

Hormonal Contraception: Review and Update

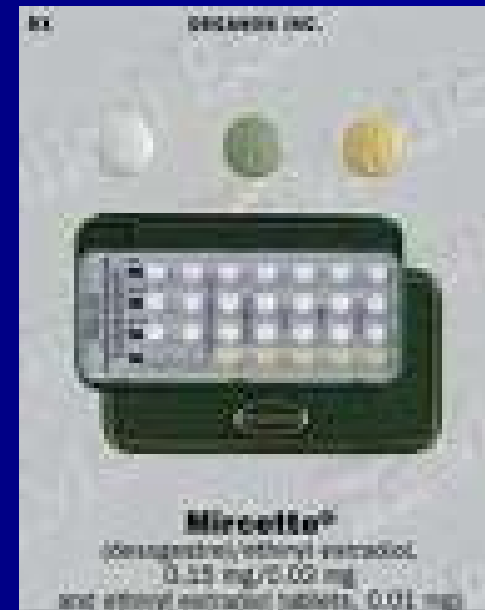
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What Will I Cover?

- Not a comprehensive review
- Mini-review
- What's new and/or interesting
- Patient education
- Special populations

Oral Contraceptives



Newer OCs

- Yasmin® (*not that new; but unique*)
 - Monophasic
 - Drospirenone 3 mg / EE 30 mcg
 - Drospirenone: spironolactone analog, antiandrogen
 - Monitor K⁺ during 1st cycle if at risk
- Yaz® and Loestrin 24 FE®
 - Ethinyl estradiol 20 mcg
 - Drospirenone 3 mg (Yaz)
 - Norethindrone 1 mg and ferrous fumarate in placebo pills (Loestrin 24 FE)
 - Both have 24 active pills and only 4 placebo pills
 - Shorter menses; possibly less dysmenorrhea/PMDD, headaches

Newer OCs: Long-cycle

- Seasonale®

- Ethinyl estradiol 30 mcg
- Levonorgestrel 0.15 mg
 - Taken daily for 12 weeks (84 days)
 - Followed by placebo for 7 days
- Menses occurs once every 12 weeks

- Seasonique® same as above, but 10 mcg EE x 7 days instead of placebo

- LoSeasonique®

- Ethinyl estradiol 20 mcg
- Levonorgestrel 0.1mg
 - Taken daily for 12 weeks, then 10 mcg EE x 7 days (no placebo)

Newer OCs: Long-cycle

- Lybrel®
 - Ethinyl estradiol 20 mcg
 - Levonorgestrel 90 mcg
 - Taken daily with no placebo
 - No regular menstrual periods

Newer OCs: Long-cycle

- Unscheduled breakthrough bleeding and spotting is common
- More common with Lybrel® than Seasonale® and Seasonique®
 - Usually improves over time; with Lybrel® may improve after first 7 months
- Discuss with patients if they would prefer regular scheduled, predictable bleeding, or unpredictable breakthrough bleeding

Oral Contraceptives: Starting

■ When to start

- The Sunday after the next menses begins
- Anytime in the first 5 days of the next menses
- Day it is prescribed (Quick Start method)

