

## Practical Gynecology, 2<sup>nd</sup> Edition – Chapter 16 References

1. **Hulley S, Grady D, Bush T, et al.** Randomized trial of estrogen plus progestin for secondary prevention of coronary heart disease in postmenopausal women. Heart and Estrogen/progestin Replacement Study (HERS) Research Group. JAMA. 1998;280:605-13.
- \*2. **Writing Group for the Women's Health Initiative Investigators.** Risks and benefits of estrogen plus progestin in healthy postmenopausal women: principal results from the Women's Health Initiative randomized controlled trial. JAMA 2002;288:321-333. *This NIH-sponsored, prospective, randomized, controlled, multicenter trial of more than 16,000 healthy menopausal women assigned to the combination estrogen plus progestin arm was terminated early. Release of these data, which demonstrated that HT's risks of cardiovascular disease, thromboembolism, and breast cancer outweighed the decrease in fractures and colon cancer, led to the widespread recommendation to prescribe HT at the lowest effective dose for the shortest duration of time to relieve menopausal symptoms of vasomotor distress and vulvovaginal atrophy. Since these results were reported in 2002, HT has no longer had a role in primary prevention.*
- \*3. **Hsia J, Langer RD, Manson JE, Kuller L, et al. for the Women's Health Initiative Investigators.** Conjugated equine estrogens and coronary heart disease: the Women's Health Initiative. Arch Intern Med. 2006;166:357-65. *Subgroup analysis of healthy women, aged 50 to 59, without a uterus assigned to the conjugated equine estrogens only arm in the WHI, revealed a reduction in myocardial infarction, coronary revascularization, and coronary death with estrogen use.*
4. **Estrogen and progestogen use in peri- and postmenopausal women: March 2007 position statement of the North American Menopause Society.** Menopause. 2007;14:168-182.
5. **AACE Menopause Guidelines Revision Task Force.** American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of menopause. Endocr Pract. 2006;12:315-37.
6. **Stephenson J.** FDA orders estrogen safety warnings: agency offers guidance for HRT use. JAMA. 2003;289:537-538.
- 6a. **Utian W, Archer D, Bachmann G, et al.** Estrogen and progestogen use in postmenopausal women: July 2008 position statement of the North American Menopause Society. Menopause. 2008;15;4:584-602.
7. **Nelson HD.** Commonly used types of postmenopausal estrogen for treatment of hot flashes: scientific review. JAMA. 2004;291:1610-20.
- \*8. **Barnabei VM, Cochrane BB, Aragaki AK, et al.** Menopausal symptoms and treatment-related effects of estrogen and progestin in the Women's Health Initiative. Obstet Gynecol 2005;105:1063-1073.

9. **Tice JA, Ettinger B, Ensrud K, et al.** Phytoestrogen supplements for the treatment of hot flashes: the Isoflavone Clover Extract (ICE) Study: a randomized controlled trial. *JAMA*. 2003;290(2):207-14.

\*10. **Newton KM, Reed SD, LaCroix AZ, et al.** Treatment of vasomotor symptoms of menopause with black cohosh, multibotanicals, soy, hormone therapy, or placebo: a randomized trial. *Ann Intern Med*. 2006;145:869-79. *This small randomized trial comparing soy and black cohosh to hormone therapy and placebo for relief of vasomotor symptoms failed to show significant benefit from these alternative therapies.*

11. **Nedrow A, Miller J, Walker M, et al.** Complementary and alternative therapies for the management of menopause-related symptoms: a systematic evidence review. *Arch Intern Med*. 2006;166:1453-65.

\*12. **Hendrix SL, Cochrane BB, Nygaard IE, et al.** Effects of estrogen with and without progestin on urinary incontinence. *JAMA*. 2005;935-48. *Analysis of data from the WHI trial found that oral ET and EPT both increased the risk of urinary incontinence among continent women, and worsened the characteristics of incontinence among symptomatic women. Thus, although HT is officially endorsed by the FDA for treatment of vulvovaginal atrophy, clearly topical estrogen is superior.*

13. **U.S. Preventive Services Task Force.** Hormone therapy for the prevention of chronic conditions in postmenopausal women: Recommendations from the U.S. Preventive Services Task Force. *Ann Intern Med*. 2005;142:855-60.

14. **Effects of hormone therapy on bone mineral density: results from the postmenopausal estrogen/progestin interventions (PEPI) trial.** The Writing Group for the PEPI. *JAMA*. 1996;276:1389-96.

\*15. **Cauley JA, Robbins J, Chen Z, et al. for the Women's Health Initiative Investigators.** Effects of estrogen plus progestin on risk of fracture and bone mineral density: the Women's Health Initiative randomized trial. *JAMA*. 2003;290:1729-1738.

16. **Management of osteoporosis in postmenopausal women: 2006 position statement of The North American Menopause Society.** *Menopause*. 2006;13:340-67

17. **Prestwood KM, Kenny AM, Kleppinger A, Kulldorff M.** Ultralow-dose micronized 17beta-estradiol and bone density and bone metabolism in older women: a randomized controlled trial. *JAMA*. 2003;290:1042-8.

