LESS EFFECTIVE?
Review of hormonal contraception in obese women

Sara Whetstone, MD, MHS

OBJECTIVES
◆ To describe the safety of hormonal contraception among obese women
◆ To review evidence about contraceptive effectiveness among women who are obese

I HAVE NO DISCLOSURES

OBESITY IN THE US
OBESITY

- Defined by body mass index (BMI)
- Calculated using weight and height

\[ BMI = \frac{\text{weight (kg)}}{\text{height (m)}^2} \]

BMI CATEGORIES

<table>
<thead>
<tr>
<th>Terminology</th>
<th>BMI (kg/m²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Underweight</td>
<td>&lt; 18.5</td>
</tr>
<tr>
<td>Normal weight</td>
<td>18.5 - 24.9</td>
</tr>
<tr>
<td>Overweight</td>
<td>25.0 - 29.9</td>
</tr>
<tr>
<td>Obese</td>
<td>&gt; 30</td>
</tr>
<tr>
<td>a) Class I</td>
<td>30.0 - 34.9</td>
</tr>
<tr>
<td>b) Class II</td>
<td>35.0 - 39.9</td>
</tr>
<tr>
<td>c) Class III</td>
<td>&gt; 40</td>
</tr>
</tbody>
</table>

IMPLICATIONS OF OBESITY

WHAT PERCENTAGE OF YOUR PATIENTS ARE OBESE?

A. 0-10%
B. 11-20%
C. 21-30%
D. 31-40%
E. 41-50%
F. More than 50%
DO YOU THINK THE PERCENTAGE OF OBESE PATIENTS IN YOUR PRACTICE IS INCREASING?

A. Yes
B. No

OBESITY TRENDS* AMONG U.S. ADULTS
BRFSS, 1985

OBESITY TRENDS* AMONG U.S. ADULTS
BRFSS, 1990

OBESITY TRENDS* AMONG U.S. ADULTS
BRFSS, 1995
OBESITY TRENDS* AMONG U.S. ADULTS
BRFSS, 2000

(*BMI ≥30, or ~ 30 lbs. overweight for 5' 4" person)

No Data       <10%         10%–14% 15%–19%        ≥20%

---

OBESITY TRENDS* AMONG U.S. ADULTS
BRFSS, 2005

(*BMI ≥30, or ~ 30 lbs. overweight for 5' 4" person)

No Data      <10%         10%–14% 15%–19%       20%–24%        25%–29%        ≥30%

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BRFSS, 2009

(*BMI ≥30, or ~ 30 lbs. overweight for 5' 4" person)

No Data       <10%         10%–14% 15%–19%       20%–24%        25%–29%        ≥30%

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THE CURRENT STATE OF OBESITY

- Two-thirds of Americans are overweight or obese
- More than one-third (36.5%) of US adults are obese
- In every state, at least 20% of adults are obese
- The South has the highest prevalence of obesity
Obese women at higher risk for pregnancy-related complications including:

- spontaneous abortion
- congenital anomalies
- intrauterine fetal demise
- gestational diabetes
- hypertensive disorders of pregnancy
- venous thromboembolism
- postpartum hemorrhage, and
- cesarean delivery

**CASE VIGNETTE**

JS is a 35yo G0 woman presenting requesting contraception. She is sexually active with 1 male partner. She currently uses condoms inconsistently and does not desire pregnancy at this time. She strongly desires combined oral contraceptive pills as she has been dissatisfied with other contraceptive methods.

**HISTORY**

PMH: class III obesity
PSH: none
OB/GYN Hx: G0, no relevant GYN history
SH: denies TOB and drug use; endorses 3-4 alcoholic drinks a week
Meds: none
Family history: no history of VTE

**PHYSICAL EXAM**

Well-appearing woman in no acute distress

**VITAL SIGNS**

Blood Pressure: 112/72 mmHg
Height: 65 inches  Weight: 265 lb
BMI: 44.1 kg/m²
WOULD YOU PRESCRIBE COMBINED ORAL CONTRACEPTIVE PILLS TO JS?