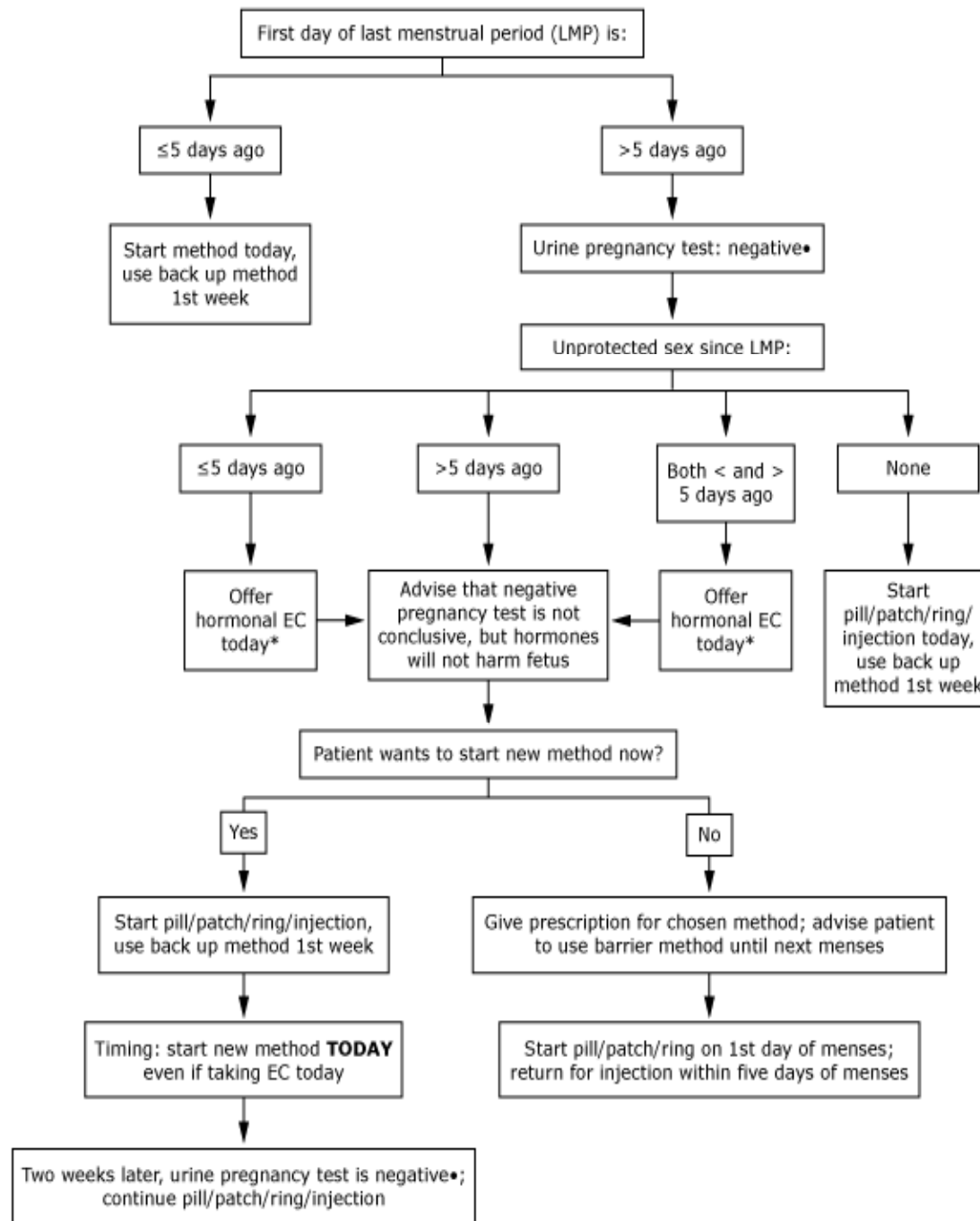
■ Onset of effectiveness

- Use backup contraception for at least 7 days with any method of starting

Oral Contraceptives

- Quick Start method:
- Start OCs immediately with no pregnancy test if:
 - First day of LMP \leq 5 days ago
- Start OCs immediately after negative pregnancy test if:
 - LMP started $>$ 5 days ago and no unprotected intercourse since LMP
 - LMP started $>$ 5 days ago and unprotected intercourse $>$ 5 days ago*
- Start OCs next day after ECP today if:
 - LMP started $>$ 5 days ago and unprotected intercourse \leq 5 days ago*

* Woman should do home pregnancy test 2 weeks after starting OCs



* Check pregnancy test in 2 weeks

Oral Contraceptives

- Quick Start method (con't):
 - Must use backup contraception for first 7 days (as always)
 - Improves use
 - With standard delayed initiation, 25% of women never fill their prescription
 - May decrease risk of pregnancy while waiting to start OCs
 - However, recent Cochrane review states there is insufficient evidence to prove that the Quick Start methods improves overall use or reduces pregnancy₁₁

Oral Contraceptives: Missed Pills

pills

Instructions

1

Take missed OC, then next OC at regular time. If at beginning of pack, offer ECP if necessary.

2*

Take 2 OCs daily x 2 days, then resume regular schedule. Alternate: take OCs q 12 hr until caught up. Offer ECP if necessary.

- ≥ 3* If she had intercourse, offer ECP and restart OCs the next day. If ECP not necessary or desired, skip missed pills, and continue on regular regimen, but

* Use backup contraception with 5 days after the onset of menses or 7 days after last active pill, whichever is earlier, then start new pill pack.

Ortho Evra® Contraceptive Patch



Ortho Evra®

- Each patch worn for one week
- Apply to abdomen, upper outer arm, torso or buttocks
- Start on first day of menses or within 5 days of onset (Sunday may be desirable)
- Use back up contraception for first week
- Replace patch every week for 3 weeks on same "patch change day"
- No patch worn on 4th week (no placebo)
- Patch can be changed any time on "patch change day"

Adverse Effects: Ortho Evra® Patch

- New **bolded** warning in package insert
- 60% higher SS concentrations of estrogen, but 25% lower peak concentrations compared with 35 mcg EE OCs
- Increased estrogen exposure could increase risk of VTE
- Three epidemiologic studies showed conflicting results, two showed ~ 2-fold increase in VTE risk, and one showed no increased VTE risk with the patch vs. 35 mcg OC.
- No long-term studies with CV outcomes

