## Contraceptive for obese women

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# considerations

#### By Beth Kelsey, EdD, WHNP-BC

hirty-four percent of the U.S. adult population is obese (body mass index [BMI] equal or greater than 30) with the prevalence in reproductive-age women ranging from 30.5% in 20- to 30-year-olds to as high as 41% in women age 40 and older.<sup>1</sup> Obesity is associated with severe health consequences including an increased risk for cardiovascular disease, metabolic disorders, and some cancers.<sup>2</sup> Obese women are at increased risk for pregnancy complications such as hypertensive disorders, gestational diabetes, postpartum hemorrhage, and infections.<sup>3</sup>

NPs are major providers of reproductive healthcare for women and it is important for them to be equipped with the most up-to-date knowledge to provide evidence-based care individualized to each woman's contraceptive needs and health profile. It is essential that obese women who choose to use contraception receive effective contraception without increasing their health risks.

#### Case study

Alice is a 22-year-old obese woman. She has struggled with her weight since early adolescence. Currently, she weighs 216 pounds and is 5 feet 5 inches with a BMI of 36. She is in college and has a boyfriend with whom she plans to be sexually active. She has no history of venous thromboembolism (VTE) and does not smoke. Her family history is significant for high cholesterol in her father and 28-year-old brother, and type 2 diabetes in her maternal grandmother. There is no family history of premature heart disease or stroke. Her BP with an appropriately sized cuff is 120/70 mm Hg.

*Questions to consider in helping Alice choose an effective and safe method of contraception include the following:* 

Are any contraceptive methods contraindicated because of her obesity?

*Does obesity impact the effectiveness of any contraceptive methods?* 

Will any of the contraceptive methods cause her to gain more weight or to have more difficulty in losing weight?

There are many effective and safe contraceptive methods that meet Alice's personal needs. The NP plays an important role in helping patients make contraceptive choices that fit their personal needs while considering health and disease risk factors. Appropriate assessment, counseling, and decision-making should be based on upto-date, evidence-based findings. The NP must be able to interpret these findings and put them in perspective for the individual woman.

Issues concerning the impact concomitant obesity and hormonal contraceptive use may have on risk for VTE, cardiovascular disease, and diabetes are discussed in this article. The relationship between obesity and contraceptive effectiveness and the potential for a contraceptive method to contribute to weight gain are also discussed.

#### Venous thromboembolism

Obesity, pregnancy, family history of VTE, inherited or acquired thrombophilia, older age, and the use of estrogencontaining contraceptives are independent risk factors for VTE.<sup>4</sup> The likelihood of VTE increases as risk factors are combined. VTE remains a rare event in women using combination oral contraceptives (COCs) without other risk factors. Until recently, the reference figures used to compare risk of VTE in nonpregnant women not using COC with risk of VTE in COC users have been an absolute risk of 1 event per 10,000 annually in nonpregnant women not using COC and 3 events per 10,000 in women using COC.<sup>2,4</sup>

More recent estimates for VTE incidence in nonpregnant women not using COC used results from communitybased or cohort studies and more sophisticated technology for validation of an event. These studies indicate the absolute risk ranges from 5 to 10 events per 10,000 annually.<sup>5-7</sup>

The new data for women not using COC leads to questions about the previously estimated three-fold increased risk (3 events per 10,000) of VTE in low estrogen dose (35 mcg or less) COC users.<sup>2,4</sup> One recent study reported an incidence of 4.4 events per 10,000 in nonpregnant women not using COC and an incidence of approximately 9 events per 10,000 in COC users. These numbers suggest a twofold increase in relative risk for COC users.<sup>8</sup> To put VTE risk with COC use in further prospective, the absolute risk of VTE during pregnancy is 19.9 events per 10,000 pregnant women annually.<sup>5,9</sup>

Obese women who use COC are at an increased risk of VTE compared with nonobese women using COC.<sup>7, 20-23</sup> Data from one large case-control study were used to estimate the absolute risk for VTE among COC users in each BMI category. The absolute risk for VTE among COC users with a BMI of 30 to 34 is estimated at 6 events per 10,000 annually, and for COC users with a BMI of 35 or higher, the estimate is 10.5 events per 10,000 annually.<sup>8</sup> In comparison the risk for VTE among COC users with BMI of 20-24 is estimated as 4.7 events per 10,000.<sup>9</sup>