A. Yes
B. No

SAFETY OF COMBINED HORMONAL CONTRACEPTION (CHC) IN OBESE WOMEN

US MEDICAL ELIGIBILITY CRITERIA (2016): OBESITY

<table>
<thead>
<tr>
<th>Sub-Condition</th>
<th>Cu-IUD</th>
<th>LNG-IUD</th>
<th>Implant</th>
<th>DMPA</th>
<th>POP</th>
<th>CHC</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) BMI ≥ 30</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>b) Menarche to &lt;18 years and BMI ≥ 30</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

Key:
1: no restriction
2: advantages generally outweigh theoretical or proven risks
3: theoretical or proven risks generally outweigh advantages
4: unacceptable health risk
RISKS OF OBESITY & CHC

Limited data suggests that obese women who use COCs do not have a higher risk for acute myocardial infarction or stroke than do obese nonusers (Curtis, 2016)

No large, prospective randomized studies comparing the risk of VTE among various doses of estrogen, types of progestin, or routes of administration (ASRM, 2017)

OBESITY, COCs, & VTE

Table. Relative risk of VTE by BMI category among combined oral contraceptive users

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;20</td>
<td>0.5</td>
<td>0.4</td>
<td>0.6</td>
<td>0.5</td>
</tr>
<tr>
<td>20–24</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25–29</td>
<td>reference category (=1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30–34</td>
<td>1.0</td>
<td>2.0</td>
<td>1.3</td>
<td>2.7</td>
</tr>
<tr>
<td>35+</td>
<td></td>
<td></td>
<td>2.2</td>
<td></td>
</tr>
</tbody>
</table>

Trussell, 2008

OBESITY AND VTE

- Obesity is recognized as a risk factor for VTE in the general population
- Obese women have a 2-3 fold risk of VTE in comparison to normal weight women

Table: Multivariate Hazard Ratio for VTE by BMI (Tsai et al 2002)

<table>
<thead>
<tr>
<th>BMI</th>
<th>Hazard Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;25</td>
<td>1.00</td>
</tr>
<tr>
<td>25 to &lt;30</td>
<td>1.47 (1.04-2.10)</td>
</tr>
<tr>
<td>30 to &lt;35</td>
<td>2.23 (1.50-3.11)</td>
</tr>
<tr>
<td>35 to &lt;40</td>
<td>1.52 (0.78-2.96)</td>
</tr>
<tr>
<td>&gt; 40</td>
<td>2.71 (1.26-5.84)</td>
</tr>
</tbody>
</table>

Table. Relative risks and 95% CIs of VTE for combined oral contraceptive users relative to nonusers in each body mass index (BMI) category

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;25</td>
<td>Netherlands</td>
<td>Denmark</td>
<td>United States</td>
<td>Netherlands</td>
</tr>
<tr>
<td>4.0 (3.2-4.9)</td>
<td>4.6</td>
<td>3.3 (2.0-5.5)</td>
<td>4.3 (2.9-6.2)</td>
<td></td>
</tr>
<tr>
<td>25–29</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.0 (3.2-4.9)</td>
<td>11.3</td>
<td>4.8 (2.6-9.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30+</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.0 (3.2-4.9)</td>
<td>6.5</td>
<td>6.0 (3.1-11.7)</td>
<td>8.4 (4.0-17.4)</td>
<td></td>
</tr>
</tbody>
</table>

Trussell, 2008
BEYOND THE PILL

Increased number of cases of VTE among obese women in comparison to non-obese women (Jick et al. 2010)

No data to evaluate risk of VTE among obese women using the combined hormonal ring

INFORMATION GAPS

• No safety data about VTE risk and CHC use in women with BMI ≥ 40 kg/m²

• No data about safety in women with obesity and other co-morbidities

LIKELIHOOD OF VTE

The likelihood of developing a VTE

Risk of VTE affected by BMI

THE LARGER PICTURE ...

