectively. PRO responses were converted to standardized T-scores (mean 50, SD:10). Change in biometric and PRO data were measured as mean differences at 12 weeks from baseline. Data were analyzed at baseline and weekly intervals and correlation statistics were computed. **Results:** 92 women (mean age 67.5 years ± 6.9; BMI 27.5 ± 13.2) were enrolled. One (1.1%) was on systemic hormone therapy. Longer sleep (per 1 hr increase) at baseline was associated with more steps (Coef: 0.26 per 1000 step increase, p=0.01), lower resting HR (Coef; -0.20 per BPM increase, p=0.02) and more MVPA (0.19 per 10 min MVPA, p=0.02) (Figure). Reduced sleep (per 1 hr decrease) at 12 weeks from baseline was correlated with fewer steps (0.57 per 500 step decrease, p<0.0001), increased HR (-0.31 per BPM increase, p=0.016) over time, as well as worse physical (0.25 per 1-unit increase in T-Scores, p=0.05) and mental health scores (0.44 per 1-unit increase in T-Scores, p=0.0036). **Conclusion:** In menopausal women with IHD, increased sleep duration by Fitbit was associated with higher activity, lower HR and increased global physical and mental health scores. These results identify sleep as an important measure for predicting overall health and highlight both sleep and exercise as targets for intervention. Further work is needed to study the utility of remote monitoring for improving outcomes and quality of life.

Sources of Funding: CA Initiative to Advance Precision Medicine; Cedars-Sinai Medical Center; National Heart, Lung and Blood Institute



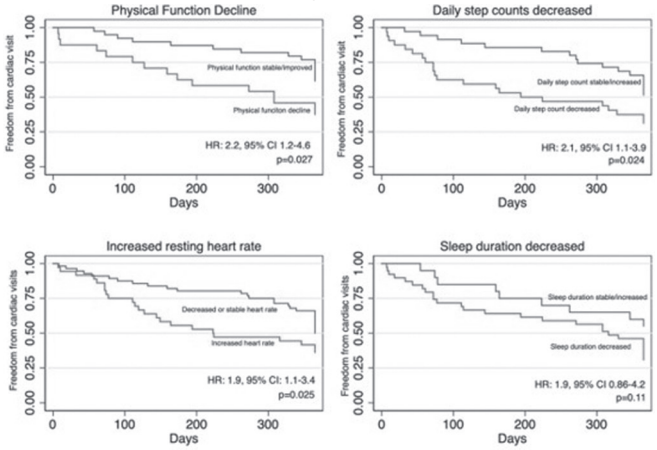
P-67.

Digital Health for Predicting Cardiac Hospital Visits in Menopausal Women with Stable Ischemic Heart Disease

Benita Tjoe, MD[1], Gillian Gresham[2], Sandy Joung[2], Corey Arnold[3], Garth Fuller[2], William Speier[3], Mitra Mastali[2], Irene van den Broek[2], Janet Wei[1], Brennan Spiegel[2], Jennifer Van Eyk[2], Noel Bairey Merz[1], Chrisandra Shufelt[1]. [1]Barbra Streisand Women's Heart Center, Cedars-Sinai Medical Center, Los Angeles, CA; [2]Cedars-Sinai Medical Center, Los Angeles, CA; [3]Computational Diagnostics Lab, University of California Los Angeles, Los Angeles, CA

