GLOBAL ENDOMETRIAL ABLATION TECHNOLOGY
Training: Part 1
Anatomy and Physiology
Female Anatomy – Normal Uterus

- Ovary
- Fimbria
- Uterine cavity
- Fallopian tube
- Internal os
- Cervix
- External os
- Vagina
- Uterus
- Endocervical canal
- Endocervix
- Ectocervix
Female Anatomy – Normal Uterus
Female Anatomy – Uterine Positions

Normal Uterus – Anteverted

Abnormal Uterus – Retroverted

Abnormal Uterus – Retroflexed

Abnormal Uterus – Prolapsed
Female Anatomy – Abnormal Uterine Shapes

Bicornuate unicollis

Bicornuate Uterus: Incomplete uniting of the uterus

Septate

Uterine Septum / Septate Uterus:
Wedge of fibrous tissue dividing uterine cavity

Subseptate

Subseptate Uterus: Similar to septate uterus, but Septum only extends part way to the cervix
Female Anatomy – Abnormal Uterine Pathologies

- Adhesions (scar tissue)
- Fibroids
- Endometriosis
- Adenomyosis
- Polyp
Benign Uterine Pathology

A variety of benign (non-cancerous) intrauterine pathologies are common. Two of the most common are:

- Myomas/ Fibroids
- Polyps
The most common and severe symptom is abnormal uterine bleeding.

The cause is anovulation – due to a hormonal imbalance of progesterone formation.

Estrogen continues to stimulate the endometrium, causing overgrowth and endometrial hyperplasia.

Benign Uterine Pathology

Polyps
Endometrial or Uterine Polyps

- Endometrial polyps are localized overgrowths of the endometrium that project into the uterine cavity.
- Usually benign (non-cancerous).
- The prevalence of polyps is estimated to be 10% to 24% of women undergoing hysterectomy or endometrial biopsy.
- Endometrial polyps are rare among women younger than 20 years of age.
Endometrial or Uterine Polyps

- The cause of endometrial polyps isn't clear; some are associated with excess estrogen in the body.
- The incidence of polyps rises steadily with age, peaks and then gradually declines after menopause.
- Most polyps are small and cause no symptoms, however some may cause abnormal bleeding or spotting (metrorrhagia) not associated with menstruation.
- Women who suffer from menorrhagia and who also have polyps may still be treated for menorrhagia.
Endometrial or Uterine Polyps

- Hyperplasia defined as uncontrolled growth of cell types,
- Atypia defined as atypical cells of endometrial lining
- All polyps should be removed in postmenopausal women
- Malignant potential is often age and size dependent


n = 430 pre and post menopausal women
Uterine Fibroids

- Affects 20-50% of reproductive age women
- Most common benign tumor in this population
- Prevalence increases with age
- Present in at least 5-10% of infertile patients
- Sole factor identified in 1-2.4% of infertile patients
- Fibroids are commonly called myomas or leiomyomas

Fibroids are commonly called myomas or leiomyomas.
Facts About Fibroids:

- Most common cause of benign uterine enlargement
- Occur in 70% of women by age 50
- More common in African-American women
- Arise from smooth muscle cells in the myometrium
# Uterine Fibroids

## Types of fibroids

<table>
<thead>
<tr>
<th>Submucosal</th>
<th>Intramural</th>
<th>Subserosal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under the lining of the womb, can grow on stalk (called pedunculated).</td>
<td>Within the wall of the womb, most common type, may distort the uterine cavity, or cause irregular external uterine contour.</td>
<td>On the outer wall of the uterus and usually causes no symptoms until it grows large enough to cause interference to adjacent organs. Sometimes, they grow on stalk.</td>
</tr>
</tbody>
</table>
Submucosal Fibroids can be further classified based on their location within the uterus:
- Type 0 - Fibroids totally in cavity
- Type 1 - More than 50% in cavity
- Type 2 - Less than 50% in cavity
Uterine Fibroids

- **Causes:**
  - The cause of fibroids is unknown
  - Familial/genetic relationship is suggested
  - Estrogen stimulates the growth of fibroids

- **Symptoms**
  - Dysmenorrhea – pain during menstruation
  - Menorrhagia – heavy bleeding
  - irregular bleeding
  - clots with bleeding
  - increased urination
  - constipation
  - Bloating
Adenomyosis

- Adenomyosis is a condition of the uterus in which the cells that compose the uterine lining (endometrial cells) penetrate deep into the uterine muscle (myometrium). This condition causes the uterus to become enlarged and hard.

