



Menopause

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Editorials

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Genitourinary syndrome of menopause—I know it when I see it—or do I?

Amanda L. Clark, MD, MCR, FACOG, NCMP

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Endometrial safety and efficacy of ospemifene

Steven R. Goldstein, MD, CCD, NCMP, FACOG, FRCOG(H)

Original Study

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The complexity of genitourinary syndrome of menopause: number, severity, and frequency of vulvovaginal discomfort symptoms in women enrolled in a randomized trial evaluating treatment for genitourinary syndrome of menopause

Caroline M. Mitchell, MD, MPH, Joseph C. Larson, MS,

Susan D. Reed, MD, MPH, NCMP, and Katherine A. Guthrie, PhD

The data in this study highlight the complexity of genitourinary syndrome of menopause symptoms in quantity, severity and frequency, suggesting that measuring distress, bother or interference may be the most comprehensive measure.

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Sleep-light interventions that shift melatonin rhythms earlier improve perimenopausal and postmenopausal depression: preliminary findings

Barbara L. Parry, MD, Charles J. Meliska, PhD, Diane L. Sorenson, MPH,

L. Fernando Martinez, BA, Ana M. Lopez, BS, Sharron E. Dawes, PhD,

Jeffrey A. Elliott, PhD, and Richard L. Hauger, MD

The preliminary findings of this study suggest a potential safe, efficacious, rapid-acting, non-pharmaceutical, affordable home intervention that can be administered by paraprofessionals in underserved communities to reduce global health disparities.

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Anticipated age of perimenopausal experiences, stress, satisfaction, and health and well-being: observations from the Women Living Better Survey

Nancy Fugate Woods, PhD, BSN, FAAN, FGSA, Nina Coslov, MBA,
and Marcie Richardson, MD, FACOG

Being “off-time” (experiencing perimenopause-related menstrual cycle changes or symptoms in a timeframe before a person expects them) alone had little effect on measures studied with the exception of poorer perceived health. In contrast, those who were “off-time” and experiencing more bothersome volatile mood symptoms reported effects on health stress, satisfaction with life roles and activities, and perceived health.

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A phase 1/2, open-label, parallel group study to evaluate the safety and pharmacokinetics of DARE-HRT1 (80 µg estradiol/4 mg progesterone and 160 µg estradiol/8 mg progesterone intravaginal rings) over 12 weeks in healthy postmenopausal women

Andrea Thurman, MD, M. Louise Hull, MBChB, PhD, FRANZCOG,
Bronwyn Stuckey, MBBS, FRACP, Jessica Hatheway, MBA, Nadene Zack, MS,
Christine Mauck, MD, MPH, and David Friend, PhD

DARE-HRT1, an intravaginal ring (IVR), which releases 17 2-Estradiol (E2) with progesterone (P4) for 28 days is being developed for the treatment of vasomotor symptoms. This study found that two strengths of DARE-HRT1 were safe and released E2 and P4 with resulting plasma concentrations in the range of the normal early follicular phase (20 – 80 pg/mL) for E2 and at > 1 ng/mL for P4, meeting initial benchmarks for further clinical development.

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Comparative safety of conjugated estrogens/bazedoxifene versus estrogen/progestin combination hormone therapy among women in the United States: a multidatabase cohort study

Sarah R. Hoffman, MS, MPH, PhD, Samuel Governor, MD, MPH, Kimberly Daniels, PhD, MS,
Ryan M. Seals, MPH, ScD, Najat J. Ziyadeh, MA, MPH, Florence T. Wang, ScD,
Dingwei Dai, MD, PhD, Cheryl N. McMahon-Walraven, MSW, PhD, Patty Shuminski, AS,
Vera Frajzyngier, PhD, Xiaofeng Zhou, PhD, Rongjun Shen, MS, Renu K. Garg, PhD, MPH,
Nicole Fournakis, MPH, Stephan Lanes, PhD, and Daniel C. Beachler, MHS, PhD

The results of this multi-database study suggest that users of conjugated estrogens/bazedoxifene might experience slightly higher rates of endometrial cancer and endometrial hyperplasia and a lower rate of breast cancer than estrogen/progestin users.