Objective: Ischemic heart disease (IHD) is prevalent amongst women in midlife, a time coinciding with menopause. Patients with IHD are at risk for major adverse cardiac events (MACE). Remote patient monitoring using consumer-grade biosensors allows for collection of clinical data beyond the traditional health care setting, but the utility of these measures in predicting outcomes is not well known. We analyze associations between remotely monitored biosensor data, patient reported outcomes (PROs) and cardiac hospital visits in women with stable ischemic heart disease. **Design:** Women 55 years or older with stable IHD were followed for 12 weeks for biometric (steps, resting heart rate, sleep duration) and psychometric (physical function, anxiety, depression) measures. This data was obtained via Fitbit and weekly smartphone administered NIH-PROMIS surveys, respectively. Participants were then followed for 12 months for cardiac hospital visit including MACE, revascularization, suspected acute coronary syndrome, transient ischemic attack or arrhythmia. Multivariable regression models were fit to evaluate for associations between change in biometrics and PROs at 12 weeks from baseline with occurrence of cardiac hospital visits to 12 months, adjusted for age and BMI. **Results:** 92 women (mean age 67.5 years ± 6.9; BMI 27.5 ± 13.2) were enrolled. One (1.1%) was on systemic hormone therapy. There was a total of 51 adjudicated cardiac hospital visits. Cardiac hospital visits were twice as likely in women reporting physical function decline (NIH-PROMIS) (HR: 2.2, 95% CI: 1.2-4.6, p=0.027), reduced steps from baseline (HR: 2.1, 95% CI: 1.1-3.9, p=0.024), and increased resting heart rate (1.9, 95% CI 1.1-3.4, p=0.025) (Figure). Sleep duration, anxiety and depression were not associated with an increased risk of cardiac hospital visits. **Conclusion:** In menopausal women with stable IHD, patient reported decline in physical function and Fitbit measures of decreased daily step count and increased heart rate at 12 weeks from baseline were predictors of cardiac hospital visits within a year. Additional analyses will evaluate heart rate more closely including measures of variability and maximum rate during exercise. Future studies will also seek to concurrently collect remote data while following patients for hospitalization and other outcomes to assess for acute predictors.

Sources of Funding: CA Initiative to Advance Precision Medicine; Cedars-Sinai Medical Center; The National Heart, Lung, and Blood Institute



Change in physical function, steps, resting HR and sleep at 12 weeks compared to baseline

P-68.

S-equol improves Quality of Life for peri- and menopausal women with high vasomotor symptoms

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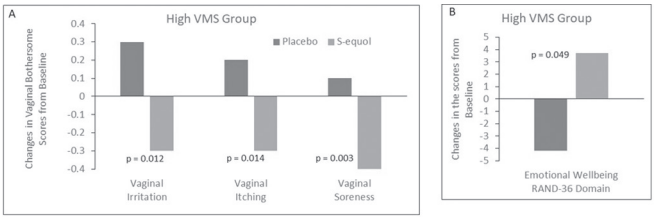
Objective: Numerous symptoms related to menopause impact the quality of life of women. We have previously reported the benefits of S-equol on vasomotor symptoms (VMS) (1,2); however, other symptoms (sleep, mood, and vaginal disturbances) are also associated with menopause and often have a higher impact on quality of life. The aim of this study was to assess the effects of S–equol, a novel fermented soy isoflavone, over 12 weeks on various symptoms related to menopausal transition including VMS and quality of life measures in otherwise healthy women (40-65 years). **Design:** A double-blind, randomized, placebo-controlled, parallel study was conducted comparing the effects of oral consumption of an S-equol (10 mg/day) (N = 58) vs. placebo (N = 60) for 12 weeks in perimenopausal or menopausal women aged 40-65 experiencing menopausal-related VMS. This study was conducted at Biofortis Research (Addison, IL). **Results:** Though a decline in VMS was observed, a large placebo effect, not uncommon in VMS studies (3,4), resulted in a lack of statistical significance in the reduction of VMS episodes and severity between placebo and S-equol in the intent to treat (ITT) and per protocol (PP) populations. There was a statistically significant increase in sleep minutes (p = 0.013) and the duration in bed (p = 0.035) from baseline to 12 weeks in the S-equol group, which was non-significant in the placebo group. Post-hoc analysis was performed when subjects were categorized into groups based on reporting ≤9 vasomotor episodes/day (Low VMS) and >9 vasomotor episodes/day (High VMS). In the High VMS group, participants receiving S-equol suffered fewer Vaginal Bothersome Symptoms and had an improvement in the measure of health-related quality of life (RAND-36), and Profile of Mood States (POMS), particularly lower vaginal irritation (p = 0.012), itching (p = 0.014), and soreness (p = 0.003) (Fig. A), better emotional well-being (p = 0.049) (Fig. B), and a different pattern of change in the POMS anger-hostility domain score (p = 0.049), total mood disturbance (p = 0.049), and vigor-activity (p = 0.017) compared to the placebo group. **Conclusion:** Peri- and menopausal women experiencing high episodes of VMS demonstrated an improvement in quality of life measures, particularly sleep, mood and vaginal health benefits in response to S-equol therapy. By alleviating multiple menopausal symptoms, quality of life can thereby be improved. **References:** 1. Aso et al. J Women's Health, 2012, 21(1), 92-100. 2. Jenks. et al. J Women's Health, 2012, 21(6) pg 674-682 3. Li et al. Menopause, 2017, 24(8) 932-937 4. MacLennan et al. *Cochrane Database of Systematic Reviews* 2004, Issue 4. Art. No.: CD002978.