- Common symptoms include excessive, heavy, or prolonged menstrual bleeding and painful periods (dysmenorrhea).

- Suspicion of adenomyosis may be revealed on exam, by transvaginal ultrasound, or MRI. Diagnosis is generally only confirmed by hysterectomy and pathological review of the uterine tissue.
Endometriosis

- Endometriosis is the abnormal growth of cells (endometrial cells) similar to those that form the inside or lining the tissue of the uterus, but in a location outside of the uterus.

- The cells of endometriosis attach themselves to tissue outside the uterus and are called endometriosis implants. These implants are most commonly found on the ovaries, the Fallopian tubes, outer surfaces of the uterus or intestines, and on the surface lining of the pelvic cavity.

- The exact cause of endometriosis has not been identified but is more common in women who are experiencing infertility than in fertile women.

- Pelvic pain during menstruation or ovulation can be a symptom of endometriosis, but may also occur in normal women. Most women with endometriosis have no symptoms.
Training: Part 2

Menorrhagia
What is Menorrhagia?
or Abnormal Uterine Bleeding

Excessively heavy or prolonged menstrual bleeding at normal intervals with total blood loss exceeding 80 mL per cycle

OR

Menses lasting longer than 7 days

Affects approx. 20% of all women

Between the ages of 30 to 50
Abnormal Uterine Bleeding

- Bleeding that is:
  - Excessive
  - Occurs outside of normal cyclic menstruation

- Responsible for as many as 1/3 of all outpatient gynecologic visits

- Majority of cases
  - Occur just after menarche
  - In the perimenopausal period
Patient Perception

- Many times the patients perception of “too much” or “too little” is unreliable
- 15% of women with menses loss of <20ml complain of heavy bleeding
- 33% of women with >80ml loss per cycle state they have normal or light flow
- Average blood loss with menstruation is 35-60ml
  - 95% of women lose <60ml/cycle
# Normal Menstrual Bleeding

<table>
<thead>
<tr>
<th></th>
<th>Normal</th>
<th>Abnormal</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Duration of flow</strong></td>
<td>4 – 6 days</td>
<td>&lt; 2 days or &gt; 7 days</td>
</tr>
<tr>
<td><strong>Volume</strong></td>
<td>30 - 60 mL</td>
<td>&gt;80 mL</td>
</tr>
<tr>
<td><strong>Length of cycle</strong></td>
<td>24 – 35 days (average 28 d.)</td>
<td>&lt;24 days &gt;35 days</td>
</tr>
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</table>

- Intermenstrual bleeding or postcoital spotting is also abnormal.
## Abnormal Uterine Bleeding Terminology

<table>
<thead>
<tr>
<th>Condition</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Oligomenorrhea</td>
<td>Cycle length &gt; 35 days</td>
</tr>
<tr>
<td>Polymenorrhea</td>
<td>Cycle length &lt; 24 days - frequent, regular periods that occur less than every 21 days</td>
</tr>
<tr>
<td>Menorrhagia (Hypermenorrhea)</td>
<td>Regular, normal intervals; excessive volume and duration of flow</td>
</tr>
<tr>
<td>Metrorrhagia</td>
<td>Irregular intervals with normal or reduced volume and duration of flow; NOT heavy</td>
</tr>
<tr>
<td>Menometrorrhagia</td>
<td>Irregular interval; excessive or heavy blood loss and long duration of flow</td>
</tr>
<tr>
<td>Amenorrhea</td>
<td>No Bleeding</td>
</tr>
<tr>
<td>Hypomenorrhea</td>
<td>Very light bleeding / spotting</td>
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</table>
Summary of AUB