RISKS OF CONTRACEPTION

RISKS OF PREGNANCY
CLINICAL CONSIDERATIONS

Is it effective?  Is it safe?

EFFECT OF OBESITY ON HORMONAL CONTRACEPTION

OBESITY & HORMONAL CONTRACEPTION

Excluded from clinical trials

No evidence that hormonal contraception is ineffective for obese women

Limited studies suggest effectiveness of contraception varies by BMI or body weight

THE INCITING STUDY


FINDING

Women with a body weight of ≥ 70.5kg had a 60% higher risk of oral contraceptive failure than women of lower weight.
CONTRACEPTIVE FAILURE

Adherence

Method effectiveness

Contraceptive failure

Sexual Behavior

Fecundity

BIOLOGICAL PLAUSIBILITY

increased metabolic rate

increased hepatic clearance

increased blood volume

increased absorption

Decreased serum drug levels

DIFFERENCES IN PHARMACOKINETICS

 Decreased drug levels

Ovulation

Pregnancy

Westhoff, 2010

Mean EE levels

Mean ENG levels

Westhoff, 2012

PKs of CHCs in obese and normal weight women

FIGURE. Serum concentrations of EE and ENG in 18 normal-weight and 19 obese contraceptive vaginal ring users.
EFFECTIVENESS OF COCS IN OBESE WOMEN

COCHRANE SYSTEMATIC REVIEW

COCS

• Aim: to examine effectiveness of hormonal contraception among women who are overweight and obese

• Methods: Reviewed studies that reported information on specific contraceptive methods

• Results: 5 individuals studies on COCs, 1 study of pooled data
  • 3 showed no difference between BMI and pregnancy risk
  • 2 found BMI to be associated with pregnancy risk but in opposite directions
  • Pooled analysis: obese women had a 44% higher relative risk for pregnancy

• Conclusion: Most studies did not indicate a higher risk of pregnancy for overweight or obese women

Lopez 2016

SYSTEMATIC REVIEW

EFFECTIVENESS OF COCS IN OBESE WOMEN

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Study Design</th>
<th>Result</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yamazaki, 2015</td>
<td>Pooled analysis</td>
<td>aHR 1.44</td>
<td>Fair</td>
</tr>
<tr>
<td>Schramm, 2011</td>
<td>Pooled analysis</td>
<td>No difference</td>
<td>Fair</td>
</tr>
</tbody>
</table>

Individual studies

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Study Design</th>
<th>Result</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vessey, 2001</td>
<td>Prospective cohort</td>
<td>No difference</td>
<td>Fair</td>
</tr>
<tr>
<td>Dinger, 2009</td>
<td>Prospective cohort</td>
<td>No difference</td>
<td>Fair</td>
</tr>
<tr>
<td>Dinger, 2011</td>
<td>Prospective cohort</td>
<td>aHR 1.5</td>
<td>Fair</td>
</tr>
<tr>
<td>Brunner, 2005</td>
<td>Retrospective cohort</td>
<td>No difference</td>
<td>Fair</td>
</tr>
<tr>
<td>Brunner Huber, 2007</td>
<td>Retrospective cohort</td>
<td>No difference</td>
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</tr>
<tr>
<td>Nakajima, 2016</td>
<td>Retrospective cohort</td>
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<td>Fair</td>
</tr>
<tr>
<td>Westhoff, 2012</td>
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<td>Fair</td>
</tr>
<tr>
<td>Holt, 2002</td>
<td>Retrospective cohort</td>
<td>aHR 1.6</td>
<td>Poor</td>
</tr>
<tr>
<td>Brunner Huber, 2006</td>
<td>Case cohort</td>
<td>No difference</td>
<td>Poor</td>
</tr>
<tr>
<td>Holt, 2005</td>
<td>Case control</td>
<td>OR 2.17</td>
<td>Fair</td>
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<td>Poor</td>
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Poiled analysis: COCS & OBESITY

Table. Effect of obesity (BMI ≥ 30 kg/m²) on pregnancy rate (7 COC trials)