Patient Education: Ortho Evra®

- If patch falls off, should be reapplied immediately. If no longer sticky, apply new patch
 - If patch detached for > 24 hours (or unknown how long), start new cycle and use back up contraception for 1 week
 - Will have new “patch change day”

Patient Education: Ortho Evra®

- If “patch change day” is missed:
- At start of new cycle:
 - Change as soon as remember; have new “patch change day”; use condoms for 1 wk
- Week 2 or 3 (up to 48 hr late):
 - Change patch; return to usual “patch change day”; no backup needed
- Week 2 or 3 (> 48 hr late):
 - Start a new cycle of patches immediately; have new “patch change day”; use backup for 1 wk

Nuva Ring®



Nuva Ring®

- Flexible, transparent vaginal ring
- Ring inserted into the vagina & removed 3 weeks later (same day; approx. same time)
- Wait 1 week, then insert new ring (same day; approx. same time)

Patient Education: Nuva Ring®

- If ring slips out & has been out for < 3 hrs
 - Rinse and reinsert ring ASAP. No back-up needed.
- If ring slips out & has been out for > 3 hrs
 - Rinse in lukewarm water and reinsert ring ASAP. Use back-up for 7 days

(NOTE: can remove for < 3 hr for intercourse)

Patient Education: Nuva Ring®

- Estrogen & progestin levels in week 4 are only slightly lower than weeks 1-3
- If ring is left in > 3 wk but < 4 wk
 - Remove ring; insert new one after a 1 wk break; no back-up needed
- If ring is left in > 4 wk
 - Insert new ring; use back-up for 7 days

Depo-Provera® (DMPA) Contraceptive Injection



Adverse Effects: Depo Provera®

- **Osteoporosis risk / ↓ BMD – black box warning**
 - 5-10% ↓ IN BMD over 5 years
 - Increases with longer duration
 - May not be completely reversible
 - Not recommended for longer than 2 years (unless necessary)
 - Encourage calcium/vitamin D supplementation

Adverse Effects: Depo Provera®

- October 2008:
- ACOG issued a statement refuting the black box warning
- They support use for > 2 years and state BMD measurements not necessary
- Bone loss is mostly reversible
- Still recommend Ca/Vit D supplementation

Implanon® implant



Implanon®

- Etonogestrel 68 mg
- Single rod implantable contraceptive
 - Size of a matchstick
 - Implanted subdermally
- Effective for up to 3 years
 - Inhibits ovulation during the entire 3 years
- Has been used in 30 countries by 2.5 million women since 1998
- Must be trained by company personnel on insertion and removal
 - Available in some OB/GYN clinics and Planned Parenthood

Implanon®

- Adverse effects:
 - Irregular bleeding (most common), headaches, acne, emotional lability, dysmenorrhea
 - Implant site reactions (3.6 %)
 - Removal complications (1.7%)
- Must be removed in 3 years

Emergency Contraception (ECP)



Emergency Contraception (ECP)

- Progestin-only (preferred)
 - “Plan B” (levonorgestrel 0.75 mg)
 - Now OTC (behind the counter)
 - 1 tablet q 12 hours x 2 (FDA approved labeling)
 - 89% decrease in risk of pregnancy (1% vs 8%)
 - Data shows can take second pill up to 24 hr after 1st
 - Data shows can take 2 pills once (1.5 mg)
 - MUST TELL PT PACKAGE INSTRUCTIONS DIFFERENT!
 - Data shows may take up to 5 days post-intercourse (3-5 days: efficacy 63%)

Special Populations



Smoker

- A 27 year old woman who smokes 1 ppd (otherwise healthy) wants to start oral contraceptives.

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- *WHO Category 2 (generally use)*

Smoker

- WHO Category 4; Do not use:
 - > 35 y/o & smoke > 15 cig/day
- WHO Category 3; Not usually recommended unless other methods are unavailable or unacceptable
 - > 35 y/o and smoke < 15 cig/day
- WHO Category 2; Generally use
 - Smoker $<$ age 35

Postpartum

- A woman gave birth 4 weeks ago and is exclusively breastfeeding. She wants to start OCs, and does not want the MiniPill.

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- *WHO Category 4 (Do not use < 6 wk PP if nursing)*

Postpartum

- She is now 5 months post-partum and still exclusively breastfeeding. Her baby is nursing well and gaining an appropriate amount of weight. Can she use OCs now?

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- She is now 5 months post-partum and still exclusively breastfeeding. Her baby is nursing well and gaining an appropriate amount of weight. Can she use OCs now?
- *WHO Category 3: Not usually recommended 6 wk-6 mo PP if nursing unless other methods are unacceptable....BUT; OK in many women; monitor feeding/weight*

Postpartum

- Estrogen-containing contraceptives generally not recommended up to 21 days postpartum (WHO category 3) because of VTE risk

Venous Thromboembolism

- A woman had a DVT in her leg 3 years ago when she was on the pill (she is now 19 years old). She presents today, and says, "I was told I couldn't take the pill again. But, I have a new boyfriend & I want to be sexually active again."