- Thorough history and evaluation is required to rule out abnormal conditions or pathology
- Age and ovulatory status must be considered
- Rule-out pregnancy!
- Treatment failures require further evaluation
- AUB: diagnosis of exclusion
DUB – Dysfunctional Uterine Bleeding

- Dysfunctional uterine bleeding (DUB) is heavy or irregular menstrual bleeding that is not caused by an underlying anatomical abnormality, such as a fibroid, lesion, or tumor.

- DUB is the most common type of AUB.
Causes Of Menorrhagia

25% - For other reasons (e.g. fibroids, cancer)

75% - DUB – Dysfunctional Uterine Bleeding

- Structural
- Not Structural
Step 1: Evaluate Anatomy

- Transvaginal or Transabdominal ultrasound
- Saline infusion Sonohysterogram
- Diagnostic Hysteroscopy
- Endometrial Biopsy / Dilation and Curretage
## Pathology Diagnosis

<table>
<thead>
<tr>
<th>Technique</th>
<th>Method</th>
<th>Visual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transabdominal ultrasound</td>
<td>• A transducer is placed on the patient’s abdomen.</td>
<td><img src="image1" alt="Transabdominal Ultrasound Image" /></td>
</tr>
<tr>
<td></td>
<td>• Small amount of gel is applied to the skin to improve sound conduction</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Inaudible high frequency sound waves from transducer probe image soft tissues.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• When sound wave encounters tissues of different densities, part of the wave reflects back to the transducer and makes an image on the monitor.</td>
<td></td>
</tr>
<tr>
<td>Transvaginal ultrasound</td>
<td>• A smaller more linear probe is inserted into the vagina to image the uterus and adnexia.</td>
<td><img src="image2" alt="Transvaginal Ultrasound Image" /></td>
</tr>
<tr>
<td></td>
<td>• This ultrasound usually produces images with more detail than abdominal images.</td>
<td></td>
</tr>
</tbody>
</table>
Saline Infused Sonohysterography (SIS)

- Transvaginal ultrasound following installation of saline into the uterus
- Most useful for differentiating focal from diffuse endometrial abnormalities
- Can help guide the decision of doing a hysteroscopy to evaluate a focal abnormality versus performing an endometrial biopsy or dilatation and curettage
Saline Infused Sonohysterography (SIS)
Diagnostic Hysteroscopy

- Hysteroscopy is a procedure that allows a surgeon to look inside the uterus using a narrow tube-like telescopic camera called a hysteroscope.

- Direct exploration of the uterus is useful in identifying structural abnormalities like fibroids and endometrial polyps.

- In general, diagnostic hysteroscopy is combined with a D&C or endometrial biopsy.

- A hysteroscopy can be used either to diagnose or treat a gynaecological condition.
Hysteroscopy

Hysteroscopy is used to:

- help find out what is causing symptoms, for example heavy bleeding or pain
- check for abnormal pathology (polyps or fibroids)
- treat scar tissue (adhesions)
- Insert or remove an intra-uterine system (IUS)
- carry out a permanent form of contraception (Essure Sterilisation)
- Hysteroscopic morcellation of polyps, fibroids, septum, etc. (TruClear, MyoSure)
Endometrial Biopsy

- In the office use a clear, flexible endometrial curette with an inner plunger or piston that generates suction during the procedure.

- Rates of obtaining an adequate endometrial sample depends on the age of the patient.

