Intrauterine Contraceptive Placement and Removal

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Disclosures
• Advisory Board
  Teva (ParaGard, LeCette)
  Merck (HPV vaccines)
  Actavis (Levosert IUD in development)
• Speakers’ Bureau
  Teva (ParaGard)
  Merck (Nexplanon, Gardasil, NuvaRing, Contraception))
  Bayer (Mirena, Skyla)

Objectives
• Demonstrate the hand skills necessary for placement of the copper IUD and the two levonorgestrel IUDs
• List three major complications that are a risk with IUC placement and how to manage them

Terminology

Levonorgestrel IUDs
• LNG 20 IUD (Mirena)
• LNG 13.5 IUD (Skyla)
• In reference to either or both:
  —LNG IUD
  —LNG IUC
  —Intrauterine System (IUS)

Copper IUD
• Cu IUD
• Copper IUD
• Cu IUC
• Cu-T380A
• ParaGard®
• Can’t call it an IUS
Take Home the “IUDs”

- Keep one in your lab coat
- One in each room
- Give them to your patient to hold, feel and play with while discussing the method
- Show her how to feel the threads with it

US Medical Eligibility Criteria

<table>
<thead>
<tr>
<th>Category</th>
<th>Definition</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No restriction in contraceptive use</td>
<td>Use the method</td>
</tr>
<tr>
<td>2</td>
<td>Advantages generally outweigh theoretical or proven risks</td>
<td>More than usual follow-up needed</td>
</tr>
<tr>
<td>3</td>
<td>Theoretical or proven risks outweigh advantages of the method</td>
<td>Clinical judgment that this patient can safely use</td>
</tr>
<tr>
<td>4</td>
<td>The condition represents an unacceptable health risk if the method is used</td>
<td>Do not use the method</td>
</tr>
</tbody>
</table>

Contraindications

Any IUC US MEC 2010

- Distorted uterine cavity
- Post-partum endometritis/sepsis
- Post-abortion endometritis
- Current GC/CT/purulent cervicitis/PID
  - Initiate: 4 Continue: 2
  - Pelvic TB
  - Initiate: 4 Continue: 3
- Malignant GTD or ↑ hCG
- Cervical/endometrial cancer

US Medical Eligibility Criteria 2010

<table>
<thead>
<tr>
<th>Category</th>
<th>Definition</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>LNG IUD only</td>
<td>Current breast cancer</td>
<td>Breast cancer (&gt; 5 yrs NED)</td>
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<tr>
<td>Cu IUD</td>
<td>Allergy to copper</td>
<td>Lupus with severe thrombocytopenia</td>
</tr>
<tr>
<td></td>
<td>Wilson’s disease</td>
<td>*</td>
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</table>
Effectiveness and Continuation Rates

<table>
<thead>
<tr>
<th></th>
<th>Perfect Use</th>
<th>Typical Use</th>
<th>Continuation rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>ENG Implant</td>
<td>0.05</td>
<td>0.05</td>
<td>84%</td>
</tr>
<tr>
<td>Male sterilization</td>
<td>0.10</td>
<td>0.15</td>
<td>100%</td>
</tr>
<tr>
<td>IUC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>*LNG 20 IUD</td>
<td>0.2</td>
<td>0.2</td>
<td>80%</td>
</tr>
<tr>
<td>*Cu IUD</td>
<td>0.6</td>
<td>0.8</td>
<td>78%</td>
</tr>
<tr>
<td>*LNG 13.5 IUD</td>
<td>0.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female sterilization</td>
<td>0.5</td>
<td>0.5</td>
<td>100%</td>
</tr>
<tr>
<td>DMPA</td>
<td>0.2</td>
<td>6.0</td>
<td>56%</td>
</tr>
<tr>
<td>OCs, Patch, Ring</td>
<td>0.3</td>
<td>9.0</td>
<td>67%</td>
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</tbody>
</table>


Cost

IUDs are among the most cost-effective contraceptive methods available in the United States