<table>
<thead>
<tr>
<th>Trial</th>
<th>AHR (95% CI)</th>
<th>% Weight</th>
</tr>
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<tbody>
<tr>
<td>DSG/E</td>
<td>2.07 (0.84, 4.91)</td>
<td>6.82</td>
</tr>
<tr>
<td>LING/E1</td>
<td>1.32 (0.63, 2.73)</td>
<td>17.36</td>
</tr>
<tr>
<td>LING/E2</td>
<td>1.04 (0.64, 2.51)</td>
<td>37.89</td>
</tr>
<tr>
<td>LING/E3</td>
<td>1.01 (0.79, 1.28)</td>
<td>13.49</td>
</tr>
<tr>
<td>NET/E</td>
<td>1.07 (0.61, 1.87)</td>
<td>7.38</td>
</tr>
<tr>
<td>NET/E1</td>
<td>0.90 (0.54, 1.52)</td>
<td>6.32</td>
</tr>
<tr>
<td>NET/E2</td>
<td>0.09 (0.03, 2.81)</td>
<td>10.80</td>
</tr>
<tr>
<td>NOM/E</td>
<td>1.61 (1.05, 2.45)</td>
<td>100.00</td>
</tr>
</tbody>
</table>

1. aHR Adjusted Hazard Ratio using the obese women as a reference group. Age and Race were adjusted. 2. Weights are for fixed effects analysis.

Dragoman 2017

Yamazaki 2015
## SYSTEMATIC REVIEW

### EFFECTIVENESS OF COCS IN OBSESE WOMEN

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<td>Case control</td>
<td>No difference</td>
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</tbody>
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### LIMITATIONS

- Evidence limited to fair to poor quality studies
- Similar methodological limitations
  - Self-reported weight & height
  - Self-reported pregnancies
  - No information on adherence or sexual behavior
- Exclusion of women in the highest BMI categories
- Only 3 studies powered to address association of BMI/weight with pregnancy risk

Dragoman 2017

### SUMMARY: COCS & OBESITY

*Society of Family Planning* (2009):

“Obese and overweight users appear to be at a similar or slightly higher risk of pregnancy as compared to normal BMI women”

- **Dinger 2011**
  - RR 1.5 of contraceptive failure for women with BMI >35
  - Estimated failure rate 4.5% (vs. 3%)
- **Holt 2005**
  - OR 2.17 of contraceptive failure for women with BMI >27
  - Estimate 2-4 more pregnancies per 100 woman years in women with BMI >27
EFFECTIVENESS OF COMBINED HORMONAL PATCH

Ethinyl estradiol/ norelgestromin (EE/NGMN) patch

POOLED ANALYSIS: PATCH & OBESITY

Yamazaki 2015

Table. Effect of obesity (BMI ≥ 30 kg/m²) on pregnancy rate (8 COC or patch trials)

<table>
<thead>
<tr>
<th>Trial</th>
<th>AHR (95% CI)</th>
<th>% Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2.07 (1.84, 2.31)</td>
<td>9.87</td>
</tr>
<tr>
<td>2</td>
<td>1.92 (1.68, 2.20)</td>
<td>14.91</td>
</tr>
<tr>
<td>3</td>
<td>1.64 (1.38, 1.95)</td>
<td>17.89</td>
</tr>
<tr>
<td>4</td>
<td>1.81 (1.75, 1.87)</td>
<td>22.49</td>
</tr>
<tr>
<td>5</td>
<td>1.86 (1.64, 2.12)</td>
<td>14.87</td>
</tr>
<tr>
<td>6</td>
<td>1.80 (1.61, 2.00)</td>
<td>12.88</td>
</tr>
<tr>
<td>7</td>
<td>0.80 (0.54, 1.17)</td>
<td>6.55</td>
</tr>
<tr>
<td>8</td>
<td>0.80 (0.52, 1.22)</td>
<td>12.58</td>
</tr>
<tr>
<td>Overall (p² = 41.0%, p = .105)</td>
<td>1.05 (1.00, 2.27)</td>
<td>100.00</td>
</tr>
</tbody>
</table>

