Demystifying Menopause

- Anita Montes M.D., F.A.C.O.G.
 - A Woman's View OB/GYN
- 18 years post menopausal.....





What is Menopause?

Begin Period (menarche) - age 12.5

End Period (menopause) - age 51

Or earlier age if ovaries surgically removed

Life expectancy for women at turn of century: 49 years

Life expectancy for women in 1950: 72 years

Current life expectancy for women: 81 years





Menopausal Population

Current US statistics

Total population is 325 million.

50.8% women general population = 165 million

Baby boomers born 1946-1964 are now menopausal

65 and older group is **projected to more than double** from 46 million today to over 98 million by 2060.

This group that is currently 15 % of total population will rise to nearly 24 %.





What is Perimenopause?

The time period beginning often 8-10 yrs before menopause when hormone levels begin to become erratic.

Symptoms can include:

Irregular periods - in timing and/or flow	Muscle aches
Worse PMS before periods	Fertility issues (in women who are trying to conceive)
Breast tenderness	Headaches
Weight gain	Depression/anxiety/mood swings
Hair changes	Insomnia
Loss of sex drive/vaginal dryness	Fatigue
Concentration difficulties/forgetfulness	Dry skin





History of Hormones

- **Premarin™** was first marketed in 1942- there is more than 75 years of experience.
- 30 years ago: Premarin™ 0.625 mg or 1.25 mg was the only hormone choice.
- The names derives from the fact that it is produced from pregnant mares urine.
- Recommendation 30 yrs ago was to take it a lifetime once menopausal.
- We believed hormone use prevented all the symptoms of menopause, heart disease, pelvic relaxation, increased bone strength, and decreased Alzheimer's based on the observational studies at the time. We did already know that hormones could cause increase blood clots.





History of Hormones

WHI (Women's Health Initiative) study was a randomized controlled study started in 1993 and ended in 2002.

Objectives were to verify hormone effect on heart disease prevention, bone strength and breast cancer.

Premarin™ was the estrogen used. **Provera™** was the progestogen used. (The companies that make these funded the study)

The study was stopped early because of an association with an increased risk of breast cancer, increased risk of cardiovascular disease, and "more harm than benefit overall in the combined estrogen and progesterone group".

Premarin™ sales fell, Wyeth and gynecologists were stunned, and now 80% fewer patients take hormones.





"New" Hormones Available

Oral Estrogen	Estrogen Patches	Estrogen cream/spray	Oral Combination	Patch combination
Estrace	Alora	Divigel	Premphase	Combipatch
Premarin	Climara	EstroGel	Prempro	Estalis
Enjuvia	Estraderm	Elestrin	Femhrt	ClimaraPro
Menest	Estradot	Evamist	Activella	
Estragyn	Minivelle		Angeliq	
	Oesclim		Prefest	
	Vivelle Dot			

Many claimed to not have the same risks as Premarin™.

Bioidentical hormones became popular.





When discussing hormones, there are 2 types of patients that take hormones

Women with a uterus – need estrogen and progestogen

(for protection from uterine cancer)

Women without a uterus – need estrogen only

Risk is different for each group





Initial report of findings of WHI Study from 2002:

Per 10,000 women, when comparing the hormone using group vs. the placebo group there were:

8 more breast cancers (0.08%)

6 cases of coronary heart disease

8 more strokes

8 more pulmonary emboli (clots)

6 fewer colorectal cancers

47 fewer osteoporotic fractures





There were problems/inconsistencies with the original WHI study....