Cu IUD: Mechanism of Action

• Primary mechanism is prevention of fertilization
  – Reduce motility and viability of sperm
  – Inhibit development of ova
• Possible secondary mechanism inhibition of implantation

LNG IUDs: Mechanism of Action

• Cervical mucus thickened
• Sperm motility and function inhibited
• Unlikely secondary mechanism of action
  – Endometrium suppressed
  – Ovulation inhibited occasionally for LNG 20

LNG 20 IUD: “Off Label” Non-contraceptive Benefits

• Decreased
  – Dysmenorrhea
  – Iron deficiency anemia
  – Long term risk of endometrial cancer
• Can be left in place during and after transition to menopause for use with ET

LNG 20 IUD Additional Therapeutic Uses

• Symptomatic fibroids
• Endometrial hyperplasia
• Symptomatic endometriosis, adenomyosis

Fraser IS. Contraception. 2013.
Menstrual Effects: Cu IUD

- Patients have their usual "cycles" because there is no hormonal effect.
- Menses often heavier or longer menses or dysmenorrhea.
- May have irregular spotting and sometimes bleeding in the first few weeks.

Menstrual Effects: Cu IUD

NSAIDs prophylactically WITH FOOD
- Pre-emptive use for first 3 cycles.
- Start before onset of menses-- anti-prostaglandin effect.
  - Naproxen sodium 220mg x2 BID (max 1100mg/day).
  - Ibuprofen 600-800mg TID (max 2400mg/day).

Menstrual Effects: LNG 20 IUD

- If there is initial spotting or frequent bleeding, it usually resolves by 3-6 months.
- Amenorrhea 20-50%.
- Up to 90% reduction in menstrual bleeding.

Menstrual Effects: LNG 13.5 IUD

- Less data.
- Increased irregular bleeding and spotting first 3-6 months.
- Decreased bleeding and spotting after 6 months.
  - Bleeding may remain irregular.
  - May be cyclic.
  - Amenorrhea 6%.

Spotting, Frequent/Prolonged bleeding

- Check for anemia if heavy prolonged bleeding.
- If indicated by history exclude:
  - PID.
  - Pregnancy; ectopic.
  - Cervical polyp, lesion, cancer.
  - Endometrial cancer.
- Remove IUC if abnormal bleeding is unacceptable to patient.

Mauro D. Contraception 2012.
Mansour D. Contraception 2012.
Skyla Package insert.
Copper T380A
For Emergency Contraception

A pilot study of the Cu T380A IUD and Oral Levonorgestrel for EC
• 60% chose oral LNG
• 40% chose the copper IUD

Turok OK, et al. Contraception. 2010

Underutilization

IUC Use By Female Ob/Gyns vs. All Women in the U.S.

Myths

IUCs Do Not Cause PID
• PID incidence for IUC users same as the general population
• Risk is increased only during the first month after placement
• Preexisting STI at time of placement, not the IUC itself, increases risk
• No reason to restrict use based on sexual behaviors

Rate of PID by Duration of IUC Use

- Baseline PID risk: 1-2 cases /1000 Woman-Years
- Rate per 1000 Woman-Years
- Duration of Use ≤20 days vs. 21 days - 8 years


Dalkon Shield

- Multi-filament string

IUC is Safe in Nulliparous Patients and Adolescents

- Menarche to age 20 US MEC -2
- Age 20 and older US MEC -1
- Nulliparity US MEC -2
- Parous US MEC -1

IUC Use
Post abortion

Ectopic Pregnancy Risk When Contraception Fails

<table>
<thead>
<tr>
<th>Contraceptive Method</th>
<th>Ectopic Pregnancy (%)</th>
<th>Myomectomy (%)</th>
<th>Tubal ligation (%)</th>
<th>Miscarriage (%)</th>
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</thead>
<tbody>
<tr>
<td>Copper IUD</td>
<td>2</td>
<td>8</td>
<td>1.5</td>
<td>1.8</td>
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<tr>
<td>Copper-releasing IUD</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Copper T-380</td>
<td>1</td>
<td>1.5</td>
<td>0.6</td>
<td>0</td>
</tr>
<tr>
<td>Copper T-380</td>
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<td>1.5</td>
<td>0.6</td>
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<td>0.6</td>
<td>0</td>
</tr>
</tbody>
</table>

