CLINICAL CONSIDERATIONS OF IMMEDIATE POSTPARTUM CONTRACEPTION

TIPQC ANNUAL MEETING
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Disclosures

• Drs. Young and Zite have no financial disclosures

• All health care providers who perform implant insertions and removals must receive training from the manufacturer. Therefore, the insertion process is deferred to the manufacturer and not covered in this presentation.
Learning objectives

1. Understand the clinical considerations for before, during, and after IPP LARC insertions
2. Observe and practice immediate postpartum (IPP) IUD insertion techniques

Method efficacy & considerations: postpartum contraception

<table>
<thead>
<tr>
<th>Method</th>
<th>Effectiveness</th>
<th>Special Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilization (male &amp; female)</td>
<td>99%+</td>
<td>Permanent</td>
</tr>
<tr>
<td>Mirena (Hormonal IUD)</td>
<td>99%+</td>
<td>Must be placed and removed by trained clinician. Clinician must attend manufacturer’s training prior to placement</td>
</tr>
<tr>
<td>Nexplanon (Etonogestrel Implant)</td>
<td>99%+</td>
<td>Must be placed and removed by trained clinician. Clinician must attend manufacturer’s training prior to placement</td>
</tr>
<tr>
<td>Copper IUD</td>
<td>99%+</td>
<td>Must be placed and removed by trained clinician.</td>
</tr>
<tr>
<td>Levonorgestrel IUD (LNG IUD)</td>
<td>99%+</td>
<td>Must be placed and removed by trained clinician.</td>
</tr>
<tr>
<td>Levonorgestrel injectable</td>
<td>94%</td>
<td>Must obtain injection every 3 months.</td>
</tr>
<tr>
<td>Injectable (Medroxyprogesterone)</td>
<td>82-84%</td>
<td>May be impractical for many women; this effectiveness is reached when infant feeds at least every 3-4 hours during the day &amp; &lt;6 hours at night.</td>
</tr>
<tr>
<td>LAM</td>
<td>92-98%</td>
<td>May be impractical for many women; this effectiveness is reached when infant feeds at least every 3-4 hours during the day &amp; &lt;6 hours at night.</td>
</tr>
<tr>
<td>Copper/progestin combined method</td>
<td>95%</td>
<td>Cannot be used within 3 weeks of delivery due to increased risk of blood clot disease. Risk factor must be met 6 weeks after delivery to pursue these methods safely.</td>
</tr>
</tbody>
</table>

Current LARC methods on the market

<table>
<thead>
<tr>
<th>Description</th>
<th>Brand Name of Method</th>
<th>Type of Method</th>
<th>FDA-Approved Duration of Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hormonal IUD</td>
<td>Mirena®</td>
<td>52 mg LNG IUD</td>
<td>5 years</td>
</tr>
<tr>
<td></td>
<td>Skyla®</td>
<td>11.5 mg LNG IUD</td>
<td>3 years</td>
</tr>
<tr>
<td></td>
<td>Nexplanor®</td>
<td>18 mg LNG IUD</td>
<td>5 years</td>
</tr>
<tr>
<td>Non-hormonal IUD</td>
<td>Liletta®</td>
<td>52 mg LNG IUD</td>
<td>4 years</td>
</tr>
<tr>
<td></td>
<td>Paragard®</td>
<td>Copper IUD</td>
<td>10 years</td>
</tr>
<tr>
<td>Contraceptive Implant</td>
<td>Nexplanor®</td>
<td>18 mg EMA implant</td>
<td>3 years</td>
</tr>
</tbody>
</table>
Levonorgestrel IUDs

- Mechanism of Action:
  - Prevent fertilization by changing amount and viscosity of cervical mucus, making it impenetrable to sperm
  - Evidence supports that LNG IUDs do not disrupt pregnancy and are not abortifacients
  - Most women ovulate normally but experience diminished menstrual bleeding because of the local effect of levonorgestrel on the endometrium
  - 99.8% effective; the one-year typical use failure rate is 0.2 per 100 women

Copper IUD

- Mechanism of Action – Prevents fertilization by:
  - Inhibition of sperm migration
  - Change in transport speed of ovum
  - Damage to or destruction of the ovum
- Evidence supports that the Copper IUD does not disrupt pregnancy and is not an abortifacient
- The most common adverse effects reported are abnormal bleeding and pain
- 99.2% effective; the one-year typical use failure rate is 0.8 per 100 women