\*18. **Greendale GA, Espeland M, Slone S, et al. for the PEPI Safety Follow-Up Study (PSFS) Investigators.** Bone mass response to discontinuation of long-term hormone replacement therapy: results from the Postmenopausal Estrogen/Progestin Interventions (PEPI) Safety Follow-up Study. *Arch Intern Med*. 2002;162:665-72.

\*19. **Margolis KL, Bonds DE, Rodabough RJ, et al. for the Women's Health Initiative Investigators.** Effect of oestrogen plus progestin on the incidence of diabetes

in postmenopausal women: results from the Women's Health Initiative Hormone Trial. *Diabetologia*. 2004;:1175-87.

20. **Kanaya AM, Herrington D, Vittinghoff E, et al. for the Heart and Estrogen/Progestin Replacement Study.** Glycemic effects of postmenopausal hormone therapy: the Heart and Estrogen/progestin Replacement Study. A randomized, double-blind, placebo-controlled trial. *Ann Intern Med*. 2003;138:1-9.

21. **\*Women's Health Initiative Steering Committee.** Effects of conjugated equine estrogen in postmenopausal women with hysterectomy. *JAMA*. 2004;291:1701-1712.

22. **Woodson K, Lanza E, Tangrea JA, et al.** Hormone replacement therapy and colorectal adenoma recurrence among women in the polyp prevention trial. *JNCI*. 2001;93:1799-1805.

\*23. **Stefanick ML, Anderson GL, Margolis KL, et al.** Effects of conjugated equine estrogens on breast cancer and mammography screening in postmenopausal women with hysterectomy. *JAMA* 2006;295:1647-1657. *Subgroup analysis of women's status post hysterectomy who were randomized to the estrogen-only arm in the WHI showed no increase in breast cancer risk after 7.1 years of follow-up.*

24. **Collins J.** Hormones and breast cancer: Should practice be changed? *Obstet Gynecol* 2006;108:1352-3.

\*25. **Rossouw JE, Prentice RL, Manson JE, et al.** Postmenopausal hormone therapy and risk of cardiovascular disease by age and years since menopause. *JAMA*. 2007;297:1465-77.

\*26. **Cushman M, Kuller LH, Prentice R, et al. for the Women's Health Initiative Investigators.** Estrogen plus progestin and risk of venous thrombosis. *JAMA*. 2004;292:1573-80.

\*27. **Canonico M, Oger E, Plu-Bureau G, et al. for the Estrogen and Thromboembolism Risk (ESTHER) Study Group.** Hormone therapy and venous thromboembolism among postmenopausal women: impact of the route of estrogen administration and progestogens: the ESTHER study. *Circulation*. 2007;115:840-5. *The Estrogen and Thromboembolism Risk (ESTHER) Study Group, a French multicenter case-control study of VTE among postmenopausal women 45 to 70 years of age, confirmed that oral estrogen users had a 4-fold-increased VTE risk over nonusers, but found that transdermal estrogen and micronized progesterone were not associated with increased risk.*

\*28. **Cirillo DJ, Wallace RB, Rodabough RJ, et al.** Effect of estrogen therapy on gallbladder disease. *JAMA*. 2005;293:330-9.

\*29. **Manson JE, Allison MA, Rossouw JE, et al. for the WHI and WHI-CACS Investigators.** Estrogen therapy and coronary-artery calcification. *N Engl J Med*. 2007;356:2591-602.

\*30A. **Shumaker SA, Legault C, Kuller L, et al.** for the Women's Health Initiative Memory Study. Conjugated equine estrogens and incidence of probable dementia and mild cognitive impairment in postmenopausal women: Women's Health Initiative Memory Study. *JAMA*. 2004;291:2947-58. *The results of the Women's Health Initiative Memory Study (WHIMS), an ancillary study of the WHI, contradicted those of prior observational studies which suggested a protective effect of estrogen against dementia. In both the combined estrogen plus progestin group and the estrogen only group, there were more cases of dementia in women receiving hormone compared with placebo. However results did not reach statistical significance until data from both treatment groups were pooled, yielding an overall hazard ratio 1.76 for probable dementia with hormone therapy use.*

30B. **Beral V, Bull D, Green J, Million Women Study Collaborators.** Ovarian cancer and hormone replacement therapy in the Million Women Study. *Lancet* 2007;369:1703-10.

31. **Moorman PG, Schildkraut JM, Calingaert B, Halabi S, Berchuck A.** Menopausal hormones and risk of ovarian cancer. *Am J Obstet Gynecol*. 2005 ;193:76-82.

\*32. **Neves-E-Castro M.** An analysis of ovarian cancer in the Million Women Study *Gynecol Endocrinol*. 2007;23:410-3

\*33. **Rapp SR, Espeland MA, Shumaker SA, et al.** Effect of estrogen plus progestin on global cognitive function in postmenopausal women: the Women's Health Initiative Memory Study: a randomized controlled trial. *JAMA*. 2003; 289:2663-72.