Furlong LA. / Reprod Med. 2002
Excellent Time for IUC Placement - Post Abortion

- Most women ovulate by 21 days post abortion
- Range 8-37 days
- This is true for:
  - 1st trimester
  - 2nd trimester
  - Medical abortion
  - Spontaneous abortion

IUC Placement Post Abortion

- Half of abortions are repeat procedures
- 40% of women scheduled for IUC placement did not return for the procedure
- Immediate post-abortal IUC placement can reduce repeat unintended pregnancy by two-thirds.

Immediate Postabortion vs. Interval IUD Placement

- No differences between the two groups in:
  - Duration of bleeding
  - Pain
  - Expulsions*
    - Pelvic inflammatory disease (PID)

*Increased risk of expulsion after second-trimester abortion. Later in the first trimester higher expulsion rates than early first-trimester.

IUC After Medical Abortion

- Verify patient is no longer pregnant; may place IUC once medical abortion is complete
- 4% expulsions
- Continuation rate at 3 months- 80%.

Screening Tests and Patient Instructions

- No routine screening tests other than a bimanual exam and inspection of the cervix
- CT/GC:
  - if age <26 and due for annual screening
  - if screening is recommended based on risk
- Pap test if due
- Any indicated screening test can be done on the day of IUC placement
Pre-placement

- Prophylactic antibiotics
  - No value for routine administration
  - May reduce PID if high personal risk
- Premedication
  - NSAID 30-60 minutes before placement is common, but no effect on pain or discontinuation
  - Consider paracervical block if history of cervical os or canal stenosis

Post-IUC Placement Counseling

- The client should return if
  - String cannot be located (use barrier method)
  - Symptoms of pregnancy
  - Symptoms of infection
    - Pain, deep dyspareunia, fever, foul discharge
    - Sudden unexplained pelvic pain occurs
    - Excessively heavy bleeding

Placement Practicum

First steps

- Bimanual pelvic exam to determine uterine position and flexion and to rule out anatomic contraindication
- Inspect cervix for mucopurulent discharge
- Cleanse cervix with antiseptic
- Use of sterile gloves vs. “no-touch” technique

Tenaculum

- Dominant hand in palm-up position
- Slowly, quietly squeeze closed
- Selective local anesthetic
- Horizontal or vertical application (purchase)
- Change hands to sound and for IUC placement

Sound the Uterus

- Stabilize the cervix
- Determine the “pathway” to the fundus
  - Through cervical canal and endometrium
  - Preliminary dilation of the internal os
  - Establish depth/distance in centimeter to fundus to set flange

Walsh T et al. Lancet. 1998
Sound
• Can use metal, plastic sound or endometrial pipelle
• Bend sound to mimic uterine flexion
• Hold it like a pencil or dart
• Wrist action
• Brace fingertips on speculum to achieve control of force while advancing the sound

Cu IUD

ParaGard Placement*
• Load arms into inserter

ParaGard Placement
• Load arms into inserter

ParaGard Placement
• Advance insertion tube to fundus
• Fundal resistance should be coincident with the marker reaching the exocervix

ParaGard Placement
• Pull back on inserter tube while holding white rod steady to deposit IUC in cavity

* Excerpted from package insert
Most Important step
ParaGard Placement
• Push inserter tube until resistance to seat the arms of the IUC in the fundus

ParaGard Placement
• Withdraw the white rod while holding inserter tube steady

ParaGard Placement
• Slowly withdraw the inserter from the cervical canal
• Use inserter tube as a guide for cutting the strings
• Trim threads to 3-4 cm.

IUC Placement Practicum
• Placement of LNG-IUC 20 Mirena

Mirena: The Inserter
“Never let go of the Slider!!”

