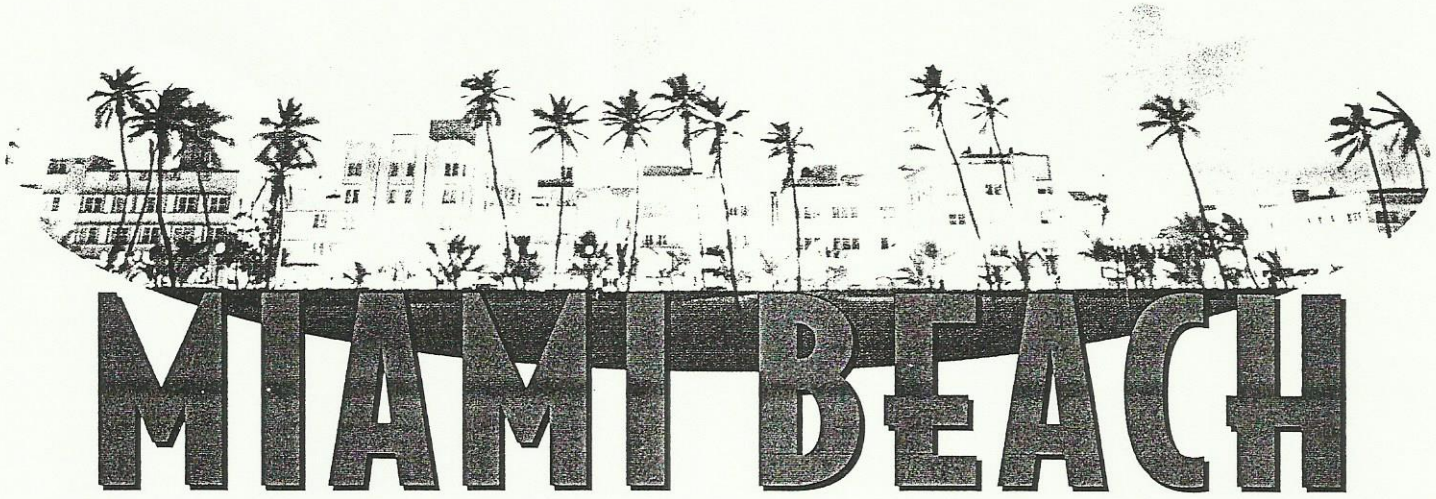
PROGRAM & ABSTRACT BOOK

14th annual meeting

"Prevention of Disease Through Menopause and Beyond"



September 17-20, 2003

NAMS

THE NORTH AMERICAN MENOPAUSE SOCIETY

Poster Presentations continued

P-70.

Testosterone Patches for the Treatment of Low Sexual Desire in Surgically Menopausal Women

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Objective: To evaluate the safety and efficacy of 3 doses of transdermal testosterone in surgically menopausal women with Hypoactive Sexual Desire Disorder (HSDD). **Design:** Surgically menopausal women (n=447) receiving oral estrogen with low sexual desire causing distress were enrolled in a 24-week, randomized, double-blind, multi-center trial. They received placebo (PL) or testosterone (T) 150, 300 or 450 µg/day by patch twice weekly. Primary efficacy endpoints were the frequency of satisfying sexual activity from the Sexual Activity Log (SAL) and the sexual desire domain of the Profile of Female Sexual Function (PFSF). Hormone levels were assessed. Adverse events (AEs) and clinical labs were evaluated. **Results:** At 24 weeks in the 300 µg/day group, there was a 30% increase in the frequency of total satisfying sexual activity vs PL ($p<0.05$) and an 81% increase vs baseline ($p<0.05$). The 150 µg/day group was similar to PL; there was no advantage of the 450 µg/day group over the 300 µg/day group. Significant differences vs PL in the sexual desire score were observed for the 300 µg/day group ($p<0.05$). No significant differences were observed for the 150 µg/day group ($p=0.3540$); a positive trend ($p=0.0970$) was seen for the 450 µg/day group. Dose-related increases in mean concentrations of free, total, and bioavailable T were observed. Androgen concentrations significantly correlated with multiple PFSF and SAL domains. There were minimal changes in laboratory assessments with T. Overall, AE reports were similar in the PL and T groups. **Conclusions:** In this prospective phase II study using validated instruments, the T patch improved sexual functioning; 300 µg/day was the optimal dose. Treatment with the 300 µg/day T patch significantly increased sexual activity and desire in oophorectomized women with HSDD and was well-tolerated.

P-71.