- The average age of patients starting the study was 63
- No increased death rate in treated vs placebo group
- The estrogen only group never showed the risks of the combined estrogen/progestin group





The WHI study has been re-evaluated....numerous times

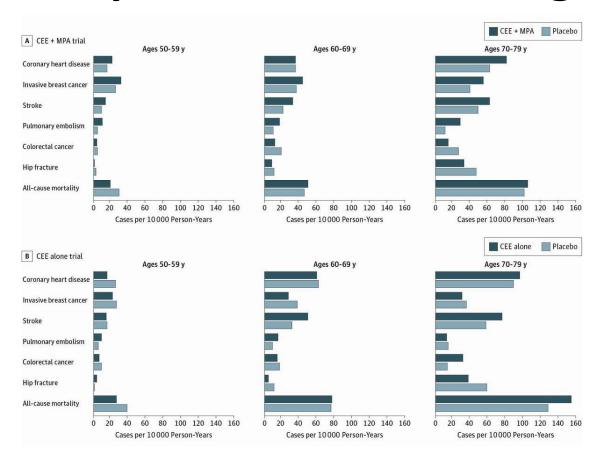
Results have been broken down by age group

The Estrogen/Progestin group has been evaluated separately from the Estrogen only group





Comparative WHI Findings







What are the lessons learned?

- Use the smallest effective dose
 - Lower doses were possible than what was previously used
- Start within 10 years of the menopause and/or < 60 yrs
 - Beginning in women over 60 clearly associated with more risks
- Use to treat hot flashes, bone thinning, vaginal sx
 - Not for cardio-protection, dementia, prevention of colon cancer, or urinary health
- Reassess need every year
 - Consider at least 5 years if combined HRT. ? Longer (the increased risk seems to occur after 5 yrs)
 - Consider longer term use if needed when using ERT only (some studies show no increase in risk after using 10-15 yrs)
 - No data to support "routine" discontinuation at age 65





Who Should Consider Hormones?

- Significant Symptoms
 - Hot Flashes and night sweats- NOT INCONSEQUENTIAL
 - Insomnia
 - Mood swings
- Known bone thinning, or very young or at risk for bone thinning options if only symptom
- Vaginal/Vulvar Symptoms options if only symptom
 - Decreased libido
 - Pain with sex
 - Vaginal dryness/Chronic burning
- Frequent bladder infections (vaginal estrogen)





Alternative Treatments

Hot Flashes:

Black Cohosh (Remifemin™) 20 mg twice daily	Effexor™
Vitamin E – 500 IU daily	Paxil™
Soy – 60 gm daily	Celexa™
St John's Wort – 2-4 mg daily	Clonidine™
	Pregabalin (<i>Lyrica</i> ™)
Remember to check:	Gabapentin (<i>Neurontin</i> ™)

Bone Loss:

Calcium, Vitamin D, Weight Bearing Exercise	Prolia™ injections every 6 months prevents bone resorption
Bisphosphonates, daily, weekly, monthly. Or yearly injection- prevents bone resorption	Evista ™daily. Binds to estrogen receptors. Increase clot formation





Vaginal Treatment Options

Mona Lisa Touch™ laser therapy	1-3 treatments
Intrarosa™ – DHEA -metabolizes to estrogen, testosterone - daily suppositories	Can't use with breast cancer hx. Risk of clots.
Osphena™ – daily by mouth	"anti estrogen". No use with breast cancer. Risk of clots
Lubricants - <i>Astroglide™</i>	Water based
Estrogen cream- <i>Premarin™, Estrace™,</i> Compounded twice weekly	No progesterone needed even if uterus.
Vagifem™ tablets twice weekly	No association with increased risk of clots or breast cancer.
Estring™/Femring™ every 3 months	Must discuss use in breast cancer pt with oncology





Final Considerations

Compounded Bioidentical HRT/ERT

- No evidence it is safer or works better than current pharmaceuticals
- Not regulated as to safety or impurity
- Not recommended by ACOG

Transdermal doses vs oral

- Consider if oral not effective or not tolerated
- Transdermal HRT/ERT bypasses the liver
 - · less gall bladder issues (consider if history of gallstones for example)
 - less elevation of triglycerides (consider if patient has known elevation
- Seems to be associated with fewer DVT
- Based on observational studies