Sources of Funding: Funded by Pharmavite LLC.



P-69.

Attitudes Regarding Vaginal Dilation Following Pelvic Radiotherapy for Cancer Treatment

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Objective: Radiation therapy may cause scarring, dyspareunia, and painful pelvic examinations. Vaginal dilators are often recommended to female patients completing pelvic radiation therapy in order to mitigate these known side effects, but there are no evidence-based guidelines on the quality and timing of counseling provided on vaginal dilator use. Aims: To determine patient preferences regarding the timing, quantity, and quality of information they receive regarding dilator use along with their overall preception of its value. **Design:** Four online, hour-long focus groups with 4-5 women per group, aged 18-70 years, all of whom had been treated with pelvic radiation therapy for gynecological and/or rectal cancers, are planned. Facilitators are trained to elicit information about the counseling patients received regarding vaginal dilation and their experiences and preferences. Transcription of the recordings will be performed and common themes will be extracted. Examples of facilitator questions include: Do you recall being given information about the need to perform vaginal dilation as part of pelvic radiation treatment. If so, at what visit did this occur? What do you remember being told regarding how to perform dilation and how often to perform dilation? Were you given dilators or did you have to purchase your own? How did you feel (emotionally and/or physically) about performing vaginal dilation? How might counseling have been improved regarding vaginal dilation? Do you think multiple sessions where this information was discussed would have been helpful? Who do you feel was the best provider to deliver this information? **Results:** Of 45 patients who meet inclusion criteria for the focus groups based on medical record review, 21 are eligible after screening. Focus groups are being scheduled. **Conclusion:** These results will be used to develop institutional guidelines for manual vaginal dilation use to better manage gynecologic cancer survivors.

Sources of Funding: None

P-70.

Is there a disconnect? Gynecologic oncology patients' and providers' perspectives of surgical menopause

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Objective: Surgical menopause occurs in 30 to 40% of pre- and perimenopausal women with gynecologic malignancy. The symptoms and sequelae of surgical menopause have been well characterized and numerous studies have summarized the safety of hormonal and non-hormonal treatments for these symptoms in patients with gynecologic malignancies. The primary objective of this study was to assess gynecologic oncology patients' perspectives about surgical menopause care during their perioperative, treatment and surveillance visits. A secondary objective was to assess gynecologic oncology providers' preferences for managing surgical menopause and to compare these perspectives. **Design:** We surveyed women under age 51 who underwent surgical menopause as a part of their treatment of gynecologic malignancies between 2017 and 2019 at a tertiary academic medical center. The survey included a modified Utian Quality

