Contraceptive Update
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Contraceptive Developments
- Hysteroscopic Sterilization
- Expanded IUD Indications
- Contraceptive Implant
- Injectable Contraception and Bone Density

Contraceptive Developments
- Hormonal Contraception and Weight
- Transdermal Contraception and VTE
- Extended Cycle Hormonal Contraception

Hysteroscopic Sterilization

Hysteroscopic Sterilization

- Essure™ permanent birth control system
- PET fibers surrounded by a stainless steel inner coil and wrapped in a super-elastic outer coil
- 4 cm in length and 0.8 mm diameter expands to 2 mm
- Placed hysteroscopically into tubal ostium

Micro-Insert: Design

- Fiber Material: PET
- Dynamic Expanding Superelastic Outer
- Coil Material: Nitinol
- Inner Coil Material: Stainless Steel
- length = 4cm

Hysteroscopic Sterilization

- Contraindications:
  - Previous tubal ligation
  - Less than 6 weeks from pregnancy
  - Pelvic infection
  - Hypersensitivity to nickel confirmed by skin test
  - Uterine abnormalities
  - Immunosuppression

Hysteroscopic Sterilization

- Local, sedation, or general anesthesia
- Place in early follicular phase
- Give NSAID prior to placement
- Requires back up contraception and HSG at 3 months to document tubal occlusion
- Hysteroscopic time approximately 20 minutes
Hysteroscopic Sterilization

- 84% successful placement
- 96% of those placed had occlusion at 3 months
- Additional 2% successful at second attempt
- 99.5% occlusion at 12 months
- Post marketing surveillance: 64 reported pregnancies for an approximate failure rate of 2.6/1000 at 5 years

Abbott Best Practice & Research Clinical Obstetrics and Gynecology 2005 19:743-756

Intrauterine Devices

- Copper T380A
  - 10 year duration of action
  - 380 mm² of copper surface area
- Levonorgestrel IUD
  - 5 year duration of activity
  - Released at 20 mcg/d falling to 5 mcg/d at 5 years of use

Intrauterine Devices

- Primary mechanism of action is prevention of fertilization
- Copper and inflammatory reaction are spermicidal and ovacidal
- Levonorgestrel thickens cervical mucous
- Sensitive BHCG assays do not show evidence of implantation

Ortiz ME, Croxatto HB Contraception 2007; 75:S16-30

IUD and Sterilization Efficacy

5-year gross cumulative failure rate per 100 women

- 0.5 for LNG IUS
- 1.4 for Cu T 380
- 1.3 for All Sterilization
- 0.6 for Postpartum Salpingectomy

LNG IUS Off-Label Uses

- ACOG supports use of levonorgestrel IUD for:
  - Menorrhagia
    - With or without fibroids
    - More acceptable than oral progestin
    - Reduction in blood loss less than achieved with ablation
    - Equally acceptable as ablation
  - Prevention of hyperplasia in users of hormone replacement therapy

LNG IUS Off-Label Uses

- Other potential uses of the LNG IUS
  - Treatment of hyperplasia
  - Adjuvant use with tamoxifen
  - Pelvic pain related to endometriosis or adenomyosis

Luukkainen and Toivonen, 1992;90
**IUD Management**

- IUD should be removed from pregnant women when possible without an invasive procedure
- Actinomyces on Pap in IUD user: expectant management, oral antibiotics +/- IUD removal
- ACOG “The importance of clearing actinomyces colonization is still not established”

**DMPA and Bone Density**

- Bone mineral density declines in current users, similar to lactating women
- Adult bone density at 30 months after discontinuation returns to normal
- Adolescents’ bone density returns to normal within 12 months
- Supplementation of estrogen can prevent bone loss
- No increased fracture rates have been reported.

**DMPA and Bone Density**

- ACOG “skeletal health concerns should not restrict use of DMPA in adult women. In adolescents the advantages of DMPA likely outweigh the theoretical safety concerns…
- “Regardless of age, short or long-term use of DMPA in healthy women… should not be considered an indication for DXA…”

**Contraceptive Implant**
Contraceptive Implant

- Single 40-mm × 2-mm rod made of ethylene vinyl acetate copolymer
- Contains 68 mg of etonogestrel (3-keto-desogestrel), the active metabolite of desogestrel
- Inhibits ovulation during the entire treatment period
- Effective for 3 years, 0 failures in Phase III study, in use failure rate of 1/1000 insertions

Contraceptive Implant: Bleeding Patterns

Contraceptive Implant: Bleeding

Percentage of Women Discontinuing

<table>
<thead>
<tr>
<th>Bleeding Type</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Frequent Bleeding</td>
<td>10.9</td>
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<tr>
<td>Spotting</td>
<td>3.3</td>
</tr>
<tr>
<td>Prolonged Bleeding</td>
<td>2.5</td>
</tr>
<tr>
<td>Amenorrhea</td>
<td>1.7</td>
</tr>
<tr>
<td>Heavy Bleeding</td>
<td>0.3</td>
</tr>
</tbody>
</table>

