Permanent contraception (sterilization) update

MARYAM GUIHI, MD, MSC
ASSOCIATE PROFESSOR
UNIVERSITY OF COLORADO SCHOOL OF MEDICINE

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- None

Lecture outline

- Epidemiology of permanent contraception (PC)
- Male
- Female
  - CREST data
  - Modern LSC methods
  - Managing HSC (Essure) patients
Terminology

- Permanent contraception vs. sterilization
  - “Sterilization” can imply involuntary or coercion
  - “Permanent contraception” alternative that recognizes the patient’s active and informed decision to complete childbearing

Epidemiology

- Worldwide, 220 million couples, 15 million U.S. women
- Most common method for U.S. married couples (2006-10)
  - 30% tubal occlusion, 17% vasectomy
  - 19% OCs, 15% male condom, 7% IUD, 4% injectable
  - Each year approx. 600,000 tubals, 200,000 vasectomies
- Fifth most common surgical procedure

Hatcher et al. Contraceptive Technology, 20th ed.; ACOG CO #695, ACOG PB #133

National data (2011-2013)

- 62% on contraception
- 19% not on because no sex in last 3 mos/ever
- 19% no contraception and sexually active

Male contraception: Vasectomy

- "Vas isolation"
- Scalpel technique
- No-scalpel technique
- Interrupts the vas deferens
- Outpatient procedure
- 0.15% failure in first year

Vasectomy Considerations

- Must confirm azospermia on two semen analyses
  - Most at 3 mos, 98-99% at 6 mos
  - Low rates of follow-up contribute to early failures
  - Late failures can occur secondary to recanalization of vas
- No impact on sexual function
- Minor complications 0.4-10%
- Postop pain: 10-15% chronic discomfort
- 3-5% ask for reversal
- Freeze semen before
- 50-75% pregnancy success after reversal

Female methods

- Method of action
  - Blocks fertilization by preventing sperm and egg from uniting
Collaborative Review of Sterilization (CREST)

- Large, prospective, multicenter observational study in 1996
  - 10,685 women followed for 8-14 years
  - Total of 143 sterilization failures
  - Cumulative 10-year probabilities
    - Highest = Clip sterilization = 36.5/1000 procedures
    - Lowest = Unipolar coagulation and postpartum salpingectomy = 7.5/1000

Peterson HB et al AJOG 1996

Other key findings from CREST

- Cumulative risk of failure highest when sterilized at young age
  - Bipolar (54.3/1000), clip application (52.1/1000)
  - Younger at time of sterilization = higher risk for ectopics
    - 10 year cumulative probability of 7.3/1000 procedures
    - Bipolar coagulation before age 30 → 27 times increased risk
      - 31.9 vs 1.2 ectopics per 1000 procedures


Other key findings from CREST

- Compared to women whose partners had vasectomy
  - No difference in menstrual abnormalities, somewhat better changes
  - More likely to obtain hysterectomy within 5 years (8% vs 2%)}
  - No evidence of effect on sexual interest or pleasure

CREST: Risk of regret

- Cumulative probability of regret over 14 yrs= 12.7%
- ≤30 risk 20.3%; >30 risk 5.9%
- Meta-analysis supports 2-fold increased risk by age
- Regret decreases as interval between delivery and sterilization increases
- 1% actually obtained reversal
- Ages 18-30 aRR=2.1 (95% CI 0.9, 3.4)
- Ages >30 aRR 0.2 (95% CI 0.0, 0.3)


CREST Limitations

- Only studied transabdominal methods
- Completed prior to titanium clips, hysteroscopic
- Complete in 1980s/90s
- More reproductive coercion concerns
- Less LARC/ highly effective options

Modern approaches

- Postpartum
- Interval sterilization
  - LSC
  - HSC- currently unavailable
Postpartum sterilization

- Performed prior to discharge, should not extend
- Accounts for 8-9% of U.S. deliveries
- Accounts for > half of all tubals
- Approach
  - Mini-laparotomy
  - Laparotomy at time of CS

Postpartum sterilization concerns

- Ideally counseling should occur with prenatal care
- Consider postponing in cases of intrapartum/postpartum maternal/neonatal complications
- Should obtain pathology confirmation
- **Up to 50% of women do not get their requests**
  - Concerns about age/regret, anesthesia, unavailable OR, religious hospitals, Medicaid consents
  - Up to 47% of women have repeat pregnancy within one yr

Postpartum sterilization techniques

- **Traditional partial salpingectomy methods**: modified pomeroy, parkland
- **Titanium clips (Filshie®)**
  - Retrospective cohort 290 women over 9 years difference of 1 failure with clips
  - RCT demonstrated higher probability of failures with titanium clips over 24 months
    - Cumulative probability of pregnancy was 0.017 with titanium vs. 0.0004 for Pomeroy (p=0.04)
  - Systematic review recommends against use of titanium clips for postpartum PC
- **Opportunistic salpingectomies**
  - Small studies demonstrates same amount of time/ somewhat longer
  - Similar blood loss and rates of complications
Interval permanent contraception

- Outside of postpartum period
- Can include post-abortal
- Scheduling concerns
  - Safest in follicular phase
  - Luteal phase concerns, have documented UPT and counseling
  - (HSC- consider endometrial prep)