- If inadequate sample is obtained, must use additional diagnostic studies to fully evaluate the cause of the vaginal bleeding.
Dilation and Curettage

- Dilation and curettage (D&C) is a procedure to remove tissue from inside the uterus, not just a small tissue sample as in a biopsy.
- Small instruments (dilators) are used to open (dilate) the cervix and a “curette” is used to remove uterine tissue. Curettes used in a D&C can be sharp and used to scrape the lining or use suction.
- Used to diagnose and treat conditions such as:
  - Excessive bleeding after delivery by clearing out any placenta that remains in the uterus.
  - Remove polyps or fibroids.
  - Clear out any tissue that remains in the uterus after a miscarriage or abortion to prevent infection.
Treatment Goals for AUB

- Alleviation of any acute bleeding
- Prevention of future noncyclic bleeding
- Decrease in the patient’s future risk of long-term health problems secondary to anovulation
- Improvement in the patient’s quality of life
Training: Part 3

Treatment Options
Patient Centered Definition of Menorrhagia

**Heavy Menstrual Bleeding**

Diagnosis of HMB based on more subjective factors:
- Negative impact on patient’s daily life
- Interferes with physical, emotional and/or social well being

Treatment Goal: Improved Quality of Life

**Patient Satisfaction!**
Patient Centered Definition

Heavy Menstrual Bleeding

A recent study published in April 2013 on “Women’s Attitudes towards HMB and their impact on QOL”² researched 6179 women from 15 countries, aged 18-55 years old, and found that 39% of those diagnosed with HMB believed there was no treatment available.

This Study also confirms that HMB has a profound negative impact on women’s lives and outlines the need for increased education and information about available treatment options.
Impact of Heavy Menstrual Bleeding on Daily Activities

Treatment Options

- Medical therapies
  - Hormone therapy – Mirena, Analogues, oral contraceptives

- Surgical therapies
  - Hysterectomy
  - 1st Generation Ablation (Hysteroscopic)
  - 2nd Generation Ablation (Global)
Treatment Options

- Medical therapy is often offered as a first line treatment ie. oral tablets to reduce blood loss by improving clotting, hormone tablets or a levonorgestrel-releasing intrauterine system (LNG-IUS).

- Women who suffer with HMB who no longer want any more children and desire a more permanent, but less-invasive solution, should consider endometrial ablation. Hormones are not designed for the treatment of menorrhagia.

- The Thermablate Endometrial Ablation System is an advanced, next-generation technology for the treatment of heavy menstrual bleeding, and should be made available for women who have completed their families.
Levonorgestrel-Releasing Intrauterine System  MIRENA IUD

Mirena is placed in the uterus, not the vagina, so neither you nor your partner should be able to feel it during sex. Sometimes male partners may feel the threads.

Inhibits sperm from reaching/fertilizing egg

Thins uterine lining

Two threads are attached to the stem of Mirena that help ensure it remains properly placed. These threads are the only part you should be able to feel when Mirena is positioned correctly. Your healthcare provider can explain how to check them.

Thickens cervical mucus to prevent sperm from entering uterus
A recent study by Gupta (UK) compared the effectiveness of an LNG-IUS (MIRENA) to medical treatment in women with menorrhagia. The primary finding of this study is:

- At two years, 36% of patients discontinued the use of the LNG-IUS

Consistent with the findings of Ewies (2009) showing:

- a 41% discontinuation rate of the Mirena Intrauterine System at 2 years\(^2\).
- Discontinuation rate increased as time went by, with 50% of patients discontinuing the use of an LNG-IUS by year 5\(^2\).
Levonorgestrel-Releasing Intrauterine System  MIRENA – why it fails…

Common reasons for discontinuation of the LNG-IUS:

- lack of effectiveness and irregular or prolonged bleeding
- progestin-related adverse events such as headaches, depression, acne
- sexual dissatisfaction due to lower abdominal pain
- unscheduled bleeding, weight gain and decreased sex drive in women due to hormones
Summary

- Oral contraceptives fail to control menorrhagia in 53% of women.
- Mirena fails to achieve amenorrhea or oligomenorrhea in 61% of women with menorrhagia, yet an increasingly large number of women are prescribed them for HMB.
- Thermablate EAS provides improvements in Menorrhagia in 95% of patients and reduces painful bleeding in 76%.