CONTRACEPTIVE PATCH: POOLED ANALYSIS ABOUT EE/NGMN PATCH

Study population by weight N=3319

- 97%: 10 pregnancies
- 3%: 5 pregnancies

EFFECTIVENESS OF COMBINED HORMONAL RING

Ethinyl estradiol/etonogestrel (EE/ENg) ring

Zieman 2002
EVIDENCE: RING & OBESITY

No data comparing effectiveness between obese and non-obese users as large clinical trials excluded obese women.

EFFECTIVENESS OF INJECTABLE CONTRACEPTIVE

Depo-medroxy progesterone acetate (DMPA)

MPA LEVELS BY BMI

Segall-Gutierrez 2010

COCHRANE SYSTEMATIC REVIEW DMPA

Jain J et al. Contraceptive efficacy and safety of DMPA-SC. Contraception 2004

- Two large, open-label, Phase 3 studies over 1 year
- Total of 16,023 women-cycles of exposures to DMPA-SC
- Zero pregnancies reported
- Substantial numbers of overweight or obese women.
EFFECTIVENESS OF ETONOGESTREL (ENG) IMPLANT

PHARMACOKINETICS: ENG LEVEL IN OBESE WOMEN

Morrell KM et al (2016)
- Small cross-sectional study of ENG implant
- ENG levels were comparable across BMI groups (normal weight, overweight, and obese)
- No participant fell below threshold for ovulation

EVIDENCE: ENG IMPLANT & OBESITY

Xu H et al (2012), N=1168
- 1 pregnancy in 1377 woman-years of use
- Woman who became pregnant had baseline BMI 30.7
- Substantial inclusion of overweight (28%) and obese women (35%) in study population

Bahamondes L et al (2015), N=1000
- No pregnancies in women ≥ 70 kg
- 3 pregnancies occurred in women < 70 kg
- Small proportion of implant users ≥70 kg was <20%, and <8% were obese

BOTTOM LINE: No association between pregnancy risk and weight/BMI among ENG users

EFFECTIVENESS OF LEVONORGESTREL (LNG) IUD
EVIDENCE: IUD & BMI

Xu H et al (2012), N=4200
- Overall low failure rate (less than 1 pregnancy per 100 woman years)
- Failure rate did not vary by BMI
- Substantial inclusion of overweight (27%) and obese women (35%) in study population

Gemzell-Danielson K et al (2015), N=2884
- LNG-IUS 8 vs. LNG-IUS 13
- BMI not associated with failure rates in either group at 1 or 3 years
- 17% of study population was obese

SUMMARY: IUD is highly effective regardless of weight/BMI

SUMMARY: CONTRACEPTIVE EFFECTIVENESS & OBESITY

Extensive data, little concern
No data, no concern (?)
Little data, some concern
Little data, no concern
Little data, no concern

SUMMARY: CONTRACEPTIVE EFFECTIVENESS & OBESITY

CLINICAL CONSIDERATIONS

Is it effective?
Is it safe?

CASE VIGNETTE

JS is a 35yo G0 woman presents requesting contraception. She is sexually active with 1 male partner. She currently uses condoms inconsistently and does not desire pregnancy at this time. She strongly desires oral contraceptive pills as she has been dissatisfied with other contraceptive methods.

PHYSICAL EXAM
Well-appearing woman in no acute distress
Vital signs
Blood Pressure: 112/72 mmHg
Height: 65 inches  Weight 265 lb
BMI: 44.1 kg/m²
CASE VIGNETTE

JS is a 35yo G0 woman presenting requesting contraception. She is sexually active with 1 male partner. She currently uses condoms inconsistently and does not desire pregnancy at this time. She strongly desires combined hormonal patch as she has been dissatisfied with other contraceptive methods.