of Life Scale focusing on health, emotional and sexual quality of life. We collected baseline demographic characteristics and documented counseling about surgical menopause and management plans from the electronic medical record. Additionally, we surveyed gynecologic oncology providers at this institution about their preferences and barriers for surgical menopause counseling and management. Findings are reported as descriptive statistics. **Results:** We identified 75 patients with pathology confirmed gynecologic malignancies whose cancer treatment resulted in surgical menopause. After excluding those lacking follow up or contact information, 34/66 patients (52.3%) were surveyed. We also surveyed 13/15 gynecologic oncology providers (87%), including attending physicians, fellow physicians, physician assistants, and a nurse practitioner. Of the 28 patients (82%) who had post-operative menopause symptoms, 53% reported that they were "not at all" or only "somewhat satisfied" with the overall menopause symptoms management by their health care providers. The majority (70.5%) of all patients preferred to receive information about surgical menopause from their oncologist; however, 28.5% of patients were "not at all" to only "somewhat comfortable" in initiating discussion about menopause with their oncologist. Additionally, one third of patients (32.3%) did not recall discussions about surgical menopause at their preoperative visit, in contrast to 92.3% of providers who "always" discuss surgical menopause at the pre-operative visit when planning bilateral oophorectomy. Despite this, only 23.5% of patients' medical records had documented counseling of surgical menopause at preoperative visits. Finally, 66.7% of providers reported time as a barrier to discuss surgical menopause, whereas 23.5% of patients reported lack of time and perception that their oncologist is not the appropriate person to discuss symptoms of menopause as barriers. **Conclusion:** Gynecologic oncology patients and providers have discrepant perspectives about surgical menopause counseling. Most gynecologic oncology patients prefer to obtain information about surgical menopause from their oncologist. Understanding patient and provider preferences may improve counseling and management of surgical menopause in pre- and perimenopausal gynecologic oncology patients.

Sources of Funding: None

P-71.

Sedentary Behavior Predicts Objectively Measured Hot Flashes in Midlife Women

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Objective: In women around the age of menopause, some data suggest that greater number and severity of hot flashes (HFs) are related to increased risk for cardiovascular disease (CVD). This is remarkable as approximately 80% of women report experiencing HFs. Sedentary behavior (SB) often constitutes a large portion of a midlife woman's wakeful day and is related to CVD risk. Few studies have evaluated the effect of SB on hot flash experience. These findings were based on self-reports and did not consider objective measures of HFs or SB. Our aim was to determine whether objectively measured SB is a predictor of objective and subjective HF experience. **Design:** Women aged 45-55 who were not taking hormone therapy or other medications that may reduce HF frequency or severity were recruited for the study. We targeted women with irregular menstrual cycle length or their last menstrual period within the past two years. HF experience and SB were monitored simultaneously for 24hr. Sternal skin conductance (Biolog, UFI) was used for ambulatory objective HF measurements. Increases of > 2 μmhos within 30s and/or a representative pattern (sudden spike and slow descent) were deemed an objective HF. Subjective HFs were reported by the participant by pressing a button on the monitor when they perceived a HF or by recording the HF on a HF diary. When an objective HF and subjective HF occurred within 20 minutes of one another, they were deemed concordant. Frequency of HFs per hour was calculated for each HF type. The Actigraph (AG) GT3X+ PA monitor was worn on the wrist and used to objectively measure SB (hrs) and moderate-vigorous PA (MVPA, mins). Individuals who did not wear both monitors for at least 12hrs were excluded from the analysis. Bivariate correlational analyses and hierarchical regressions were completed. Models for predicting HF frequency (HF/hr) by type from SB controlled for Biolog and AG wear times, menopausal status, and time spent in MVPA using SPSS (v.21). **Results:** To date, 66 women (50.9 ± 2.8 yr; Pre-, 9.7%; Peri-, 43.9%; and Post-Menopausal, 36.4%) were included in the analysis. In bivariate analyses, objective HFs were significantly negatively correlated with hrs of SB ($r = -.279$, $p = .023$) and positively correlated with mins of MVPA ($r = .303$, $p = .013$). Subjective HFs were not significantly correlated with SB ($r = -.063$, $p = .617$) or MVPA ($r = .129$, $p = .300$). Concordant HFs were significantly positively correlated with MVPA ($r = .286$, $p = .020$), but not with SB ($r = -.115$, $p = .358$). When Biolog (17.4 ± 7.2hr) and AG wear times (92.5 ± 8.5%), and menopausal status were controlled for, the number of hours spent in SB significantly predicted objective ($\Delta R2 = .178$, $\beta = -.417$, $p = .000$) and concordant HFs ($\Delta R2 = .063$, $\beta = -.280$, $p = .036$), but not subjective HFs ($\Delta R2 = .029$, $\beta = -.191$, $p = .131$). When MVPA (161.57 ± 74.82min) was added to the model, SB significantly predicted objective HFs ($\Delta R2 = .134$, $\beta = -.423$, $p = .002$). SB did not predict concordant ($\Delta R2 = .037$, $\beta = -.224$, $p = .098$) or subjective ($\Delta R2 = .029$, $\beta = -.196$, $p = .139$) HFs with MVPA included. **Conclusion:** Our findings suggest that SB predicts objective and concordant HFs in women ages 44-55, independently of time spent participating in MVPA. As time spent in sedentary behaviors represents a large portion of daily activity among this population, it is important to understand its influence on menopausal HFs. Knowledge regarding the influence of SB on HFs can improve evidence-based lifestyle recommendations for women experiencing HFs.