<table>
<thead>
<tr>
<th>TREATMENT</th>
<th>TIME TO TAKE EFFECT</th>
<th>POST PROCEDURE HYSTERECTOMY RATES</th>
<th>COMMON SIDE EFFECTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>THERMABLET EAS</td>
<td>≤ 1 to 2 days</td>
<td>2.5% after 1 year(^3)</td>
<td>Minimal cramping, nausea and/or vomiting</td>
</tr>
<tr>
<td>MEDICAL THERAPY</td>
<td>Up to 2 months</td>
<td>53% after 2 years(^4)</td>
<td>Depression, acne, tenderness, nausea, headaches, increased risk cervical cancer</td>
</tr>
<tr>
<td>LNG-IUS (MIRENA)</td>
<td>Up to 6 months</td>
<td>20% after 1 year(^4) 42% after 5 years(^4)</td>
<td>Breakthrough bleeding depression, acne headache, weight gain</td>
</tr>
</tbody>
</table>
Indications for Ablation or Surgery

- Failure of medical management
- Intolerance of medical management
- Patient preference
- Physician preference
Surgical Options

Hysterectomy

Transabdominal (TAH)
  Ave Time 90 mins
Laparoscopic Assisted Vaginal (LAVH)
  Ave Time 140 mins
Vaginal (VH)
  Ave Time 60 mins

Endometrial Ablation

Hysteroscopic/Surgical
  First Generation Ablation
Non-hysteroscopic/Global
  Second Generation Ablation
Hysterectomy

Major invasive operation!

- Second most frequently performed major surgical procedure among reproductive-aged women
- 30-45% of all hysterectomies are performed on women who suffer from menorrhagia
- By age 43, 10% chance of having a hysterectomy
- Average 6 weeks recovery time
- Average 10% complication rate
Hysterectomy

- 1.5 million annually worldwide
- 40 - 46% structurally Normal Uteri removed for menorrhagia
- Associated with increased morbidity, cost, and recovery time
Endometrial Ablation vs. Hysterectomy

- Shorter procedure
  - Reduced or no Anesthesia Time
- Less Invasive
  - Reduced Complications
- Shorter Post-Operative Recovery
- Cost Effective
Endometrial Ablation

Definition

Endometrial ablation has been described as any method used to destroy or ablate the regenerative capacity of the endometrium

Offered as an alternative to hysterectomy to those patients with AUB and benign pathology
Endometrial Ablation – Resection and Roller Ball
Hysteroscopic Ablation - TCRE, ROLLERBALL

ADVANTAGES

• Performed under direct visualization

• Allows treatment of benign pathology such as fibroid removal

• Allows treatment of abnormal cavities
Hysteroscopic Ablation - TCRE, ROLLERBALL

DISADVANTAGES

- Steep learning curve and highly skill dependent – need to do them frequently in order to become and stay proficient
- Higher failure rate in earlier cases
- Limited access to cornual areas
- Requires general anesthesia / O.R. setting
- Risk of fluid overload
- Risk of electrosurgical trauma and mechanical injury
  - Visceral injuries or vulvar-vaginal burns
  - Cervical laceration or uterine perforation
  - Risk of hemorrhage
- Risk of gas or air embolism
1st Generation Endometrial Ablation requires a skilled surgeon to manually ablate or destroy the endometrial lining of the uterus

Complications common to 1st Generation Ablation

1. Access (Mechanical Trauma)

1. Distend (Excessive Fluid - Drowning)

1. Energy (Thermal Burns)
Second generation Endometrial Ablation Technologies (SEATs)
Global Endometrial Ablation (GEA)
Non-Hysteroscopic Endometrial Ablation

- Automated destruction of the endometrium without the use of operative hysteroscopy

- 1st Generation Endometrial Ablation Technologies were introduced in 1980’s as alternative to hysterectomy