PHYSICAL EXAM
Well-appearing woman in no acute distress
Vital signs
Blood Pressure: 112/72 mmHg
Height: 65 inches  Weight 265 lb
BMI: 44.1 kg/m²

Would you prescribe combined transdermal contraceptive patch to JS?

JS is a 35yo G0 woman presenting requesting contraception. She is sexually active with 1 male partner. She currently uses condoms inconsistently and does not desire pregnancy at this time. She strongly desires combined hormonal patch as she has been dissatisfied with other contraceptive methods.

PHYSICAL EXAM
Well-appearing woman in no acute distress
Vital signs
Blood Pressure: 112/72 mmHg
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Would you prescribe combined transdermal contraceptive patch to JS?

SHARED DECISION-MAKING

Figure. The Interdependence of Evidence-Based Medicine and Shared Decision Making and the Need for Both as Part of Optimal Care

CLINICAL CONSIDERATIONS

Is it effective? Is it safe? Is it the best method for me?

SUMMARY

- Limited evidence around contraceptive failure and obesity
- Most evidence finds no association between high BMI/weight and contraceptive failure
- Incorporate discussion about potential risk of decreased effectiveness in obese women in a shared decision model
- Access to contraception should be a priority to women with obesity who do not desire pregnancy
THANK YOU

Questions?

EMERGENCY CONTRACEPTION (EC) AND OBESITY

Table. Emergency contraception: birth control that works after sex

<table>
<thead>
<tr>
<th>Type of emergency contraception</th>
<th>How soon does it work?</th>
<th>How does it work?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Copper IUD</td>
<td>Almost 100% effective</td>
<td>Immediate</td>
</tr>
<tr>
<td>Ulipristal acetate</td>
<td></td>
<td>5 days</td>
</tr>
<tr>
<td>LNG</td>
<td></td>
<td>Immediate</td>
</tr>
</tbody>
</table>

OOPS!

Thompson, 2014

KEY STUDIES

KAPP ET AL, 2015
- Efficacy of LNG EC by weight/BMI
- Pregnancy rate by body weight
  - 1.4% for women weighing 65-75kg
  - 6.4% for women weighing 75-85kg
  - 5.7% for women weighing > 85kg

GLASIER ET AL, 2011
- To compare efficacy of ulipristal acetate and LNG EC
- The risk of pregnancy was at least 3x more for obese women compared with women with normal BMI
- Risk greater for those who took LNG (OR 4.41) than UPA users (OR 2.62)
WEIGHT GAIN AND HORMONAL CONTRACEPTION

SHORT & SWEET SUMMARY

• Evidence that the following methods are not associated with substantial weight gain:
  - CHC
  - POPs
  - IUDs
  - Contraceptive implants

• Observational studies that report overweight and obese adolescents gain more weight with DMPA than when using COCs or no contraception

MORE ABOUT DMPA: COCHRANE REVIEW

COCHRANE REVIEW

• DMPS vs CHC (3 studies): no significant difference between groups in weight gain
• DMPS vs no contraception (one study): DMPS was associated with a greater increase in body fat and a greater decrease in percent lean body mass
• DMPS versus Cu-IUC (2 studies): in one study, mean weight gain was greater for DMPS users while another study found no difference between groups at 10 years.

CONTRACEPTION AFTER BARIATRIC SURGERY
**US MEDICAL ELIGIBILITY CRITERIA (2016): HISTORY OF BARIATRIC SURGERY**

<table>
<thead>
<tr>
<th>Sub-Condition</th>
<th>Cu-IUD</th>
<th>LNG-IUD</th>
<th>Implant</th>
<th>DMPA</th>
<th>POP</th>
<th>CHC</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Restrictive procedure</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>I</td>
</tr>
<tr>
<td>b) Malabsorptive procedure</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>3</td>
<td>1</td>
</tr>
</tbody>
</table>

**Key**
1: no restriction
2: advantages generally outweigh theoretical or proven risks
3: theoretical or proven risks generally outweigh advantages
4: unacceptable health risk