Venue: The Estates of Sunnybrook
2075 Bayview Avenue, Toronto
Phone: 416-487-3841
Parking: Available onsite

SIGMA Canadian Menopause Society is proud to present the
2017 SIGMA Distinguished Lecture Series

Date: Monday May 29, 2017
Time: 6 to 9 PM
Speaker: Dr. JoAnn Pinkerton
Moderator: Dr. Wendy Wolfman
Topic: Clinical Utilities of TSEC, a Novel Hormonal Therapy for Menopausal Women

AGENDA:
18:00 - 18:30 Reception
18:30 - 20:00 Dinner & Lecture
20:00 - 20:20 Q and A

RSVP: by May 15
either Phone 604-736-7267
or Fax 604-736-7268
or email: info@sigmamenopause.com
OBJECTIVES

Novel Hormone Therapy- Conjugated Estrogens/Bazedoxefine (CE/BZA): Whom to Consider Therapy and Why

(1) Understand new options compared to traditional HT

(2) Describe the concept of Tissue Selective Estrogen Compound (TSEC)

(3) Results from SMART 5 trials on CEE/BZA

VMS and Sleep
Bone
Vagina
Safety- endometrium, breast and heart
Adverse events- VTE risk

(3) Differentiate on basis of bleeding and breast tenderness between CE/BZA (TSEC) and CE/MPA (EPT)

Dr. JoAnn Pinkerton is a Professor of Obstetrics and Gynecology and Division Director of Midlife Health Center at the University of Virginia Health System in Charlottesville, Virginia, Executive Director of North American Menopause Society (NAMS) since October 2015 and became President of South Atlantic Association of Obstetrics and Gynecology SAAOG in 2016. She is a certified Menopause Specialist, a longtime fellow of ACOG, 2008-09 President of NAMS and as served on many national and international committees and local University of Virginia Committees. Awards include the 2013 UVA Sharon Hostler Women in Leadership award, BEST DOCTORs and TOP DOCTORS in America since 2010. She won an American Library Association Award for her book, Understanding Midlife Health. She is the Associate Editor for the Journal Menopause and the section director for menopause for the Journal of Women's Health. She serves on the Editorial Boards for Menopause and Climacteric. She has published more than 100 peer-reviewed publications, 30 invited papers and 11 invited chapters and served as PI for over 30 clinical trials on treatment of hot flashes with hormonal and non-hormonal therapies. She is a strong proponent of education at the national level as well as within the community, holding Midlife Community Educational Symposiums-two per year to allow tailored education appropriate for different backgrounds.

She is married and the mother of three children, Jeremy, (deceased 2010 MVA), Katie, who is married and has a Masters in graphic design, and Liz, who is a second year medical student at Wake forest. She provides medical safety for the Women's 4 mile Breast Cancer Training Program, runs herself, and plays mandolin.
ABSTRACT

Novel Hormone Therapy – Conjugated Estrogens/Bazedoxifene: Whom to Consider for Therapy, and Why?
JoAnn V. Pinkerton, MD
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University of Virginia Health System; Charlottesville, Virginia

The 5 Phase 3 clinical trials known as the SMART trials (Selective estrogens, Menopause, And Response to Therapy) were conducted in postmenopausal women with a uterus. The trials demonstrated the efficacy and safety of conjugated estrogens (CE) combined with the selective estrogen-receptor modulator (SERM)bazedoxifene (BZA), CE/BZA for symptomatic relief, while preventing endometrial hyperplasia without need for a progestogen.

Vasomotor symptoms. In postmenopausal women with moderate-to-severe vasomotor symptoms (SMART-1 subset trial; SMART-2 trial), CE 0.45 mg/BZA 20 mg reduced hot flush frequency and severity at 12 weeks vs placebo (P<.05). Hot flush frequency was reduced by 74% for CE 0.45 mg/BZA 20 mg vs 51% for placebo.

Bone. In SMART-1, CE 0.45 mg/BZA 20 mg prevented loss of bone mass in the lumbar spine and hip in postmenopausal women at risk for osteoporosis (P<.01). Lumbar spine BMD increased from baseline by 1.05%, whereas a loss of 1.81% with placebo was seen at 12 months; at 24 months, lumbar spine bone mineral density had increased by 1.6%, vs a loss of 1.8% for placebo. Fracture prevention has been reported for the use of BZA alone, but no randomized, controlled trials have been conducted with CE/BZA.

Vulvar-vaginal atrophy. In SMART-1 and -3, 2 doses of CE/BZA—CE 0.45/BZA 20 and CE 0.625/BZA20 mg—were compared with placebo in postmenopausal women with vulvar and vaginal atrophy. CE 0.45/BZA 20 mg increased vaginal superficial and intermediate cells and decreased parabasal cells vs placebo after 12 weeks of treatment. Women receiving active treatment also had a lower incidence of dyspareunia (P<.05 for both doses) at weeks 9 and 12 (P<.05).

Breast pain and tenderness. In SMART-5, the effect of CE 0.45 mg/BZA 20 mg on breast pain and tenderness was similar to that of placebo, showing a decrease of 5% to 8% for both, while in the same study CE 0.45 mg/medroxyprogesterone acetate (MPA) 1.5 mg increased it by 20%-24% (P<.001). Similarly, the effect of CE 0.45 mg/BZA 20 mg on breast density was similar to that of placebo at 1 year, whereas CE 0.45 mg/MPA 1.5 mg significantly increased breast density vs placebo (P<.001). Rates of breast cancer for women treated with CE 0.45 mg/BZA 20 mg were similar to placebo for up to 2 years.

Endometrial hyperplasia. No increase in endometrial hyperplasia was observed with CE 0.45 mg/BZA 20 vs placebo (<1%) at 1 and 2 years. Endometrial thickness increased from baseline (<1 mm) after 2 years, comparable to placebo. High rates of amenorrhea were reported; and bleeding and spotting for women treated with CE 0.45 mg/BZA 20 mg were less than with CE 0.45 mg/MPA 1.5 mg. In SMART-5, cumulative amenorrhea rates were >87% for CE 0.45/BZA 20 mg, >83% for placebo, and >54% for CE 0.45/MPA 1.5 mg. Rates of endometrial cancer were not increased with CE 0.45 mg/BZA 20 mg for up to 2 years.
Cardiovascular events. In the women aged 40 to 65 years treated with CE 0.45 mg/BZA 20 mg, the rates of cardiovascular and cerebrovascular events, cancers (breast, endometrial, ovarian), and mortality were similar to placebo. With BZA 20 mg used alone, a 2-fold increased risk of venous thromboembolism was seen, but no additive effects with CE/BZA was evident.

REFERENCES

- Pinkerton JV, Utian WH, Constantine GD, Olivier S, Pickar JH. Relief of vasomotor symptoms with the tissue-selective estrogen complex containing bazedoxifene/conjugated estrogens: a randomized, controlled trial. Menopause. 2009;16(6):1116-1124.