Etonogestrel implant

- Mechanism of Action:
  - Primary: ovulation suppression
  - Additional: thickening of cervical mucus and alteration of the endometrial lining
  - After implant insertion, changes in bleeding patterns are common and include amenorrhea or infrequent, frequent, or prolonged bleeding
  - Placed subdermally in upper arm; size: 4cm x 2mm (comparable in size to a match stick)
- 99.9% effective; the one-year typical use failure rate is 0.05 per 100 women
ASSESSING CANDIDACY
for Immediate Postpartum LARC

CDC recommendations for IPP LARC

<table>
<thead>
<tr>
<th>Condition</th>
<th>CBC</th>
<th>MDF</th>
<th>Copper IUD</th>
<th>LNG-IUD</th>
<th>Ca-IUD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postpartum (within the first 30 days of delivery)</td>
<td>2  ≤ 30 days</td>
<td>1  ≤ 7 days</td>
<td>1  ≤ 10 days</td>
<td>1  ≤ 10 days</td>
<td>1  ≤ 10 days</td>
</tr>
<tr>
<td>Postpartum (within the first 14 days of delivery)</td>
<td>2  ≤ 14 days</td>
<td>1  ≤ 7 days</td>
<td>1  ≤ 10 days</td>
<td>1  ≤ 10 days</td>
<td>1  ≤ 10 days</td>
</tr>
<tr>
<td>Postpartum (within 48 hours of delivery)</td>
<td>2  ≤ 48 hours after delivery of the placenta</td>
<td>1  ≤ 48 hours after delivery of the placenta</td>
<td>1  ≤ 48 hours after delivery of the placenta</td>
<td>1  ≤ 48 hours after delivery of the placenta</td>
<td>1  ≤ 48 hours after delivery of the placenta</td>
</tr>
</tbody>
</table>

IPP IUD contraindications – U.S. MEC & ACOG

LARC has few contraindications & should be offered routinely as safe & effective contraceptive options for most women. There are some contraindications unique to IPP use.

Routine Contraindications
- Uterine anomaly
  - Dependent on severity of anomaly
- Active gynecologic malignancy
- Pelvic tuberculosis
- Rheumatic diseases
- Cervical cancer
- Endometrial cancer
- Breast cancer (LNG IUD only)
- Liver tumors (LNG IUD only)

IPP Contraindications
- Uterine infection:
  - Peripartum chorioamnionitis
  - Endometritis
- Puerperal sepsis
- Ongoing Postpartum hemorrhage

ACOG Practice Bulletin #186: LARC, Implants and IUDs
IPP LARC & infection: key takeaways

ACOG Committee Opinion #670, IPP LARC, states that:
“IPP IUD placement is contraindicated in the setting of intrauterine infection at time of delivery, postpartum hemorrhage, and puerperal sepsis. In the absence of puerperal sepsis, IPP IUD insertion is not associated with increased risks of bleeding or infection.”

- Currently, minimal data exists on IPP IUD and endometritis and ACOG has no official guidance on treating IPP IUD and endometritis
- Although rare, if endometritis develops after IPP IUD insertion, treat per your usual clinical practice
- If infection occurs after insertion or removal of the implant, treat per your usual clinical practice

EXPULSION
Clinical Considerations

ACOG recommendations for IPP LARC & expulsion rates:
Committee Opinion #670, IPP LARC

- Expulsion rates for immediate postpartum IUD insertions are higher than for interval or postabortion insertions, vary by study, and may be as high as 10–27% (73-90% of women retain the device)
- Women should be counseled about the increased expulsion risk, as well as signs and symptoms of expulsion
- A woman who experiences or suspects expulsion should contact her health care provider and use a back-up contraceptive method
- Many women experience barriers to interval LARC placement, such that the advantages of immediate placement outweigh the disadvantages
ACOG Committee Opinion #670, IPP LARC, states that:

“Despite the higher expulsion rate of immediate postpartum IUD placement over interval placement, evidence from clinical trials and from cost-benefit analyses strongly suggest the superiority of immediate placement in reduction of unintended pregnancy, especially for those at greatest risk of not having recommended postpartum follow-up visit.”