LSC tubal ligation

- Low mortality
  - 1-2 deaths per 100,000 procedures
  - More likely in women with underlying medical problems resulting in cardiopulmonary arrest or hypoventilation with general anesthesia
- Low morbidity
  - Major complications 0.1-3.5%

LSC: Electrocoagulation

- Bipolar coagulation
  - At least 3 cm of isthmic portion must be completely coagulated
- Monopolar coagulation
  - More effective
  - Thermal bowel injury
  - Rarely used
LSC: Silicone rubber band

- Silicone band can only be applied to FT that is mobile enough to draw it into applicator

LSC: Titanium Clips

- Titanium clips lined w/silicone rubber (Flishie)
- Clamp on mesosalpinx
- Rare migration/expulsion
- Failure rate = 2-3 per 1000 women

LSC: improved experience for clips/rings

- Meta-analysis of RCTs evaluating topical application of local anesthesia during ring/clip placements (n=20)
- Benefit in pain scores up to eight hours post-op
- No difference if local was topical to the tube, injected, or placed intraperitoneally
- Greatest reduction seen 30 minutes after extubation up to one postop day out

LSC: Tubal excision

- Complete/Partial salpingectomy
- Preferred for abnormal FTs (hydrosalpinx)
- Tubal division may be technically harder
- Bleeding
- Concern for ovarian function

ACOG PB #133

Cancer prevention (Opportunistic)

- All LSC tubal occlusion methods reduce ovarian cancer risk
  - Relative Risk 0.29-0.69, most significant for those at risk (BRCA)
  - Growing evidence that epithelial ovarian cancer starts in fimbriae of FT
  - Support for complete salpingectomies (opportunistic)
  - BTL versus salpingectomy
    - BTL = risk reduction 13-41% vs. Bilateral salpingectomy = risk reduction 42-78%
    - Overwhelming majority of salpingectomy data from Sweden/Finland
    - No increase in complications or changes in ovarian reserve


LSC: ectopic pregnancy risk

- Large population-based retrospective study
- 44,829 women in Western Australia up to 20 yrs follow-up
- Compared five LSC methods
  - Referent group was LSC unspecified destruction of tube (0.8% ectors)
    - LSC partial salpingectomy and electrocautery had increased risks of ectopic
      - LSC partial salpingectomy aHR=14.57, 95% CI 3.50-60.40
      - LSC electrocautery aHR=8.40, 95% CI 3.28-21.6
    - LSC titanium clips and LSC salpingectomy were not significantly different
  - 10-year cumulative probability was 3.5 times higher for women <28 compared to >33
Risk of regret → Risk of denial

- CREST highlighted concerns about regret
- Rates of regret have to do more with requesting information, actual percentage who obtained reversal low
- Keep in mind less available LARC options during time of CREST
- Many women are speaking up these days about denials for sterilization

HSC sterilization: (Essure®)

- Nickel micro-inserts in proximal fallopian tubes
- Postop considerations:
  - Required back-up method
  - Confirmatory HSG needed
- No pregnancies in initial FDA studies of 600 women up to 5 years out (perfect use)
- Bilateral placement success: 81-98%

Essure backlash

- Typical use-lower efficacy
- Inadequate f/up and unintended pregnancies
- Misplaced devices
- Patient reports of pain
Essure Black box warning

**WARNING:** Some patients implanted with the Essure System for Permanent Birth Control have experienced and/or reported adverse events, including perforation of the uterus and/or fallopian tubes, identification of inserts in the abdominal or pelvic cavity, persistent pain, and suspected allergic or hypersensitivity reactions. If the device needs to be removed to address such an adverse event, a surgical procedure will be required. This information should be shared with patients considering sterilization with the Essure System of Permanent Birth Control during discussion of the benefits and risks of the device.

Essure - discontinued (12/31/2018)

- Reports not based on risk benefit profile, based on declining sales
- “Bayer will continue to enroll patients in the Essure postmarket surveillance study and will work closely with the FDA to ensure appropriate follow up. Bayer will also continue to fully comply with its other regulatory responsibilities regarding Essure.”

Essure - outcomes

- 7 year outcomes (median follow-up)
- Observational cohort study in NYS 2005-16
- Examined subsequent procedures for all sterilizations
- Estimated risk of undergoing an additional tubal ligation or resection
  - Higher for HSC vs. LSC (9.9% vs. 1.6%, HR 2.89, 95% CI 2.33-3.57)
  - Difference most pronounced in first year (1.5% vs. 0.2%)
  - No difference in risk of hysterectomy

Essure removal

- Techniques
  - Laparoscopic B salpingectomy w/ removal of coils at cornua
  - Hysterectomy with B salpingectomy
  - Case series (n=20) LSC B salpingectomy w/removal of coils
    - 70% requested for pelvic pain
    - 15% retained fragments even with attempted HSC removal
  - All reported pain relief after removal


Essure removal with LSC salpingectomy

Essure removal with LSC salpingectomy
Essure removal with LSC salpingectomy

Key Points

- All female sterilization methods effective
- Important to counsel on risk of failure and regret
- Risk of regret may not be as much of a concern with available LARC methods
- Patients with HSC sterilization most likely to need reoperation in first year