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Background: Poor sleep quality is related to the onset of pain, decreased pain threshold, fatigue, and psychological distress, which contribute to a worsening of the overall quality of life.

Objectives: To evaluate the quality of sleep in women suffering of endometriosis.

Methods: A total of 165 women with surgically and histopathologically confirmed endometriosis (endometriosis group - EG) and 200 women without history of endometriosis and no endometriosis-related symptoms (control group - CG) were included. In the EG group there were 67 women with minimal (I) or mild (II) stage of endometriosis and 98 with moderate (III) or severe (IV) stage. We excluded women who in the last three months previously enter in the study were user of psychotropic drugs, including medication for insomnia or illicit drugs. To assess the quality of sleep it was used the Post-sleep Inventory, composed of 30 visual analog scales of 10cm each. The final score of this questionnaire range from 0 to 10, with 10 being the best score possible. The study was approved by the Institutional Ethics Committee and all volunteers signed an informed consent. For statistical analysis the Mann-Whitney test was used.

Results: The average age and body mass index of the two groups were 34.5 ± 5.6 years and 25.6 ± 4.4 kg/m² for EG and 33.1 ± 6.4 years and 25.8 ± 4.4 kg/m² for the CG, respectively. The final score of the Post-sleep Inventory was 5.5 ± 1.6 for EG and 5.9 ± 1.7 for the CG group ($p=0.011$).

Conclusions: The quality of sleep in women with endometriosis is worse than women without the disease.

P55. Gender Differences in Health-Related Quality of Life for Patients with Bipolar Disorder

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Background: Bipolar disorder is a chronic illness associated with poor psychiatric and medical outcomes. Studies of gender differences health related quality of life (HRQOL) in various populations have found that women report a lower HRQOL than men.

Objectives: This study assessed gender differences in health-related quality of life (HRQOL) in a national sample of patients with bipolar disorder.

Methods: Recovery-oriented collaborative care (ROCC) is a multisite, randomized controlled study, in which community-based programs (sites) were randomized to receive enhanced versus standard implementation strategies to facilitate the uptake of a chronic care model program for bipolar disorder. We analyzed baseline data from ROCC, including patient factors associated with mood symptoms (measured using the Internal State Scale for manic symptoms and PHQ-9 for depressive symptoms); HRQOL was assessed using the SF-12.

Results: The sample comprised 209 women and 100 men with a mean age of 42.5 ± 11.3 years. Three quarters of the sample were Caucasian (N=207 or 69.0%), 16% were African-American (N=48), 9% Hispanic (N=27), and 1.7% Native American (N=5). Twelve percent (N=44) had not completed a high school education, 75.7% (N=234) were unemployed, and 35.6% (N=107) lived alone. In our multivariable analysis of the effect of gender on HRQOL, where we adjusted for age and race, female gender was associated with a higher score on the PHQ-9 ($B=1.95$, $SE=0.83$, $p=0.05$), compared to males. However, there was no

significant gender difference found on the SF-12 components of PCS ($B=-1.61$, $SE=0.99$, $p=0.11$) or MCS ($B=-0.43$, $SE=1.12$, $p=0.67$) after adjusting for depression and patient factors.

Conclusions: Depression symptoms may explain the association between gender and HRQOL in the multivariate, which points to the importance of assessing and treating depressive symptoms in bipolar disorder. Further studies are warranted to assess if gender differences exist in bipolar disorder.

P56. Ovarian cysts during tamoxifen use may affect the prognostic markers of premenopausal breast cancer

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Background: Only a few studies have suggested the association between ovarian cysts and serum estrogen levels during tamoxifen use. However, increased estrogen levels with ovarian cysts would affect the prognosis of breast cancer, this association has not yet been studied.

Objectives: We aimed to investigate the association between ovarian cysts and prognostic markers in premenopausal breast cancer patients undergoing tamoxifen treatment.

Methods: A retrospective review of sixty-five premenopausal breast cancer patients who underwent tamoxifen treatment was performed. Serum hormone levels were measured either specifically between cycle days 2 and 5 in menstruating patients or at any time in amenorrheic participants.

Results: The study population consisted of premenopausal patients with (n=23) and without ovarian cysts (n=42). Serum estradiol (E2) levels and tumor markers were not statistically different based on ovarian cyst status. In the subgroup analysis, serum E2 levels were significantly higher in menstruating women with ovarian cysts, and E2 levels was positively correlated with serum cancer antigen 15-3 and insulin-like growth factor-1 in these women.

Conclusions: Ovarian cysts during tamoxifen use may affect the markers associated with the clinical course of premenopausal breast cancer.

P57. Bone mineral density and breast cancer risk in the VHM&PP study

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Background: Breast cancer is the most frequent cancer and the leading cause of cancer death in females worldwide. Previous reports showed a positive association between bone mineral density (BMD) and subsequent breast cancer. BMD measurements could reflect long-term exposure to estrogens and hence serve as intermediate marker of breast cancer risk.

Objectives: To further clarify the association between BMD and breast cancer risk among women in a large prospective study with long-term follow-up.