Venous Thromboembolism

- Estrogen-containing contraceptives
 - Estrogen-related ↑ in many clotting factors, ↓ antithrombin III, ↑ fibrinogen, ↓ prostacyclin
 - Risk ↑ with age, obesity, surgery, year 1
 - Risk with OCs: < 3-fold ↑
 - Risk with desogestrel OCs: may be 4-fold higher
 - Risk higher with 50 mcg than 35 mcg OCs, but data does not support higher risk with 35 mcg than 20 or 30 mcg OCs

Previous VTE on Estrogen-Containing Contraceptive

- *Progestin-only contraceptive (e.g., Depo Provera) would be recommended*
 - IUD also an option, but would first need to know about her STI risk and test her
- Depo Provera: WHO category 2 (generally use)
 - But, contraindicated on package insert!!
- If current VTE, then WHO category 3 (not usually recommended unless other methods contraindicated or unavailable)

Migraines

- A 22 year woman who gets severe migraines with aura and lip/face numbness approximately every 1-2 months. She desires contraception.

Migraines: Estrogen-Containing Contraceptives

- *Migraines with focal neurologic sx / aura:*
 - *WHO Category 4 (do not use)*

Migraines: Estrogen-Containing Contraceptives

- *Migraines with focal neurologic sx / aura:*
 - *WHO Category 4 (do not use)*
- Migraine without aura > age 35:
 - WHO Category 3 (not usually recommended) to start and 4 (do not use) to continue
- Migraine without aura < age 35:
 - WHO Category 2 (generally use)
- Non-migraine headaches:
 - WHO Category 1 (no restrictions)

Headaches

- A 27 y/o healthy nonsmoker started Ortho Cyclen® (35 mcg EE/norgestimate monophasic) 1 year ago. For the past 7-8 months, she had noticed consistent severe headaches every month that start 1-2 days into the placebo week and resolve after restarting active pills.

Headaches from COCs

- Once thought to be due to high estrogen dose, but lowering the estrogen dose has not improved headaches
- Changing the dose or type of progestin has also not improved headaches
- Headaches/migraines often occur during the placebo week, and are likely due to estrogen withdrawal.

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- *Shortening the hormone-free time (Yaz, Loestrin 24), or providing estrogen during the placebo week (Mircette), or using long cycle OCs (Seasonique) can decrease headaches/migraines that occur.*

Hypertension

- A 38 y/o woman desires contraception. Her only medical history is hypertension, which is well-controlled on lisinopril/HCTZ and amlodipine.

Hypertension: Estrogen-Containing Contraceptives

- *Controlled hypertension:*
 - *WHO Category 1 (no restrictions)*

Hypertension: Estrogen-Containing Contraceptives

- *Controlled hypertension:*
 - *WHO Category 1 (no restrictions)*
- BP 140-159 / 100-109:
 - WHO Category 3 (not usually recommended)
- HTN with BP > 160/100:
 - WHO Category 4 (do not use)

The Overweight Patient

- A 20 year old woman who weighs 300 lbs. desires contraception. She does not want Depo Provera as she heard it can cause weight gain.

The Overweight Patient

- Effect of weight on OC efficacy
 - In obese women, estrogen metabolized more rapidly and time to reach SS of levonorgestrel doubled
 - Early studies showed increased failure of progestin-only pills in obese women
 - Some more recent observational studies suggest that higher body weight results in higher rates of COC failure
 - Lower dose OCs (< 35 mcg EE) had higher failure rates
 - Other observational studies show no increased risk of failure of COCs in obesity

The Overweight Patient

- HOWEVER, both the negative and positive trials have significant limitations; difficult to make any conclusions
- No patients > 240 lbs. studied
- May be less forgiving of a missed pill if obese
- Even with an increased risk of failure, still much more effective than barrier or no method

Trussell J, et al. Contraception 2009; in press; published online 1/17/09.

The Overweight Patient

- Remember, because of the risk of VTE, combination OCs should be used with caution in obese women over 35 y/o
 - *ACOG guidelines*
- However, data is not very good and OCs can likely be used up to BMI of 40 without significant increased risk of VTE
 - *Contraception 2008;77:143-146*

The Overweight Patient

- Ortho Evra® patch should not be used if \geq 198 lbs.
 - Decreased contraceptive efficacy
- Nuva Ring® can be used up to 272 lbs
 - Efficacy data up to this weight
- Depo Provera®
 - No data with weight and efficacy
 - Not desirable in overweight women b/c of weight gain side effect

The Overweight Patient

- *Still use COCs*

- Educate patient not well studied in obese women
- Reinforce importance of adherence
- Consider using 35 mcg EE Ocs
- Consider backup contraception if even miss 1 pill

Questions?

