Are Hormonal Contraceptives Preventive Healthcare?

1. **Cardiovascular Disease, the Leading Cause of Death in Women**

The Women’s Health Initiative was a randomized controlled trial studying hormone replacement in postmenopausal women. The study was stopped early due to serious side effects, including a 29% increased risk of cardiovascular events in women taking the hormone replacement. Prior to the study, it was standard of care to give women the replacement due to large observational studies showing a 40-50% improvement in cardiovascular risk. After the study came out, there was a dramatic change in clinical practice because clearly hormone replacement could no longer be viewed as preventive medicine. (JAMA. 2002 Jul 17;288(3):321-22) Current oral contraceptives are 5-10 times more potent than the hormone replacement therapy. The safety studies for hormonal contraception are based on large observational studies which greatly underestimated the risk in hormone replacement therapy. Since a randomized, placebo controlled trial is unethical with birth control pills, the study that would most clearly show the harm cannot be performed.

Tanner, et al. (NEJM 2001 345:1787) found women on OC’s (2nd and 3rd generation) have twice the likelihood of having a heart attack.

Reitzchel (Circulation. 2007;116:II_800-II_801) found 40% higher odds of a woman having carotid plaques if she has been on OC’s for more than 10 years.

Ford, E.( JACC. Nov 2007:2128-32) reports that since 1997, the cardiovascular death rate of women from age 35-44 has increased steadily by 1.3%. During this time, OC use increased from 4% to 17%.

To reduce bias found in industry sponsored studies and journals (advertisements), the FDA recently funded a large retrospective cohort study. The study had 835,826 women and found the newest hormonal contraceptives, like Yaz, had twice the risk of cardiovascular events compared to the older generation of OC’s. The risk of blood clots was also increased in the newer pills, the vaginal ring and contraceptive patch, with a risk ratio of 1.54-1.76 compared to older pills. (Combined Hormonal Contraceptives and the Risk of Cardiovascular Disease Endpoints, www.fda.gov/downloads/Drugs/DrugSafety/UCM277384.pdf)

Van Hylckama Vlieg( BMJ 2009;339:b2921) found the currently available OC’s increase the risk of blood clots 5 fold, with the newer agents increasing the risk almost 7 fold.

Lidegaard (NEJM 2012;366:2257-66) evaluated 1,626,158 women in a Danish Cohort Study for first thrombotic stroke or first myocardial infarction. Relative risk for myocardial infarction varied between types of pills between 1.4 to 3.7. Relative risk for first stroke was 1.6-1.97. Relative risk of stroke with the vaginal ring was 2.49. Women aged 45-49 had 100 times the risk of myocardial infarction on OC’s compared to women 15-19, suggesting the risk from the contraceptive is much greater for older women. Smoking did not confound the results. Even though this study suggests every year OC’s would cause a heart attack or stroke in 10-20 women for every 100,000 women using hormonal contraception, the editorial felt this was safe enough for women.

The Women’s Health Initiative was stopped early due to the increased risk of breast cancer, with a Hazard Ratio of 1.26. (26% increased chance of breast cancer) (JAMA 2002 Jul 17;288(3)321-33) Giving pills 10 times more potent will not be safer.

Kahlenborn (Mayo Clinic Proc. 2006;81(10):1290-1302) performed a meta-analysis of case control studies after 1980 and found a 19% increased risk of breast cancer in women who have taken OC’s, and a 44% increased Odds Ratio if OC’s were taken before their first full term pregnancy.

The epidemiology of breast cancer is consistent with the effect of OC’s on breast cancer. There has been a dramatic increase in the incidence of breast cancer since 1975, which only partially improved after HRT was no longer given for preventive care. (National Cancer Institute SEER data, 2003)

Cogliano (Lancet 2007; 370: 1609–21) reviewed data from 24 epidemiological studies and found a woman’s risk of invasive cervical cancer if she is currently on OC’s and has used them for at least 5 years is about doubled (risk of 1.9).

Due to the effect of OC’s on breast, liver and cervical cancer, the World Health Organization declared combination oral contraceptives as Group I carcinogens, the same class as tobacco. (WHO IARC. Lancet Oncology. Aug 2005:552-3)

3. Stroke, the Third Leading Cause of Death in Women

Gillum (JAMA. 2000 Jul 5;284(1):72-8) in a meta-analysis of 54 studies found the risk of ischemic stroke in current OC users if 2.75. Women with migraines have a risk of stroke of 2.16, but if they are also on OC’s, their risk increases to 8.7 fold. (BMJ. 2005;330(7482):63.)

4. Autoimmune Disease

Women currently on OC’s have a 50% increased risk of developing lupus. (Bernier MO Arthritis Rheum. 2009 Apr 15;61(4):476-81. Costenbader KH; Arthritis Rheum. 2007 Apr;56(4):1251-62)

5. Cognitive Function

Shumaker (JAMA. 2003;289(20):2651-62) In the Women’s Health Initiative Memory Study, women on HRT had twice the risk of developing probable dementia. Giving women OC’s which are 10 times more potent is probably not making them smarter.

Lynn Keenan, MD President, California Association of Natural Family Planning canfp.org 1-877-33-CANFP info@canfp.org