ABSTRACT: 20th ANNUAL MEETING OF NAMS

an adverse experience. This pilot trial sought to quantify the effect of RLX on hot flashes compared to placebo. Paroxetine (PAX), a selective serotonin reuptake inhibitor (SSRI) approved for treatment of depression and anxiety, can reduce hot flashes via non-hormonal mechanisms and was included as a positive control. This pilot trial could be used to determine the sample size for future studies comparing the hot flash effects of RLX with other agents. Design: 42 healthy postmenopausal women were randomized in a 2:1 ratio to receive either RLX (150mg) or 20mg PAX or 20mg PAX plus 20mg RLX, for 12 weeks. Eligible subjects were recently postmenopausal women ≥40 years, who had the last menstrual period within 3 months and 5 years prior to screening, and who had a total of 5 or more hot flashes per week as recorded in the study diary in the 2 weeks prior to screening period. The incidence of hot flashes and their severity (using a 4-point severity) were recorded using a paper diary for 5 one week periods during the study as follows: immediately after the screening visit to determine eligibility, the week prior to randomization, and on treatment weeks 4, 8, 10, and 12. The screening was assessed at the end of each weekly hot flash diary using the Sleep Problems Scale Questionnaire. To evaluate the primary hypothesis of the effect of RLX versus PBO on the change from baseline to week 12 for weekly hot flash frequency, an ANOVA was performed with factors for strain (222 and ≥22 baseline hot flashes per week) and treatment group. Treatment differences in the all-patients treated population were estimated and least squares means and 95% confidence intervals (CI) calculated. This study was conducted in the United States and approved by independent review boards. Results: 41 patients completed the study and were included in the analysis. Baseline values for frequency and severity were generally similar between groups (28.30 hot flashes/week, 32.57 weekly severity score). The change in frequency and severity from baseline to week 12 is shown in the table. The difference between placebo and paroxetine was not statistically significant for either measure. There was no significant difference between groups for the Sleep Problems Scale. All treatments were well tolerated. Conclusion: In this study, RLX treatment resulted in a small decrease in hot flash frequency and severity score, instead of an expected increase. However, this decrease was numerically less than the decrease in paroxetine treated group, and may be attributed to a general tendency for decreases in hot flashes in clinical studies, illustrated by the large PBO effect. The absence of a statistical significant difference between RLX and PBO should be interpreted with caution due to the small size of the study. The large effect of PBO observed (~76% reduction in weekly frequency) is consistent with other studies. PAX was included as a positive control and significantly reduced hot flash frequency and severity score compared to placebo. Although the effect of PAX should be interpreted with caution due to the small sample size, it can be considered with other studies of this therapy. Based on these results, an estimated sample size of 64 patients per group would be needed to have 80% power in a study to demonstrate a difference in hot flash frequency of 20% between paroxetine and another placebo-like agent with regard to hot flashes.

<table>
<thead>
<tr>
<th>Sympotoms</th>
<th>Baseline %</th>
<th>Treatment %</th>
<th>Improvement %</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Hot Flashes</td>
<td>60.0%</td>
<td>65.0%</td>
<td>5.0%</td>
</tr>
<tr>
<td>Hot Flashes</td>
<td>40.0%</td>
<td>35.0%</td>
<td>-5.0%</td>
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<tr>
<td>Sleep Quality</td>
<td>60.0%</td>
<td>65.0%</td>
<td>5.0%</td>
</tr>
<tr>
<td>Energy Level</td>
<td>60.0%</td>
<td>65.0%</td>
<td>5.0%</td>
</tr>
</tbody>
</table>

* Some questions were left unanswered, with lower totals in subgroups.