The risk of VTE in any woman using other combination hormonal contraceptive (CHC) methods has not been as well studied. Reports of increased risk for VTE in women using the transdermal hormonal contraceptive patch were not based on studies of clinical outcomes but

contraceptive use. <sup>3</sup>	
Category 1	Condition with no restriction on use of the contraceptive method
Category 2	Condition where advantages of us- ing method generally outweigh the theoretical or proven risks
Category 3	Condition where theoretical or proven risks usually outweigh the advantages of using the method
Category 4	Condition that represents unaccept- able health risk if the contraceptive method is used

#### WHO medical eligibility criteria for contraceptive use<sup>16</sup>

rather on nonclinical pharmacologic studies. Product labeling for the transdermal contraceptive patch describes higher steady-state concentrations and lower peak concentrations of ethinyl estradiol (EE) with the patch than in COCs containing 35 mcg EE. Epidemiologic data demonstrate that this pharmacokinetic profile does not place women using the transdermal contraceptive patch at higher risk for VTE than those using a 35 mcg COC.<sup>2,24,25</sup> No data are available concerning VTE risk using the vaginal contraceptive ring. Although data is limited, studies have shown no significant increase in VTE incidence in either nonobese or obese women using progestin-only methods.<sup>4,5</sup>

Because the absolute risk for VTE is small, the World Health Organization (WHO) has placed CHC use by obese women in category 2, which indicates that the advantages of using the method generally outweigh the theoretical or proven risks<sup>16</sup> (see *WHO medical eligibility criteria for contraceptive use*). The American College of Obstetricians and Gynecologists (ACOG) recommends that CHC be used with caution in obese women older than 35 because of the increased risk for VTE.<sup>27</sup>

#### Cardiovascular disease

Myocardial infarction (MI) and stroke are rare events in women of reproductive age. Major risk factors for MI and stroke include smoking, increased age, uncontrolled hypertension, and type 2 diabetes. Obesity presents a risk for cardiovascular disease associated with an increased incidence of hypertension, type 2 diabetes, and dyslipidemia. More than 17% of coronary heart disease cases are attributable to obesity.<sup>2</sup> Abdominal obesity, in particular, is recognized as an independent risk factor for ischemic stroke.<sup>4</sup>

The majority of evidence indicates that low-dose CHC use does not increase the risk for MI or stroke in nonsmoking, normotensive women. However, both the estrogen and the progestin components of hormonal contraceptive methods have some impact on lipid levels. The estrogen component increases high-density lipoprotein (HDL), decreases low-density lipoprotein (LDL), and increases triglycerides. The triglyceride increases are moderate and considered to be balanced by the benefit of the HDL and LDL changes. The progestin component of the CHC methods increases LDL levels while decreasing HDL and triglyceride levels.<sup>28</sup>

Progestin may affect net lipid changes. Low-androgenic progestins balance the lipid effects of estrogen and progestin components with a more favorable overall profile. The progestins in both the transdermal contraceptive patch and the contraceptive vaginal ring have low androgenicity.<sup>27</sup>

Desogestrel and norgestimate are both low-androgenic progestins used in available COCs. Drospirenone has no androgenic effect<sup>29</sup> (see *COC formulations with low-androgenic progestins*).

Use of the injectable depot medroxyprogesterone acetate (DMPA) decreases HDL, increases LDL, and has no effect on triglyceride levels.<sup>27</sup> Studies of injectable and oral progestin-only contraceptive use have found no significant changes in risk for MI or stroke compared with nonusers.<sup>22</sup> No changes in lipid metabolism have been found related to use of etonogestrel contraceptive implant.<sup>22</sup> Two prospective studies of women using the levonorgestrel intrauterine system (LNG-IUS) showed no significant changes from baseline in lipid levels.<sup>23,24</sup>

It is important to keep in mind that lipids are surrogate measures and that the changes seen with hormonal contraceptive use do not necessarily correlate with effects on cardiovascular disease.<sup>12</sup> WHO has placed CHC use by women with known hyperlipidemia in category 2 or 3 depending on type and severity of the condition and presence of other cardiovascular risk factors. WHO has placed the use of progestin-only methods by women with known hyperlipidemia in category 2.<sup>16</sup>

#### Diabetes

More than 60% of type 2 diabetes cases are attributable to obesity. Data reassure that hormonal contraception use

does not precipitate the development of type 2 diabetes. These data apply to obese women as well as women with a history of gestational diabetes.<sup>2,27</sup> CHC and progestin-only contraceptive methods in doses used today have a small effect on carbohydrate metabolism that is not clinically significant.