Contraceptive Implant: Bone Density

- An open, prospective, comparative two-year study of a single-rod implant (n=44) vs. a nonhormonal intrauterine device (n=29) found:
  - Essentially similar changes in bone mineral density from baseline
  - No relationship between 17β-estradiol concentrations and changes in bone mineral density

Contraceptive Implant: Body Weight

- In clinical trials, the mean cumulative weight gain was:
  - End of first year: +2.8 lbs.
  - End of second year: +3.7 lbs.
  - Weight gain was the reason given for discontinuation of participation by 2.3% of subjects


Oral Contraceptive Failure and Body Weight

- Contraceptive Failure by Oral Contraceptive Dose

<table>
<thead>
<tr>
<th>Ethinyl Estradiol Dose</th>
<th>Relative Risk</th>
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<tbody>
<tr>
<td>50 mcg or&gt;</td>
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<tr>
<td>&lt;50 mcg</td>
<td>1.2</td>
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<tr>
<td>&lt;35 mcg</td>
<td>3.6</td>
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Contraceptive Patch and Body Weight

<table>
<thead>
<tr>
<th>Decile</th>
<th>Weight Range (kg)</th>
<th>Weight pregnancies</th>
<th>Total</th>
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<tbody>
<tr>
<td>1</td>
<td>&lt;52</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>52 - &lt;55</td>
<td>2</td>
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<tr>
<td>3</td>
<td>55 - &lt;58</td>
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<td>4</td>
<td>58 - &lt;60</td>
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<td>6</td>
<td>63 - &lt;66</td>
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<td>66 - &lt;69</td>
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<td>69 - &lt;74</td>
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<td>9</td>
<td>74 - &lt;80</td>
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<tr>
<td>10</td>
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<td>7</td>
<td>7</td>
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<tr>
<td>80 - 85</td>
<td></td>
<td>1</td>
<td>1</td>
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<tr>
<td>&gt;85</td>
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<td>5</td>
<td>5</td>
</tr>
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</table>


ACOG on Weight and Hormonal Contraception

- “The incrementally higher ...failure rates with oral and transdermal methods should not exclude their use…”

- Obesity in an independent risk factor for VTE therefore, “consideration should be given to progestin-only and intrauterine methods when counseling obese women…”
OCPS and Venous Thromboembolism

<table>
<thead>
<tr>
<th>Estimated Average Risk per 100,000 Women/Year</th>
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<tbody>
<tr>
<td>Non-Oral Contraceptive Users</td>
</tr>
<tr>
<td>0</td>
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Transdermal Contraceptive and DVT

<table>
<thead>
<tr>
<th>Studies</th>
<th>Odds Ratio (95% Confidence Interval)</th>
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<tbody>
<tr>
<td>Jick SS, et al., 2007</td>
<td>1.1 (0.6–2.1)</td>
</tr>
<tr>
<td>Cole JA, et al., 2007</td>
<td>2.4 (1.1–5.5)</td>
</tr>
</tbody>
</table>

Jick SS, et al. Contraception. 2007;76:4-7

Extended Cycle Hormonal Contraception

- Continuous pill
  - 90mcg levonorgestrel and 20mcg ethinyl estradiol
- 91 day cycle
  - 150 mcg levonorgestrel and 30mcg of EE

Extended Cycle Hormonal Contraception

- 91 days cycle with estrogen in last week
  - 150 mcg levonorgestrel and 30mcg of EE and 10 mcg EE alone for last 7 days
- 24/4 cycle: shortened pill free interval
  - 3 mg DRSP
  - 1mg norethindrone and 20mcg EE
Extended Cycle Hormonal Contraception

• Advantages
  - More consistent suppression of follicle formation
  - Less dysmenorrhea
  - Less blood loss
  - Fewer withdrawal headaches and PMS symptoms

• Disadvantages
  - Irregular bleeding
  - Fear of pregnancy

Bleeding/Spotting Extended-Cycle (84/7) Oral Contraceptive*

*30 µg ethinyl estradiol/150 µg levonorgestrel

Vaginal Ring: Extended Use Bleeding Patterns

*Denotes higher discontinuation rate


Transdermal Contraceptive Patch: Extended Use Bleeding Patterns

Extended Cycle Oral Contraceptive

Prospective analysis of bleeding among women taking a 21/7 regimen followed by a 168-day extended regimen of 30 µg ethinyl estradiol/3 mg drospirenone

During the extended cycle:
- Continuation of active pills usually resulted in continued flow with a greater tendency to require a 3-day hormone-free interval
- Taking a 3-day hormone-free interval resulted in an initial increase in flow usually followed by a cessation of flow after a few days


Contraceptive Update

- Hysteroscopic sterilization is an effective alternative to laparoscopic procedures
- Levonorgestrel IUD can be used for treatment of menorrhagia
- Depot medroxyprogesterone acetate induced bone changes are reversible

Contraceptive Update

- Controversy remains regarding the risk of VTE associated with transdermal patch
- Elevated body weight may compromise pill and patch effectiveness
- Extended cycle contraception is safe, effective, and desirable, but may cause irregular spotting
"Well, I'm on the pill. I also use a diaphragm with a contraceptive jelly and Allen wears a condom. Thus we abstain completely from sex."