The Incidence of Women with Abnormal Cytologic Results Is Similar for the First 4 Consecutive Annual Smears in Postmenopausal Women

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Objective: To determine differences in the incidence of women with abnormal cytologic results in postmenopausal women between the first 4 consecutive annual smears. **Design:** Women, who had spontaneous menopause and who applied to our menopause outpatient clinic between 1995 and 2002 were analyzed in this retrospective analysis. Women, who were prescribed HRT and those, who had no treatment were included in the present analysis. Cervical smears of these women were recorded and those reported ASCUS, AGCUS, LGSIL or HGSIL were accepted as abnormal. McNemar test was used to compare the rates of abnormal smears between the consecutive years. The impact of HRT on the incidence of abnormal smear also was evaluated. **Results:** 3198 postmenopausal women had a smear on their initial visit. Mean (± SD) age and BMI of these women were 51.6 = 6.3 years and 26.4 ± 3.9 kg/m², respectively. 1184 of these women had their second smear in the second year. Of these, 593 had their 3rd smear on the 3rd year and 336 women had their 4th smear on the 4th year. The rates of abnormal smear were 1.3%, .9%, .3% and .9% in the 4 consecutive annual smears of these women, respectively ($P>0.05$). The rate of HRT users in these 4 consecutive years was 63%, 78%, 82%, and 83%, respectively ($P<0.001$). The rate of abnormal smears was comparable between women, who were on HRT and those, who were not on HRT ($P>0.05$). **Conclusions:** The incidence of women with abnormal cytologic results is similar for the first 4 consecutive annual smears in postmenopausal women. Therapy with oral estrogen and progestin does not significantly affect the incidence of cytologic abnormalities. Although predictive value of an abnormal smear for the cervical pathology has not been evaluated in the present study, it seems reasonable to perform annual smears for postmenopausal women.

P-72.

The Effect of One-Year Tibolone Treatment in the Spine Lumbar Bone Mineral Density among Postmenopausal Women

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Objective: The aim of this trial was to assess retrospectively one-year tibolone treatment in the Bone mineral Density (BMD) at lumbar spine among postmenopausal women. **Design:** Seventy postmenopausal women were recruited . The mean age was 47.44 ±5.04 (range 48-69). The BMD at the lumbar spine was measured by dual-energy X ray absorpsiometry (DEXA) at baseline and after one-year treatment. The patients received Tibolone 2.5 mg daily during twelve months due to climacteric symptoms. **Results:** The baseline mean bone mineral density at the lumbar spine was:0.92 ± 0.12. After twelve months such density was: 0.96 ±0.11 (confidence interval 95% 0.05 ±0.03 $p<0.001$. The mean percentage change from baseline to one-year treatment was: 4.47 ±5.72 %. Tibolone was well tolerated and it showed a positive and statistically significant change in the BMD Statistical analysis using paired t test was performed. **Conclusions:** Our findings support that Tibolone could be an alternative treatment in preserving and improving mineral bone density at lumbar spine among postmenopausal women.

P-73.

Evaluation of the Effect of Various Gestagens in HRT Regimens on Insulin Resistance in the Postmenopausal Women

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Objective: The objective of the present study was to quantify the effect of various gestagens, Micronized progesterone(P), dydrogesterone(D) , noretitisterone acetate(NETA) and medroxiprogesterone acetate(MPA) used in the HRT regimes with estrogens on insuline resistance in the postmenopausal women **Design:** This prospective study enrolled 156 postmenopausal women. Group 1 were treated with 17-bEstradiol (E) 2 mg+NETA 1 mg, Group 2 were given E 2 mg+ MPA 2.5 mg , Group 3 were given E 2 mg+D 10 mg , Group 4 were given E 2 mg + P 100 mg combined and continuously and group 5 were surgical menopausal group and were given only E 2 mg continuously. 156 subjects completed the three-months follow-up. The data of the patients, before treatment and 3 months after treatment were analyzed using HOMA(Homeostatic model assessment) for evaluating insulin resistance. We used the SPSS 10.0 computer program(Wilcoxon Signed Ranks Test and Oneway Anova test) for statistical analysis. A p value below 0.05 was considered to be significant. **Results:** 156 postmenopausal women completed the trial. No significant differences were found in baseline characteristics of the patients. The mean HOMA values were 3,19± 3,73 , 2,35±1,24 , 3,87±1,85, 2,76±1,85, 3,13±173 before HRT and 2,07±1,49 , 2,55±1,43 , 3,72±4,43, 2,42 ±1,37, 3,23 ±3,25 after HRT in the groups respectively. There were no significant differences in mean values of HOMA before in the five groups. There were statistically significant difference only in Group 1 and Group 3 in mean values of HOMA after HRT. **Conclusions:** As E 2 mg/day in surgical menopausal women and E 2 mg+ MPA 2.5 mg , E 2 mg + P 100mg/day in postmenopausal women did not change in insulin resistance but E 2 mg+NETA 1mg/day and E 2 mg+D 10 mg/day improved the insulin resistance in postmenopausal women after 3 months treatment.