Steps for Mirena Placement*
1. Open sterile package
2. Release the threads
3. Make sure the slider is in the furthest position away from you
4. Check that the arms of the IUC are horizontal

* Excerpted from package insert
Steps for Mirena Placement*

5. Pull on both threads to draw IUC system into insertion tube.

6. Both knobs at ends of IUC arms are now within the inserter.

8. Set upper edge of movable green flange to the depth of uterine sound.

9. Hold slider with forefinger, or thumb, firmly in furthermost position.

10. Move inserter thru cervical canal until flange is about 1.5-2.0 cm from cervix. - allows sufficient space for IUC arms to open.

11. While holding inserter steady, release arms of IUC by pulling slider back until it reaches the raised mark on inserter.

12. Push inserter gently until flange touches cervix. The IUC should be in fundal position.

7. Fix threads tightly into the cleft at near end of inserter shaft.
Steps for Mirena Placement*

13. Pull down on slider all the way; threads will uncleat automatically and release IUC system

Double check that the strings are uncleated before withdrawing the inserter

14. Remove inserter and cut threads about 4-5 cm from cervix

Use inserter tube as a guide for cutting the strings

15. Measure and record in patient’s chart

IUC Placement Practicum

• Placement of LNG-IUC 13.5 Skyla

How to Reload the Reloadable Demonstration Inserter

There are 2 types of demonstration units. One is like the real product, it cannot be reloaded. The other is the reloadable demo. To reload the reloadable demo:

1. When the slider is in bottom position, tension threads gently, so that the T handle is horizontally on the tip of the skyla
2. Bring slider forward to the mark to lock the threads, while keeping a gentle tension on the threads
3. Release the threads. The inserter is now ready to be reused

Do NOT attempt to reload the demo by pulling from the threads when the slider is at the mark. The threads are already loaded and they will break

Figure 10. Cutting the threads
Insertion Procedure

Step 1: Opening of the package
- Open the package. The contents of the package are sterile
- Using sterile gloves, lift the handle of the sterile inserter and remove from the sterile package

Insertion Procedure

Step 2: Lead Skyla™ into the insertion tube
- Push the slider forward as far as possible in the direction of the arms
- While moving the insert tube over the Skyla™ body to lead Skyla into the insertion tube. The tip of the arms will meet to form a rounded end that extends slightly beyond the insert tube
- Important: Maintain firm pressure with your thumb or forefinger on the slider. DO NOT move the slider downward at this time as this may prematurely release the threads of Skyla. Once the slider is moved below the mark, Skyla cannot be released

Insertion Procedure

Step 3: Setting the flange
- Holding the slider in this forward position, set the upper edge of the flange to correspond to the stimulus depth (in centimeters) measured during sonogram

Insertion Procedure

Step 4: Skyla™ is now ready to be inserted
- Continue holding the slider in the forward position
- Advance the inserter through the cervix until the flange is approximately 1.5 to 2 cm from the cervix and then pause
- Do not force the inserter. If necessary, dilate the cervical canal

Insertion Procedure

Step 5: Open the arms
- While holding the inserter steady, move the slider down to the mark to release the arms of Skyla™. Wait 10 seconds for the horizontal arms to open completely

Insertion Procedure

Step 6: Advance to the fundal position
- Advance the inserter gently towards the fundus of the uterus until the flange touches the cervix
- If you encounter undue resistance, do not continue to advance
- Skyla™ is now in the fundal position. Fundal positioning of Skyla is important to prevent expulsion
Difficult IUC Placement

- Use greater outward traction on the tenaculum to minimize canal-to-endometrial cavity angulation
- Place paracervical or intracervical block to relax cervical smooth muscle and reduce pain
- Use os finder device, if available
- Dilate internal os with metal dilators to #13F (4.1 mm)
- If unsuccessful, return at a later date with use of misoprostol cervical priming

Os Finder Device

- Cervical Os Finders (Disposable Box/25) $49.00
- Cervical Os Finder Set (Reusable Set of 3) $69.00