BREASTFEEDING

Clinical Considerations

CDC recommendations: IPP LARC & breastfeeding

<table>
<thead>
<tr>
<th>Condition</th>
<th>Sub-Condition</th>
<th>CDC</th>
<th>IPP</th>
<th>Implant</th>
<th>LARC</th>
<th>Spironolactone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breastfeeding (no d/c, no infant)</td>
<td>3+ months postpartum</td>
<td>1*</td>
<td>1*</td>
<td>1*</td>
<td>1*</td>
<td>1*</td>
</tr>
<tr>
<td></td>
<td>3+ weeks to end of 1st month</td>
<td>2*</td>
<td>1*</td>
<td>1*</td>
<td>1*</td>
<td>1*</td>
</tr>
<tr>
<td></td>
<td>3+ weeks postpartum</td>
<td>2*</td>
<td>1*</td>
<td>1*</td>
<td>1*</td>
<td>1*</td>
</tr>
<tr>
<td>Postpartum (no breastfeeding or no infant for &gt; 24 hours, no contraindication)</td>
<td>3+ months postpartum</td>
<td>1*</td>
<td>1*</td>
<td>1*</td>
<td>1*</td>
<td>1*</td>
</tr>
<tr>
<td></td>
<td>3+ weeks postpartum</td>
<td>2*</td>
<td>1*</td>
<td>1*</td>
<td>1*</td>
<td>1*</td>
</tr>
</tbody>
</table>

Legend:
1. *New* (pregnancy_inside)
2. Pre-existing pregnancy
3. Pre-existing diagnosis for medical condition
4. Pre-existing diagnosis for surgical condition
5. Contraindication
6. Pre-existing diagnosis for past condition
7. Pre-existing diagnosis for medical condition
8. Pre-existing diagnosis for surgical condition
9. Pre-existing diagnosis for past condition

*Please see the complete guidance for clarification on the contraindication.*
Evidence on IPP hormonal LARC & breastfeeding

Study 1
- **Design:** Single, randomized controlled trial
- **Aim:** Examined effect of IUDs (both Cu & LNG) on breastfeeding women randomized to insertion of LNG IUD or Cu IUD at 6-8 weeks postpartum
- **Result:** No differences in:
  - Breastfeeding duration
  - Infant growth

Study 2
- **Design:** Small, randomized controlled trial
- **Aim:** Compared breastfeeding outcomes of women receiving IPP implant with those using no contraception
- **Result:** No significant differences in:
  - Breast milk volume
  - Newborn weight
  - Exclusive breastfeeding rates

Evidence on IPP hormonal LARC & breastfeeding

Study 3
- **Design:** Prospective nonrandomized cohort study (80 women)
- **Aim:** Examined breast milk composition of women using implant vs. nonhormonal IUD, initiated 28-56 days postpartum
- **Result:** No significant differences in:
  - Breast milk composition (total protein, fat & lactose)
  - Breast milk quantity
  - Infant body length, weight & head circumference at 3-year follow-up

Study 4
- **Design:** Randomized, noninferiority trial
- **Aim:** Compared insertion of implant at 1-3 days postpartum with standard insertion at 4-8 weeks postpartum
- **Result:** No differences in:
  - Time to lactogenesis
  - Lactation failure
  - Mean milk creatarno/rt values (estimated fat & energy content)

IPP LARC & breastfeeding: key takeaway

- The Copper IUD lacks hormones, which avoids any theoretical effect on breastfeeding, and is classified as CDC MEC Category 1 (no restriction on use) for women who are breastfeeding
- For hormonal IPP LARC use, ACOG Practice Bulletin #186, LARC: Implants & IUDs, states that:

> "Given available evidence, women considering IPP hormonal LARC should be counseled about the theoretical risks of reduced duration of breastfeeding, but the preponderance of evidence has not shown a negative effect on actual breastfeeding outcomes"
IPP IUD
Insertion Techniques

Post-placental IUD insertion equipment
- Two Forceps
  - One for cervical traction and another for device placement
  - Kelly Placental forceps – longer, unratcheted
  - Ring/Ovum forceps
- Method of vaginal retraction – sim or similar blade
- Betadine, radiopaque surgical sponge
- Scissors – to cut the threads with hormonal devices
- Light source
- Ultrasound recommended, not required
- IUD

Importance of fundal placement

The ACOG LARC Work Group recommends ultrasound guidance for insertion, especially during training, but unavailability of ultrasound should not preclude insertion.
IUD ring forceps method

1. Identify cervix, place atraumatic (ring) forceps on anterior lip of cervix
2. Grasp the IUD with the forceps but do NOT close the ratchets
3. Insert the forceps through the cervix
4. Place non-forceps hand on the abdomen, palpating the fundus
5. Move the IUD-holding forceps up to the fundus
6. Open the forceps and release the IUD
7. Slowly remove the forceps, keeping them slightly open
8. If not precut, cut the strings flush with the external os
   • Strings will lengthen with uterine involution, and may require trimming

