Obesity & Contraceptive Dosing

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Body Weight and Risk of Oral Contraceptive Failure

Victoria L. Holt, M.D., 2011, Kara L. Carlisle-Haugen, M.S., and Janet R. Dubrow, M.D.

OBJECTIVE: To examine the hypothesis that higher body weight increases the risk of oral contraceptive (OC) failure.

METHODS: We conducted a retrospective cohort analysis of women who participated in the National Health and Nutrition Examination Survey (NHANES) III and NHANES IV. Participants were categorized by weight status as normal weight, overweight, and obese. We compared the rate of OC failure across weight categories using logistic regression analysis. We also estimated the effect of body weight on the risk of OC failure using a Cox proportional hazards regression model.

RESULTS: During 2022 pregnancies, 136 women in the normal weight category had OC failure, compared to 136 women in the overweight category and 136 women in the obese category. The rate of OC failure was higher in the overweight and obese categories than in the normal weight category. The adjusted hazard ratio for OC failure in the overweight category was 1.5 (95% CI 1.2-1.8) and in the obese category was 1.9 (95% CI 1.5-2.3).

In a 1998 letter to the Meds of the World, the World Health Organization (WHO) reported a cluster of low-dose OC failures among relatively heavy women. A recent study by Yeh and colleagues found that women with a body mass index (BMI) greater than 25 kg/m² had a significantly increased risk of OC failure. The authors concluded that the increased risk was independent of age, smoking status, and concomitant use of other medications.

What determines contraceptive effectiveness?

Drug efficacy x adherence x continuation
Fecundability x coital frequency

HOW WELL DOES BIRTH CONTROL WORK?

What is your chance of getting pregnant?

Less than 1 in 100

Really, really well
The Implant  Up to 5 years
Works, hassle-free...

IUDs  Up to 7 years

Copper IUD  Up to 12 years

Sterilization  Forever

Pretty well
The Pill  For it to work best, use it... Every. Single. Day.

The Patch  Every week

The Ring  Every month

The Shot  Every 3 months

Not as well

Pulling Out

Fertility Awareness

Internal Condom

Condom

Use a condom with any other method for protection from STDs.

For each of these methods to work, you or your partner have to use it every single time you have sex.

FYI, without birth control, over 90 in 100 young people get pregnant in a year.

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Short-acting methods = adherence challenges

Winner, NEJM 2012
Confirmed Compliance
Novel Levonorgestrel Injection

Ovulation-Free Survival (%)

Days after Injection

Normal BMI
Obese

Edelman et al 2017 Contraception; NICHD CCTN Task Order 11
Your chance of pregnancy each month declines with age.

A healthy 30-year old woman has about a 20% chance of getting pregnant each month.

A healthy 40-year old woman has about a 5% chance of getting pregnant each month.

For more information, visit www.reproductivefacts.org
Contraceptive steroid hormone levels & obesity

LNG Plasma Concentration

Day 5
Day 10
Day 20

Edelman, et al 2010; NIH R03HD 053611
"Pill" failure by BMI

Adjusted HR 1.5 (95% CI 1.3, 1.8) for contraceptive failure in women with $\geq 35 \text{ kg/m}^2$ versus $\leq 35 \text{ kg/m}^2$

Emergency contraception (EC) failure in obese versus normal body mass index (BMI) women:

- Any EC: OR 3.6 (CI 1.96-6.53)
- LNG EC: OR 4.41 (CI 2.05-9.44)*
- UPA EC: OR 2.62 (CI 0.89-7)

Glasier et al 2011 Contraception; Festin 2017
Levonorgestrel Emergency Contraception
Single & Double Dosing

Normal BMI 1 dose
Obese BMI 1 dose
Obese BMI 2 doses

Edelman et al 2016 Contraception; OHSU MRF Funding
Single vs. double dosing LNG EC
Time to rupture

Per Protocol Analysis. Censored at day 5
75% probability of no rupture is day 2 for both groups

2022 Edelman Obstet Gynecol
FDA In Brief: FDA issues draft guidance aiming to clarify recommendations for clinical trials for hormonal contraceptives

July 11, 2019

Media Inquiries

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“Over the years, the FDA has recommended that companies study contraceptives in the most inclusive way possible to help ensure clinical trials reflect how these products are actually used and the latest science around them,” said Amy Abernethy, M.D. Ph.D., FDA’s principal deputy commissioner of food and drugs. “Today, the agency is issuing, for public comment, a new draft guidance to support innovation and scientific advances in women’s health and help ensure contraceptive products are adequately studied. For example, it recommends that clinical trial design for contraceptives should include women of all childbearing ages regardless of their weight, including those who are younger and older, and women who are obese.”
Contraceptive Pill: Age, BMI, & VTE Risk

Rabe T, 2011
Summary

1. Obesity impacts contraceptive steroid levels
2. Adherence plays a major role in contraceptive failure
3. Values & preferences play key roles in contraceptive choice
4. Using contraception prevents more pregnancies than not using contraception.