Studies indicate the use of CHC by women with either type 1 or type 2 diabetes does not accelerate the progression of the condition.<sup>25</sup>

WHO has placed CHC use by women with diabetes who have no vascular complications in category 2. CHC use by women who have diabetes with vascular disease or with more than 20 years' duration belong to category 3 or 4 depending on the severity of the condition.<sup>16</sup> Obesity in combination with metabolic factors such as poorly controlled carbohydrate metabolism, blood glucose levels, or lipid levels may constitute a contraindication to the use of CHC.<sup>23</sup>

Based on concerns of reduced HDL levels in DMPA users, WHO has placed use of this method by diabetic women without vascular disease in category 2 and diabetic women with vascular disease or with greater than 20 years' duration in category 3. Progestin-only pills (POPs), progestin-only

### COC formulations with low-androgenic progestins<sup>14</sup>

progeetine	
Low-androgenic progestins	COC brand names—examples
Desogestrel	Mircette, Desogen, Cyclessa, Ortho-Cept, Apri, Reclipsen
Norgestimate	Ortho-Cyclen, Ortho Tri-Cyclen, Ortho Tri-Cyclen Lo, Sprintec, Tri-Sprintec, MonoNessa, TriNessa
Drospirenone	Yasmin, YAZ

implants, and LNG-IUS are category 2 for diabetic women with or without vascular complications.<sup>16</sup>

#### Contraceptive method effectiveness

Theoretically, increased body fat can affect hormonal contraception effectiveness through increased basal metabolic rate, increased hepatic enzymatic metabolism, and/or increased drug sequestration in fat.<sup>26,27</sup> Data about whether obesity may decrease the efficacy of CHC are conflicting. Two recent large prospective studies found no significant increase in pregnancy risk related to COC failure among obese women compared with nonobese women.<sup>28</sup> There have been several small studies showing evidence that COC

Obesity in combination with metabolic factors such as poorly controlled lipid levels may constitute a contraindication for CHC.



and transdermal contraceptive methods may be less effective in obese women. In one study, the estimated attributable risk for COC failure from obesity was an additional two to four pregnancies per 100 women-years.<sup>27</sup> Higher rates of pregnancy were seen in obese women using lowdose COCs.<sup>29</sup> The pooled data from three studies of the transdermal contraceptive patch showed a higher rate of method failure in women weighing 198 pounds or more compared with women weighing less.<sup>2</sup>

However, the data also indicate that with correct and consistent use, both methods remain highly effective for obese women. Women who are obese should be advised of the possibility of some decrease in efficacy so they can make an informed choice concerning their contraceptive method. COC formulations with 35 mcg of estrogen might be considered, as some data indicate higher rates of failure among obese women using lower estrogen dose formulations.<sup>2</sup> Analysis of vaginal contraceptive ring data found no higher rate of pregnancies in obese women using this method compared with nonobese women.<sup>2,26</sup>

Although there are no data showing that POPs are less effective in obese women, this may be speculated from the CHC method findings. A small, pharmacokinetic study found lower serum etonogestrel levels in heavier women using the progestin-only contraceptive implant. An analysis of the small number of pregnancies occurring while on this method has indicated that increased body weight does not decrease the efficacy and the implant does not need to be replaced earlier than the normal 3 years in obese women.<sup>3,30</sup> No increase in contraceptive failure has been noted with the use of DMPA or the LNG-IUS related to body weight.<sup>2,26,27</sup>

#### Intrauterine contraceptive methods

There are no specific contraindications to copper- or hormone-containing intrauterine contraceptive methods related to obesity. The local effect of a progestin on the endometrium in women using the LNG-IUS may offer protection against endometrial hyperplasia. This would be a noncontraceptive benefit for obese women who are considered to be at increased risk for endometrial cancer.<sup>17,25</sup>

Intrauterine device (IUD) insertion may present some challenges in obese women. Determining the position of the uterus may be difficult; however, ultrasound may be used, if needed. Adequate visualization of the cervix in obese



There are no specific contraindications to copper- or hormone-containing intrauterine contraceptive methods related to obesity.

patients is sometimes hampered by inward bulging of the vaginal walls. Positioning the patient so that she is comfortable and relaxed, along with the use of an appropriate-sized speculum, is important. A condom cut at the end can be inserted over a speculum to hold vaginal folds out of the way.