Methods: A cohort study design was used in order to investigate the association between BMD and breast cancer risk. Among 4107 women, BMD was measured by dual energy X-ray absorptiometry (DXA, N=1418) or quantitative computer tomography (QCT, N=2689). Women were on average followed-up for 13.4 (SD 2.8) years. Cox proportional hazard models were applied to estimate breast cancer risk. Adjustment has been performed for body mass index (BMI, kg/m²), smoking status (smoker, ex-smoker, non-smoker), HRT use (yes, no), menopausal status (<50, ≥50 years), and leisure time physical activity (none, 30min, 30–60 min, 60–120 min, >120 min/week). For 3306 women serum GGT levels as proxy for alcohol consumption were additionally available.

Results: Mean age at recruitment was 55.6 (SD 6.1) years. After follow-up of 13.4 (2.8) years 150 invasive breast cancer cases were identified with mean age at diagnose 63.8 (SD 6.3) years. Mean DXA was 1.00 (SD 0.13) kg/m² and QCT was 108.2 (SD 21.8). In the multivariate model, BMD was not associated with breast cancer risk (4th vs. 1st quartile HR 0.97; 95%CI, 0.60–1.55). Further adjustment for serum GGT levels did not change the risk estimates substantially (HR 0.83; 95%CI, 0.40–1.73).

Conclusions: The results of our study provide no evidence that BMD is associated with breast cancer risk among women with follow-up over 10 years.

P58. Return to Work among Women Hematopoietic Stem Cell Transplantation Survivors

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Background: Returning to work is a major cancer survivorship milestone. Survivors of hematopoietic stem cell transplant report that work-related concerns are a primary reason for feeling they have not returned to normal. Compared to male survivors, women have more work-related concerns and return to work later.

Objectives: To clarify the nature of women's treatment-related negative work events, the distress they cause, and their impact on women's work outcomes following treatment.

Methods: 116 women who underwent SCT 9-months to 3-years prior to the study and were employed at the time of diagnosis or transplant completed a measure of transplant-related negative work events (e.g., being fired, having to take an unpaid leave, having a pay cut), the distress caused by the events, and current work status.

Results: Although all women had been working at the time of diagnosis or transplant, currently only 28% were working full-time, 15% were working part-time, and 58% had not returned to full- or part-time work (i.e., they reported being a homemaker or were retired, on sick leave or disability, or looking for work). Most

(76%) reported at least one negative work event. In bivariate analyses, return to full- or part-time work was significantly negatively associated with total number of negative work events (point biserial $r = -.21$, $p = .03$) and work event-related distress burden (the mean distress caused by experienced events; point biserial $r = -.22$, $p = .02$). The more negative events a woman experienced or the greater her work event-related distress burden, the less likely she was to return to work. In two separate logistic regressions predicting return to work, the number of work events (OR 0.809; 95% CI .67, .98) and work-related distress burden (OR 0.932; 95% CI .88, .99) each predicted return to work, but both became non-significant after controlling for fatigue, which independently predicted lower likelihood of return to work.

Conclusions: Findings identify negative work-related events women experience because of cancer treatment and suggest the need for further research on fatigue as 1) a correlate of these events and associated distress after cancer treatment and 2) a factor linking these events with ability to return to work.

P59. Results From a 24-Week Clinical Trial With Flibanserin in Premenopausal Women With Hypoactive Sexual Desire Disorder

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Background: There are currently no approved treatments for Hypoactive Sexual Desire Disorder (HSDD) in premenopausal women. Flibanserin, a centrally acting 5HT1A agonist and 5HT2A antagonist, has been shown in Phase 3 trials to significantly increase the number of satisfying sexual events (SSEs), while the effect on desire as assessed by patients reporting on an e-diary was marginal.

Objectives: To assess the efficacy of flibanserin on SSEs and desire assessed with the Female Sexual Function Index (FSFI) over 24 weeks of treatment in premenopausal women.

Methods: This was a randomized placebo-controlled clinical trial in 543 women randomized to flibanserin and 547 randomized to placebo. Co-primary endpoints were change from baseline to study end in the number of SSEs and FSFI desire domain. Secondary endpoints included Female Sexual Distress Scale-Revised (FSDS-R) total and FSDS-R Item 13 scores.

Results: Mean (SD) baseline data were: SSE 2.6 (2.7) and FSFI-d 1.9 (0.7). The mean changes from baseline to study end for flibanserin treated women in the efficacy endpoints were 2.4, 1.0, and -1.0 for SSEs, FSFI-d, and FSDS-R, respectively. All changes were significantly different from placebo ($p < 0.0001$). Adverse events leading to discontinuation were experienced by 3.7% of women receiving placebo and 9.6% of women receiving flibanserin (most frequent term: somnolence, 0.4% vs 1.7%, respectively).

Conclusions: In premenopausal women with HSDD, flibanserin 100 mg qhs was associated with clinically meaningful and statistically significant improvements in the number of SSEs and sexual desire (FSFI desire domain), and the secondary endpoints for distress associated with sexual dysfunction (FSDS-R total) and distress associated with low sexual desire (FSDS-R Item 13) compared with placebo. There were no significant safety concerns associated with the use of flibanserin for 24 weeks.