Pratt Dilators
**Paracervical Block**

- Target is uterosacral ligaments
- Inject at reflection of cervico-vaginal epithelium
- 2 (5, 7 o’clock) or 4 sites (4,5,7,8 o’clock) submucosally to depth of 5 mm
- Use spinal needle or 25g, 1 ½” needle + extender
- Moore-Graves speculum allows for more movement
- Tips
  - Start with ½-1 cc. at tenaculum site
  - Disguise pain of needle insertion with cough
  - WAIT 1-2 minutes for set up before procedure

**Intra-cervical Block**

- Targets the paracervical nerve plexus
- 1 ½ inch 25g needle with 12 cc “finger lock” syringe
- Inject ½-1 cc. local anesthetic at 12 o’clock, then apply tenaculum
- Angulate needle at the hub to 45° lateral direction
- At 3 or 9, insert needle into cervix to the hub 1 cm lateral to external os, aspirate
- Inject 4 cc of local, then last 1 cc while withdrawing
- Rotate barrel 180°, then inject opposite side

**Prophylactic Misoprostol in Nulliparous Women**

- Pain scores no different in the two groups
- Increase in preinsertion side effects
- In one trial:
  - Insertion considered easier
  - “Misoprostol facilitates IUD placement and reduces the number of difficult and failed attempts of placements in women with a narrow cervical canal”

Saari I et al., Human Reproduction 2007; 22, (10): 2047
Shaefer E et al., Contraception 2010
**Tips for IUC Placement in Women with Fibroids**

- Determine fibroid location by ultrasound
  - Fundal fibroids (intramural, sub-serous) that do not distort uterine cavity do not preclude IUC use
  - Large sub-mucous fibroids, especially in lower uterine segment, contraindicate IUC use
  - Evaluate for other pathology, e.g., polyp
- Ultrasound guidance may facilitate safe placement
- No data on efficacy, but probably not compromised with LNG-IUS or with Cu-T if fundal placement

**Complications**

**Uterine Perforation**

- More likely to occur in relation to
  - Posterior uterine position
  - Extreme flexion
  - Skill/experience of provider
  - Placement 2 days-4 weeks after childbirth
- Typical location is midline at uterine fundus...if so, perforation often is asymptomatic, benign
- Suspect if sounding is much deeper than expected

**Management of Uterine Perforation**

- If before placement of IUC, stop procedure
- If during placement of IUC, remove IUC
- Monitor for 30 min for excessive bleeding, pain
- Provide alternative method of contraception
- Can insert another device after next menses

**Prevention of Uterine Perforation**

- Why sound the uterus at all?
  - Determine the “pathway” to the fundus
  - Preliminary dilation of the internal os
  - Establish depth to fundus to set flange
  - Ensure depth within 6-10 cm limits
- Bend sound to mimic uterine flexion
- Brace fingertips on speculum to achieve control of force while advancing the sound
- EMB device can be used instead of metal sound
- Open IUC package after sounding completed

**Vasovagal**

- **Mechanism**
  - Due to bradycardia + peripheral vasodilation
  - AKA: non-cardiogenic syncope, cervical shock
- **Association with IUC placement**
  - Syncope in 2% of placements
  - Convulsions in 1 per 2,000 placements
  - More likely with
    - Pain with cervical manipulation
    - Nulliparity
    - Previous episodes of vaso-vagal fainting
    - Dehydration or NPO

Markwardt-O. et al. Contraception 2002
Caliskan E, et al. The European Journal of Contraception and Reproductive Health Care 2003
Presyncopal Signs

• Facial pallor (distinct green hue)
• Yawning
• Pupillary dilatation
• Nervousness

Symptoms- Presyncopal

• Weakness
• Light-headedness
• Diaphoresis
• Visual blurring
• Headache
• Nausea
• Feeling warm or cold