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Perimenopause Meets Life: Observations from the Women Living Better Survey

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Objective: A variety of symptoms arise in the years leading to the final menstrual period, beginning in the late reproductive stage (LRS) and continuing through the menopausal transition (MT) as defined by STRAW. In addition to changes related to reproductive aging and overall health, midlife entails managing a nexus of relationships with children, aging parents, life partners, and workplace colleagues. The purpose of our analyses was to test a model relating personal characteristics, reproductive aging stages, health behaviors, life roles, stressors, stress management efforts and overall satisfaction with life to bothersome symptoms experienced during the LRS and MT. We also examined the effects of symptoms on interference with activities and relationships, perceived health, and "not feeling like myself." **Design:** The online Women Living Better Survey was open from March to August 2020. In addition to personal characteristics and reproductive aging stage, participants described their health behaviors, stress management efforts, overall stress levels and stress associated with life partners, family, other relationships, work, finances, overcommitment and health. Also they rated bother from 61 symptoms. Five symptom groups identified from principal components analysis were used in hierarchical multiple regression analysis to test models of: brain fog, volatile mood, fatigue/pain, and vasomotor/sleep onset, and vigilance/anxiety. Using two-stage models, we linked personal characteristics (age, education, difficulty paying for basics), reproductive aging stage (LRS, MT), and health behaviors (smoking and alcohol use) to symptom groups (stage 1). In stage 2 we added effects of roles (i.e., caregiver, partner, employment-related), satisfaction with life, and stressors associated with roles to symptom groups. All tests of significance used Bonferroni correction for p values, such that $p<.005$ was considered significant. **Results:** The mean bother rating for the brain fog symptom group was highest, followed by volatile moods, pain/fatigue, VSM/sleep onset, and vigilance/anxiety symptoms. More bothersome brain fog symptoms were significantly associated with lower education level, greater difficulty paying for basics, and reproductive aging stage (MT > LRS) in stage 1 and in stage 2 low satisfaction with life roles, greater health-related and over-commitment stress were significant. More bothersome volatile mood symptoms were associated with less education and greater difficulty paying for basics in stage 1, but these variables were not significant in stage 2. Instead health-related, partner relationship, and other relationship stress were significantly associated with greater volatile mood. More bothersome fatigue/pain symptoms were associated with less education and greater difficulty paying for basics in stage 1. Stage 2 also included health-related and other relationship stress. Vasomotor/sleep onset symptoms were associated with less education, more difficulty paying for basics and being in MT versus LRS in stage 1, but In stage 2, paying for basics was no longer significant and health-related and work stress were. More bothersome vigilance/anxiety symptoms were associated with lower education level and more difficulty paying for basics in stage 1 and with health and work stress in stage 2. All five symptom groups were associated with greater interference with daily activities and relationships and with "not feeling like myself." In addition, perceived health was negatively associated with each symptom group except vasomotor/sleep onset difficulty. **Conclusion:** All five symptom groups were associated with life stressors related to roles. Lower education levels and difficulty paying for basics were both associated with all symptom groups as well. Only brain fog and vasomotor/sleep onset symptoms were associated with reproductive stage. Each of the symptom groups was associated with interference with daily living and relationships. These analysis surfaces 3 ideas to improve navigation of the years preceding menopause for both those experiencing it and their providers: 1) vasomotor symptoms are not the most bothersome symptom group; 2) bothersome symptoms occur in the LRS, prior to the MT and 3) these symptoms greatly interfere with lives and relationships.

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