34. **Resnick SM, Maki PM, Rapp SR, et al. for the Women's Health Initiative Study of Cognitive Aging Investigators.** Effects of combination estrogen plus progestin hormone treatment on cognition and affect. *J Clin Endocrinol Metab*. 2006;91:1802-10.

35. **Pefanco MA, Kenny AM, Kaplan RF, et al.** The effect of 3-year treatment with 0.25 mg/day of micronized 17beta-estradiol on cognitive function in older postmenopausal women. *J Am Geriatr Soc*. 2007;55:426-31.

\*36. **Hlatky MA, Boothroyd D, Vittinghoff E, Sharp P, Whooley MA for the Heart and Estrogen/Progestin Replacement Study (HERS) Research Group.** Quality-of-life and depressive symptoms in postmenopausal women after receiving hormone therapy: results from the Heart and Estrogen/Progestin Replacement Study (HERS) trial. *JAMA*. 2002;287:591-7.

37. **Bjarnason NH.** Endometrial cancer and hormone-replacement therapy *Lancet*. 2005;366:200-1

37a. **Hanggi W, Bersinger N, Altermatt HJ, Birkhauser MH.** Comparison of transvaginal ultrasonography and endometrial biopsy in endometrial surveillance in postmenopausal HRT users. *Maturitas*. 1997;27:133-43.

- 37b. **Langer RD, Pierce JJ, O'Hanlan KA, et al.** Transvaginal ultrasonography compared with endometrial biopsy for the detection of endometrial disease. Postmenopausal Estrogen/Progestin Interventions Trial. *N Engl J Med.* 1997;337:1792-8.
38. **Goldstein SR, Zeltser I, Horan CK, Snyder JR, Schwartz LB.** Ultrasonography-based triage for perimenopausal patients with abnormal uterine bleeding. *Am J Obstet Gynecol.* 1997;177:102-8.
39. **Weber AM, Belinson JL, Bradley LD, Piedmonte MR.** Vaginal ultrasonography versus endometrial biopsy in women with postmenopausal bleeding. *Am J Obstet Gynecol.* 1997;177:924-9.
- \*40. **Lethaby A, Suckling J, Barlow D, Farquhar CM, Jepson RG, Roberts H.** Hormone replacement therapy in postmenopausal women: endometrial hyperplasia and irregular bleeding. *Cochrane Database of Systematic Reviews.* 2005;2.
- \*41. **Fugh-Berman A, Bythrow J.** Bioidentical hormones for menopausal hormone therapy: Variations on a Theme. *JGIM.* 2007;22:1030-34.
- \*42. **El-Hage G, Eden JA, Manga RZ.** A double-blind, randomized, placebo-controlled trial of the effect of testosterone cream on the sexual motivation of menopausal hysterectomized women with hypoactive sexual desire disorder. *Climacteric.* 2007;10:335-43.
43. **Buster J, Kingsberg S, Aguirre O, et al.** Testosterone patch for low sexual desire in surgically menopausal women: a randomized trial. *Obstet Gynecol.* 2005;105:944-52.
44. **Tamimi RM, Hankinson SE, Chen WY, Rosner B, Colditz GA.** Combined estrogen and testosterone use and risk of breast cancer in postmenopausal women. *Arch Int Med.* 2006;166:1483-1489.
45. **Vogel VG, Costantino JP, Wickerham DL, et al. for the National Surgical Adjuvant Breast and Bowel Project (NSABP).** Effects of tamoxifen vs raloxifene on the risk of developing invasive breast cancer and other disease outcomes: the NSABP Study of Tamoxifen and Raloxifene (STAR) P-2 trial. *JAMA.* 2006;295:2727-41.
- \*46. **Barrett-Connor E, Mosca L, Collins P, et al. for the Raloxifene Use for The Heart (RUTH) Trial Investigators.** Effects of raloxifene on cardiovascular events and breast cancer in postmenopausal women. *N Engl J Med.* 2006;355:125-37.
47. **Barrett-Connor E, Grady D, Sashegyi A, et al. for the MORE Investigators (Multiple Outcomes of Raloxifene Evaluation).** Raloxifene and cardiovascular events in osteoporotic postmenopausal women: four-year results from the MORE (Multiple Outcomes of Raloxifene Evaluation) randomized trial. *JAMA.* 2002;287:847-57.
48. **Haimov-Kochman R, Barak-Glantz E, Arbel R, Leefsma M, Brzezinski A, Milwidsky A, Hochner-Celnikier D.** Gradual discontinuation of hormone therapy does not prevent the reappearance of climacteric symptoms: a randomized prospective study. *Menopause.* 2006;13:370-6.

49. **Ockene JK, Barad DH, Cochrane BB, et al.** Symptom experience after discontinuing use of estrogen plus progestin. *JAMA*. 2005;294:183-93.

\*50. **Chelbowski RT, Wactawski-Wende J, Ritenbaugh C, et al.** Estrogen plus progestin and colorectal cancer in postmenopausal women. *N Engl J Me*