Vasovagal Prevention

• Good hydration (electrolyte/ sports drink)
• Eat before placement

How to Abort a Vasovagal

• Isometric contractions of the extremities
• Intense gripping of the arm, hand, leg and foot muscles
• No need to bring the legs together or change position—just tense the muscles
• These contractions activate the skeletal-muscle pump to augment venous return and abort the reflex

Lightheadedness and Syncope: Other Causes

• Hyperventilation
  — Due to low CO₂ levels (respiratory alkalosis)
  — Heart rate normal or tachycardia
  — Treat with shallow breaths or re-breathing bag
• Local anesthetic toxicity (if cervical block)
  — CNS: lightheadedness, restlessness, anxiety, tinnitus, tremor, twitch, perioral numbness, visual changes, seizure, respiratory arrest
  — CV: bradycardia, arrhythmia, hypotension

Bleeding from Tenaculum Site

• Remove tenaculum slowly
• Apply pressure for at least 60 seconds
• Chemical cautery
  — Silver nitrate
  — Monsel’s solution
• Suturing very rarely is necessary
IUCs: Management of Cramping

- Mild: recommend NSAIDs
- Severe or prolonged
  - Examine for partial expulsion, perforation, or PID
  - Remove IUD if severe cramping is unrelated to menses or unacceptable to patient

Genital Tract Infections

- If cervical or vaginal infection diagnosed
  - IUC removal not necessary
  - Treat infection
  - Counsel re: prevention of STI transmission

PID with IUD in Place

- Occurs in 1-10% IUC placements within first year
- Risk of expulsion related to
  - Provider’s skill at fundal placement
  - Age, parity, BMI, uterine configuration
  - Time since placement (↑ within first 6 mos)
  - Timing of placement (menses, postpartum, post-abortion)
- Asymptomatic expulsion may present with pregnancy
- Partial expulsion may present with
  - Pelvic pain, cramps, intermenstrual bleeding
  - Pregnancy

Missing IUC String: Diagnosis

- Possibilities...
  - Expulsion, pregnancy, embedment, translocation
- Initial management
  - Probe for strings in cervical canal
    - Cytology brush to tease from canal
    - Endocervical speculum or forceps
  - Rule out pregnancy
  - Prescribe back-up contraceptive method until intrauterine location is confirmed
Missing IUC String: Treatment

- In situ (intrauterine) placement: desires continuation
  - Leave in place for remainder of IUC lifespan
- In situ placement: desires removal
  - Use straight or “alligator” forcep, simultaneous real time pelvic ultrasound
  - Crochet hook best for circular IUCs; less helpful with T-shaped IUCs
  - If unsuccessful, extract via operative hysteroscopy
- Translocation (IUC in peritoneal cavity)
  - Extract via operative laparoscopy

Pregnancy With IUC In Situ

- Determine site of pregnancy (IUP or ectopic)
  - If intrauterine pregnancy confirmed
    - Termination planned: await procedure
    - Continue pregnancy: remove IUC if strings visible
    - Removal decreases risk of spontaneous abortion, premature delivery
  - Retention of IUC (if strings not visible)
    - Increase surveillance for SAB, pre-term birth
    - No greater risk of birth defects (extra-amniotic)

LNG-IUD Isn’t at the Fundus?

- There can be migration within the uterine cavity
- A LNG-IUC in lower uterine segment is still effective
- Removal of the device is necessary only if
  - A portion of it protrudes from the cervix, or
  - There is excessive cramping with a low-lying IUC

What Should I Do if the Cu 380A Isn’t at the Fundus?

- Data is unclear if fundal placement is necessary for optimal efficacy
- A copper IUC in the lower uterine segment may be less effective
- Do not “push” a partially expelled or low lying device up to the fundus
- IUDs have been shown to spontaneously move up to the fundus and down to the lower uterine segment

Perimenopause & Menopause

- Leave in place until through transition
- LNG IUC can prevent perimenopausal bleeding
- Consider leaving LNG IUC in for HT
- OK not to replace if slightly overdue

IUC Post Menopause?

- Strings seen: remove
- Consider placing LNG IUC for HT
  - Less systemic absorption of progestin