#### Weight changes and contraception

It remains a misperception among many women as well as some clinicians that CHC causes weight gain. This is a common reason women are afraid to use or discontinue using these effective contraceptive methods. Data from numerous studies have shown no association between the use of CHC and significant weight gain.<sup>2,31,32</sup>

There is still controversy over the impact of DMPA on weight. The various study designs, measurements used, and length of follow-up have produced conflicting results. In a prospective, randomized placebo-controlled study of 20 normal weight women, DMPA was not associated with increased food intake, decreased resting energy expenditure, or weight gain.33 An analysis of three clinical studies in users of DMPA showed fluctuation in weight ranging from increases of more than 20 pounds to decreases of more than 20 pounds over 1 to 3 years of use. The majority of women showed only minor fluctuations in weight of +/- 5 pounds. Such weight gain or loss is not uncommon in reproductive age women over a 1 to 3 year time period regardless of contraception use. These three studies found no significant differences in weight fluctuations in underweight, normal weight, overweight, or obese women.34 However, two longitudinal, prospective studies do raise concern about weight gain in DMPA users. One of these studies followed women 18 to 35 years of age using DMPA

(n = 178) or no hormonal contraception (n = 145) for 30 months to compare changes in weight, body fat, and ratio of central to peripheral fat in the two groups. The DMPA users had significantly greater increases in all three parameters compared with the control group.<sup>35</sup>

In the second prospective study, 450 adolescent females ages 12 to 18 years using DMPA, COC, or no hormonal contraception were followed for 18 months to compare changes in weight among the three groups. Weight gain in obese girls using DMPA was significantly greater than weight gain in obese girls using COC or no hormonal method.

Weight gain in obese girls using DMPA was also greater than weight gain of nonobese girls in all three groups.<sup>32</sup> A retrospective study of 239 adolescent females using DMPA or COC for 1 year provided similar results.<sup>36</sup> WHO criteria for DMPA use by obese females overall remains a category 1. However,

DMPA use by obese adolescents (menarche to less than 18 years of age) has been designated as a category 2 condition (WHO).<sup>16</sup>

Weight changes with the etonogestrel contraceptive implant are comparable to those in women not using hormonal contraception.<sup>37</sup> A prospective study of 82 women using LNG-IUS for 12 continuous years demonstrated no significant weight gain.<sup>38</sup>

#### Pharmacologic and surgical treatments of obesity

Medications used in the treatment of obesity include sympathomimetics such as phentermine (Adipex-P) and phendimetrazine tartrate (Bontril); the mixed neurotransmitter reuptake inhibitor, sibutramine monohydrate (Meridia); and the lipase inhibitor, orlistat (Xenical). No interaction causing decreased hormonal contraceptive efficacy has been noted with any of these medications. Early studies of orlistat, a selective, potent gastrointestinal lipase inhibitor, demonstrated that it had no negative effect on the action of oral contraceptives.<sup>39</sup>

With the growing number of obese women undergoing bariatric surgery, clinicians need to consider the impact that malabsorption may have on hormonal contraceptive efficacy. One study thus far has found decreased absorption of progestins and a decreased progestin to sex hormonebinding globulin ratio in women who have undergone jejunoileal bypass surgery compared with women who have not undergone this surgery. This may imply a reduced efficacy for oral hormonal contraceptive methods especially for POPs.<sup>27</sup> In another study, 2 out of 9 women who underwent a biliopancreatic diversion became pregnant in the postoperative period while using the same COC they were taking prior to surgery.40 There should be no impact on effectiveness of hormonal contraception delivered by injection, implant, transdermal patch, vaginal ring, or intrauterine system.19

#### When to evaluate further

None of the contraceptive methods are contraindicated based solely on obesity.<sup>16</sup> This article does not include an in-depth discussion of the implications of the presence of multiple risk factors for cardiovascular disease (see *Summary of WHO category 3 or 4 recommendations for CHC use if risks for cardiovascular disease are present* and *Summary of WHO category 3 or 4 recommendations for progestin-only methods use if risks for cardiovascular disease are present*).<sup>16</sup>

Obese women are at increased risk for VTE, hypertension, dyslipidemia, type 2 diabetes, MI, and stroke. Smoking increases the risk for MI and stroke, and risks for VTE, MI, and stroke increase with age.<sup>4</sup> Obese women with any additional risk factors for cardiovascular disease need further evaluation. CHC methods may be contraindicated. An individualized approach should be used that considers each woman's contraceptive needs and health profile.