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**LB-6.**

Gynecologists’ beliefs regarding hormone therapy for Alzheimer’s dementia and depression

Gayatri Devi1, Vanessa Lo, BS2, Michele Glodowski, BS2, Anette Tennes Pedersen, MD3, PhD,4, Eden Kim, BS, MPH2, Elizabeth Shin, BA2

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Objective: We wished to evaluate New York City gynecologists’ views on the efficacy of hormone therapy (HT) in preventing Alzheimer’s dementia and alleviating depression. Early results of epidemiologic studies on HT use in preventing and treating AD have been conflicting. In 2002, the Women’s Health Initiative Memory Study (WHIMS) found that conjugated estrogen plus progestin did not prevent mild cognitive impairment and increased the risk for probable dementia in postmenopausal women. The estrogen plus progesteron arm of the study was halted prematurely due to adverse cardiovascular and cancer risks in the placebo arm. The Women’s Health Initiative Cognitive Study (WHICS) found that WHIMS and WHIMS findings have been debated as they differ from the results of past observational studies and lacked statistical significance, meeting pre-determined end points instead. Additionally, some WHIMS participants were noncompliant with their therapy. Nevertheless, these studies have affected decision making worldwide, with a large decrease in the number of HT prescriptions. Recent findings from observational studies continue to reveal contradictory conclusions as well as variable effects of HT among older women. The need for an additional study to unequivocally determine the effects of HT use when used in a clinical setting. Similarly, the efficacy of HT for treating depression in the menopausal transition is unclear. Variation in effects of HT use on depression symptoms is likely due to the complexity of the mechanisms involved and differences in response among women users. We wished to investigate New York City gynecologists’ reported prescribing practices of HT use with regards to AD and depression in New York City and the surrounding metropolitan area, including Long Island and Westchester County. Participants: All 1,797 board-certified obstetrician-gynecologists in New York City and the surrounding metropolitan area, including Long Island and Westchester County were invited to complete the questionnaire. Measurements: Demographic data was analyzed using chi-square and binomial statistics. Logistic regression was used to analyze differences in prescribing patterns, controlling for confounding variables (SPSS). Results: We received completed questionnaires from 565 (31.5%) of NYC Obstetrician-gynecologists. About a third of respondents felt HT use prevented AD (39%); 60%), another third felt it was not useful in preventing AD (37%); 75%) and another third were unsure (24%); 20%). The beliefs of gynecologists do not appear to be greatly influenced by the WHIMS results with regard to the possibility of HT use as a risk factor for AD. Most gynecologists (69%); 141/204) felt that HT use can alleviate symptoms of depression (p=0.49). The conclusions of the WHIMS, gynecologists remain divided in their attitudes towards HT as a risk factor for AD. The majority of gynecologists believe that HT use could alleviate depression. NY gynecologists self report of prescription practices of HT*

**Footnotes:**

1. *Some questions were left unanswered, with lower totals in subgroups.

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**Abstract:** 20th Annual Meeting of NAMS

Menopausal status was not associated with the non-dipping nocturnal BP in this sample. These findings provide preliminary evidence for the significance of menopausal status in understanding diurnal blood pressure variation in middle-aged Mexican-American women. Over-napping nocturnal BP is associated with cardiovascular events potentially due to hypoperfusion during sleep or an exaggerated morning surge of BP. Thus, over-dipping may represent one manifestation of menopause’s effect on CVD risk.

**LB-7.** Longitudinal Examination of Exercise and Self-Esteem in Middle-Aged Women
Stefanie Elavsky, Ph.D., The Pennsylvania State University, University Park, PA

**Objectives:** To examine prospectively the relationships among the facets of multidimensional self-esteem and physical activity in middle-aged women using the Exercise and Self-Esteem Model (EXSEM; Sonstroem et al., 2003) to predict middle-aged women (N=143) previously enrolled in a randomized controlled trial exercise intervention. Measures of multidimensional self-esteem, physical activity, and self-efficacy as the end of the 4-month exercise trial and again two years later. To examine the EXSEM pathways, a longitudinal panel analysis was conducted within a structural equation modeling framework using Mplus Version 5.1. Results: The results indicated that across the 2-year period, enhancements in physical activity (PA) (β=.28, p<.05) and self-efficacy (β=.35, p<.05) and reductions in body mass index (BMI) (β=-.18, p<.05) were associated with improved subdomain self-esteem relative to physical condition, and reductions in BMI (β=-.31, p<.05) were associated with improved subdomain esteem relative body attractiveness. Over time, the effects of PA, self-efficacy, and BMI on changes in physical self-esteem and global esteem were mediated by changes in physical condition and body attractiveness subdomain esteem. Women reporting greater levels of PA, self-efficacy, and with lower BMI, also reported greater enhancements in subdomain self-esteem. Conclusion: Of the two relationships, with BMI and self-esteem, the relationships with BMI were stronger. The multidimensional structure of self-esteem and indicate that middle-aged women may enhance condition and body-related physical self-esteem by participating in physical activity, increasing their self-efficacy, and maintaining healthy BMI levels.