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Serum cholesterol levels and the risk of brain natriuretic peptide–diagnosed heart failure in postmenopausal women: a population-based prospective cohort study

Ahmed Arafa, MD, PhD, Rena Kashima, MD, Yoshihiro Kokubo, MD, PhD,
Masayuki Teramoto, MD, MPH, Yukie Sakai, MSc, Saya Nosaka, MSc,
Haruna Kawachi, RN, MHA, Keiko Shimamoto, MD, PhD, Chisa Matsumoto, MD, PhD,
Yoko M. Nakao, MD, PhD, Qi Gao, MD, PhD, and Chisato Izumi, MD, PhD

Total cholesterol (TC) ≥ 240 mg/dL and high-density lipoprotein (HDL) ≥ 100 mg/dL were associated with a higher risk of heart failure, defined as brain natriuretic peptide ≥ 100 pg/mL, in postmenopausal Japanese women. Monitoring TC and HDL in postmenopausal women should be considered for heart failure prevention.



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Efficacy and safety of lemborexant in midlife women with insomnia disorder

Masakazu Terauchi, MD, PhD, NCMP, Jocelyn Y. Cheng, MD, Jane Yardley, PhD, Kate Pinner, MSc, Margaret Moline, PhD, Manoj Malhotra, MD, Kanako Inabe, BPharm, Maika Nishida, BPharm, and Elizabeth Pappadopulos, PhD

In the subgroup of perimenopausal-age women with insomnia disorder who participated in the SUNRISE-2 trial, lemborexant improved subjective sleep parameters through 12 months. Lemborexant was well tolerated over the 12-month treatment, and most treatment-emergent adverse events were mild to moderate in severity in this population.

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Correlates of serum estradiol concentration among postmenopausal women in Ilorin, North-Central Nigeria

Louis Okebunor Odeigah, FWACP, Ismaila Aberi Obalowu, FWACP, Anthonia Nkechi Alabi, FWACP, Abdulkadir Mohammed, FWACP, Christy Olanike Ademola, FWACP, and Oyeronke Adekemi Oyeleke, FMCfM

This study assessed the relationship between serum estradiol levels and some menstrual, clinical, and socio-demographic factors in postmenopausal women attending a family medicine clinic in Nigeria. The only significant correlate of low serum estradiol concentration found was chronic medical care presentation for hypertension and or diabetes, out of all the studied factors.

Review Articles



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Efficacy, tolerability, and endometrial safety of ospemifene compared with current therapies for the treatment of vulvovaginal atrophy: a systematic literature review and network meta-analysis

James A. Simon, MD, Alex Ferenczy, MD, Denise Black, MD, Alex Castonguay, MSc, Catherine Royer, BSc, ASA, Rafik Marouf, MD, PhD, and Catherine Beauchemin, PhD

Ospemifene is an efficacious, well tolerated and safe therapeutic option for postmenopausal women with moderate to severe symptoms of vulvovaginal atrophy (VVA). Efficacy and safety outcomes with ospemifene are similar to other VVA therapies in North America and Europe.



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The association between menopausal hormone therapy and gastroesophageal reflux disease: a systematic review and meta-analysis

Wafa A. Aldhaleei, MBBCh, MSc, MPH, Akshaya S. Bhagavathula, PharmD, PhD, Michael B. Wallace, MD, MPH, Kenneth R. DeVault, MD, and Stephanie S. Faubion, MD, MBA, NCMP

Gastroesophageal reflux disease (GERD) is a chronic condition associated with several risk factors. This systematic review and meta-analysis aims to provide single summary estimate of the hormone therapy (HT) effect on GERD and to elucidate the combined HT effect on GERD when results from prior studies were mixed.

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Pharmacological interactions and menopausal hormone therapy: a review

Maria Fasero, MD, PhD, Francisco Quereda, MD, PhD, Leire Andraca, PhD,
Pluvio J. Coronado, MD, PhD, and HT Eligibility Criteria Group

The available evidence of hormone therapy (HT) interactions with other drugs comes mainly from biological plausibility, the knowledge of extensive concomitant use without reported incidents, and the extrapolation of hormonal contraception. These eligibility criteria can help in the decision process of HT co-administration with another group of drugs.

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