#### Major points

- Contraceptive counseling for an obese woman wanting to use CHC should consider her individual risk factors for VTE.
- The use of hormonal contraception does not precipitate development of type 2 diabetes or accelerate its progression.
- Hormonal contraception does have some impact on lipid levels. The use of CHC-containing progestins with low androgenic activity may be most appropriate.

#### Summary of WHO category 3 or 4 recommendations for CHC use if risks for cardiovascular disease are present<sup>16</sup>

Condition	Category	
Smoking and 35 years of age and older	3 (less than 15 cigarettes/day) 4 (15 or more cigarettes/day)	
Controlled hypertension	3	
Hypertension with systolic ≥160 mm Hg or diastolic ≥100 mm Hg or with vascular disease	4	
History of or current venous thromboembolism	4	
Major surgery with prolonged immobilization	4	
Known thrombogenic mutations	4	
History of or current ischemic heart disease or stroke	4	
Known hyperlipidemias	2 or 3 (assess hyper- lipidemia according to type, severity, and pres- ence of other cardiovas- cular risk factors)	
Complicated heart valve disease	4	
Diabetes with vascular disease or with over 20 years' duration	3 or 4 (assess according to severity of condition)	
Migraine headache with aura	4	
Multiple risk factors for arterial cardiovascular disease (such as older age, smoking, hypertension, diabetes)	3 or 4 (assess on individual basis in relation to severity of risk factors)	
usually outweigh the benefits of using the method. Category 4 indicates a condition in which there is an unacceptable health risk if the contraceptive method is used.		

- Obesity may decrease the efficacy of COCs and transdermal contraceptives. However, these are effective methods that may still be appropriate.
- POPs may be less effective in obese women. Higher rates of pregnancy, however, have not been noted in obese women using DMPA, etonogestrel implants, or LNG-IUS.

#### Summary of WHO category 3 or 4 recommendations for progestin-only method use if risks for cardiovascular disease are present<sup>16</sup>

Condition	Category	
Hypertension with systolic ≥160 mm Hg or diastolic ≥100 mm Hg or with vascular disease	3 (DMPA or other progestin-only injectable methods)	
Acute DVT or PE	3 (all progestin-only methods)	
History of or current ischemic heart disease or stroke	3 (DMPA or other progestin-only injectable methods initiation or continuation) 3 (POP, progestin-only im- plants, for continuation of method if event oc- curs while using)	
Diabetes with vascular disease or with over 20 years' duration	3 (DMPA or other progestin-only injectable methods)	
Systemic lupus erythematosus with positive or unknown antiphospholipid antibodies	3 (all progestin-only methods)	
Multiple risk factors for arterial cardiovascular disease (such as older age, smoking, hypertension, diabetes)	3 (DMPA or other progestin-only injectable methods)	
Category 3 indicates a condition in which the theoretical or proven risks		

Category 3 indicates a condition in which the theoretical or proven risks usually outweigh the benefits of using the method. Category 4 indicates a condition in which there is an unacceptable health risk if the contraceptive method is used.

- Women should be counseled that CHC use has not been shown to cause significant weight gain. The data on weight gain, specifically in obese adolescents using DPMA, should be discussed. Working with an obese patient to achieve weight loss is most important.
- Women who smoke should be counseled about the risks and provided with smoking cessation assistance. Nonsmokers should be advised of the risks of smoking and encouraged not to start smoking.

#### Case study patient revisited

Alice is young, does not smoke, and has a normal BP. She has no history of VTE. She is in need of an effective method of contraception. All of the hormonal and intrauterine contraception methods can be appropriate choices. Alice should be counseled that there might be some decrease in effectiveness of CHC methods and progestin-only pills related to weight. If she chooses one of the CHC methods, she should be counseled concerning possible increased risk for VTE. If she is considering DMPA, she should be advised of data concerning weight gain. Barrier methods are also options, although they have higher failure rates.

Screening for lipid disorders and diabetes is not required prior to initiation of hormonal contraception.<sup>16</sup> Alice does have a family history suggestive of familial hyperlipidemia. As part of total healthcare, the clinician may consider screening for lipid disorders. Most important, the clinician should counsel Alice concerning nutrition and exercise and provide her with referrals for assistance with a weight loss program.

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Beth Kelsey is an assistant professor at the School of Nursing, Ball State University Muncie, Ind.

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