IUD manual insertion method

1. Grasp the IUD between your 2nd and 3rd fingers
2. Insert your hand to the fundus
3. Use your other hand to palpate the fundus abdominally to confirm
4. Slowly open your fingers and remove them from the uterus
5. Cut the strings flush with the external os
   • Strings will lengthen with uterine involution, and may require trimming

IUD inserter method

1. Follow manufacture instructions for loading the IUD
2. Move the flange all the way back to the handle
3. Move inserter to appropriate place in uterus
   • Note angle of uterus can change postpartum, especially the lower uterine segment
4. Ensure fundal placement
   • If available, use ultrasound to confirm location
5. Deploy IUD per standard instructions
6. Cut the strings flush with the external os
   • Strings will lengthen with uterine involution, and may require trimming
IUD insertion tips & tricks: post vaginal delivery

- Put on new sterile gloves before beginning
- Retrieve the ultrasound prior to delivery, if possible
- Ensure appropriate bleeding, and confirm uterine tone and complete placental removal via placental examination before opening the IUD
- Can use ring forceps to apply cervical traction, if needed. If patient does not have regional anesthesia this can be uncomfortable so assess need first.
- If difficulty reaching fundus, lower your hand and adjust speculum/retractor as needed to change the angle of insertion such that the bend of the lower uterine segment can be navigated. Flattening the patient can help.
- Repair bleeding lacerations first, but can leave non-bleeding lacs to be repaired after

Post placental IUD placement at time of cesarean delivery

1. Include IUD insertion in the "time-out" before the surgery.
2. Have the device in the room, but do not open until confirmed no post-partum hemorrhage
3. Perform routine external massage and internal sweep to ensure all placental tissue is removed.
4. Grasp the body of the IUD with forceps, hand or inserter
5. Strings of an LNG IUD should be trimmed to about 10 cm. Strings of the Paragard cooper IUD do not need to be trimmed.
6. Place the IUD at the fundus
7. Carefully point strings to cervix/vagina
8. Close the hysterotomy – take care to not incorporate the strings into the closure

IMPLANT

Insertion
Contraceptive implant insertion

- The Food and Drug Association requires that all health care providers who perform implant insertions and removals receive training from the Merck, the manufacturer of Nexplanon®. Therefore, the insertion process is deferred to the manufacturer and not covered in this presentation.

- Request a Nexplanon® training:
  2. Phone number: 1-877-467-5266

Note: IPP insertion of the contraceptive implant is identical to interval insertion and can be inserted any time post-delivery

FOLLOW UP INSTRUCTIONS
For Postpartum LARC

- Many will need a follow-up appointment to have strings trimmed
  - Offering, but not mandating, a string check is important
  - Instruct patient not to mess with strings if bothersome
  - Consider scheduling an ultrasound with her PP follow-up

- If patient experiences unusual bleeding accompanied by cramping different from lochia or postpartum cramps, she should be seen by a provider for possible partial expulsion
  - Instruct patient to inspect pads for evidence of expelled IUD

- Instruct patient to remind her provider that an IUD was placed postpartum and to notify a provider if she has:
  - Fevers, chills, severe abdominal pain or temperature > 100.4°F
  - Heavy bleeding
  - Expulsion of the device
IPP implant follow-up instructions

- Bruising and soreness around the insertion site is normal and should resolve within 1-2 weeks after placement.
- A patient should see a provider if they:
  - Have redness, swelling or drainage near the implant
  - Cannot feel the implant under their skin
- A patient should always remind their provider that they had an implant placed postpartum.

KEY TAKEAWAYS
Things to Keep in Mind

ACOG clinical guidance: summary & key takeaways

1. Women should be counseled prenatally about all postpartum contraceptive options, including IPP LARC.
2. IPP LARC should be offered as a safe and effective option for postpartum contraception.
3. LARC methods have few contraindications, and almost all women are eligible for implants and IUDs.
4. Counseling should include benefits and limitations of IPP LARC.
ACOG clinical guidance: summary & key takeaways (cont.)

5. Despite higher expulsion rates, research strongly suggests the superiority of immediate placement in reduction of unintended pregnancy

6. Women considering IPP LARC should be counseled about the theoretical risk of reduced duration of breastfeeding, but that preponderance of the evidence has not shown a negative effect on breastfeeding outcomes

7. The immediate postpartum period can be particularly favorable time for IUD or implant insertion

QUESTIONS?

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