- Global Ablation Technologies were introduced in 1990’s as alternative to 1st generation
SEATs: RATIONALE

- Simpler
- Safer
- Faster
- Consistent
- Cost-effective

Minimal Analgesia Requirements (Office Procedure)
MENU FOR ENDOMETRIAL ABLATION

- Laser
- Electrocute
- Slice
- Dice
- Plow
- Poach

Nd:YAG
Rollerball
Loop
Loop with spurs
Grooved rollerball
Hot water (Balloons)
EXTENSIVE MENU FOR ENDOMETRIAL ABLATION

- Boil: Hot water (free flowing)
- Deep Fried: Thermablate
- Freeze: Cryoprobes
- Grill: Copperplated balloon
- BBQ: Bipolar 3-D wire mesh
- Nuke: Microwaves
Training: Part 4

Global Endometrial Ablation
Global Endometrial Ablation - GEA
Various Automated Ablation Technologies Now in the Market…

Current literature shows all 2nd generation techniques give similar results:

- 30-50% of patients achieve amenorrhea
- 80-90% report patient satisfaction after the treatment

Most Important Considerations:

- Patients safety
- Ability to use in outpatient setting!!!
- Versatility to use in an a variety of shape and size uterus
- Low cost for treatment

Studies show that 5-25% of women who undergo endometrial ablation will eventually receive further surgery!
Various Automated Ablation Technologies Now in the Market…

- Hot Liquid Balloons
  - ThermaChoice I, II, III (USA)
  - Cavaterm & Cavaterm Plus (Switzerland)
  - Menotreat (Sweden)
  - Thermablate (Canada/Ireland)

- HydroThermAblation (HTA)

- Cryoablation (Her Option)

- Impedance Controlled Ablation (NovaSure)

- Microwave Endometrial Ablation (MEA, MiniTouch)
The Ideal Endometrial Ablation System:

**Operator Skills:**
Short Learning Curve
Not skill dependent

**Efficacy and Versatility:**
Highly effective, with satisfactory immediate and long-term results
Suitable for a variety of most women and uterine cavities

**Anesthetic Parameters:**
Suitable for office procedures
Minimal cervical dilatation
Minimum post-operative need for analgesia

**Safety:**
Safety independent of operative skills
Device Instructions comply with recommendations of international healthcare regulatory bodies

**Economic parameters:**
Low capital cost
Low cost for treatment
Durable and easily maintainable equipment
Factors associated with Reduced Success Rates

- Start of learning curve (more for TC)
- Patients age
- Uterine retroversion (↑ chance of subsequent hysterectomy)
- Preoperative endometrial thickness of ≥4mm (recommend pre-treatment)
- Duration of menstruation Duration ≥9days (mean)

Factors not influencing success Rates

- Presence of dysmenorrhea
- Longer duration of Treatment

More studies exist on Balloon Endometrial Ablation vs. any other 2nd generation technology:

- NO EVIDENCE documenting the superiority of one Balloon Endometrial Ablation Technique over another
- Clinical success rates, patients satisfaction and quality of life comparable to Hysteroscopic Ablation Techniques
Thermachoice™ Uterine Balloon Therapy System
Johnson & Johnson / Gynecare

- First Global Ablation System on the market
- Approved by FDA in 1997
- Disposable silicone balloon catheter – circulating fluid
- Fluid (saline) heated to 87°C
- Manual adjustment of pressure and temperature
- 8 - 10 minute treatment time
• A Thermachoice treatment requires *much* more Physician involvement and has a *much* longer treatment time than one with Thermablate – **Less Suitable for Treatment Under Local Anesthesia**

  • Physician must manually monitor and control intra-uterine pressure settings throughout the treatment by infusing the balloon with cold saline
  
  • Fluid is then heated within the uterine cavity; metallic heating element inside balloon poses risk of electrical burn and/or perforation
  
  • Total treatment time 8 – 10 minutes because of the lower treatment temperature of the fluid