**LB-8.** Menopausal status and diurnal blood pressure variation in middle-aged Mexican-American Women
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**Psychiatry, University of Pittsburgh School of Medicine, Pittsburgh, PA.**

**Objectives:** Diurnal blood pressure (BP) variation has been shown to predict CVD morbidity and mortality with non-dipping nocturnal BP (less than 10% variation from daytime mean value) or over-dipping nocturnal BP (20% or greater variation from daytime mean value) being associated with increased CVD risk. The mechanisms underlying diurnal BP variation are varied and include age, ethnicity, medical conditions, and lifestyle factors. Postmenopausal status has been associated with non-dipping nocturnal BP in African-American and Caucasian women. To our knowledge, no studies to date have examined the association between menopausal status and over-dipping BP. The purpose of the current study was to examine the relationship between menopausal status and the prevalence of non-dipping and over-dipping nocturnal BP in a group of middle-aged Mexican-American women. Design: 247 women, aged 40-65, were randomly recruited from communities near the San Diego/Mexico border. Exclusion criteria included hypertension (stage 3 and above) or antihypertensive treatment, history of cardiovascular disease, diabetes, kidney disease, or other serious illness, pregnancy, and taking medications with autonomic effects. Menopausal status was assessed via self-report and women were categorized into the following groups: premenopause (regular menstrual cycles for at least 12 months), perimenopause (menstrually consistent menstruation between twelve months), and postmenopause (no menstruation within the past 12 months). Ambulatory blood pressure monitoring was conducted during a 36-hour period within a typical work week. Based on participants’ self-reported wake/sleep schedule, the monitor was programmed to take readings every 30 minutes during waking hours and 60 minutes during sleep. Participants were instructed to maintain a normal level of activity. All BP readings were reviewed and out of range values were identified and excluded from analyses. Average blood pressure during wake and sleep (based on self-reported actual sleep times) was estimated for each person via multi-level modeling analyses, to accommodate the nested structure of the data. Average daytime values accounted for momentary fluctuations in posture, temperature, physical activity, and substance and/or food consumption assessed via electronic diary. A percent dipping score for systolic (SBP) and diastolic (DBP) blood pressure was subsequently calculated (wake BP-sleep BP) and used to categorize women into groups based on the following criteria: non-dippers (≤10% variation) and over-dippers (>20% variation). Results: Of the women, 49.9% were over 65 years of age (SD=6.64). 72.8% were born in Mexico, and 68.6% reported an education level of high school or higher. Analyses reflecting the prevalence of non-dipping in menopausal status and the stage of menopause transition were not associated with the prevalence of non-dipping nocturnal SBP and DBP (all p>0.10). However, after accounting for age, recent use of hormone replacement therapy, education, income, nativity, physical activity level, and BMI, postmenopausal women displayed greater odds of over-dipping nocturnal SBP as compared to their premenopausal [OR (95%CI) = 4.85 (1.05, 22.5), p<.05] and perimenopausal [OR (95%CI) = 3.83 (1.01, 13.78), p=0.05] counterparts. Menopausal status was not significantly related to prevalence of over-dipping nocturnal DBP. Compared to Caucasian American women, menopausal status was associated with diurnal blood pressure variation with the prevalence of over-dipping nocturnal SBP being higher among postmenopausal women compared to other groups. Contrary to previous findings.