ENDOMETRIAL ABLATION: TRENDS AND CHALLENGES IN 2017

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Disclosures

• I have used products or done clinical studies for a number of endometrial ablation device manufacturers (Thermachoice, HTA, Microsulis, Thermablate, Novasure, Minerva)
• I do not own stocks or options of any company and I do not receive any salary from any company.
• I did not receive any remuneration from the industry for this lecture
• I have been a « freelance test driver » for the past 25 years ....
Plan of this lecture

1. Indications and pre-op counselling
2. Evolution of techniques since introduction
3. Endometrial ablation vs other treatment modalities
4. Trends and Troubles in 2017
   ✓ Increase treatment access
   ✓ Improve physician training
   ✓ Reduce failure rates
Indications and contraindications to EA

Indications
• AUB of benign origin (PALM-COEIN: P, L, C, O, E)
• May be considered as a primary intervention in such circumstances: (intolerance to or failure of medical therapy, or patient preference)
• Patients who refuse / poor surgical candidates for hysterectomy

Absolute contraindications
Pregnancy
Desire to preserve fertility
Known or suspected endometrial hyperplasia or cancer
Cervical cancer
Active pelvic infection
Specific contraindications related to non-resectoscopic techniques*

Change in the indication for Endometrial ablation over time

- Endometrial ablation is a safe and effective minimally invasive surgical procedure that has become a well-established alternative to medical treatment or hysterectomy to treat abnormal uterine bleeding in select cases. (Level I evidence)

- Alternative means that if a 40 y.o. patient with HMB does not wish to have a Lng-IUD, and her family is completed, there is no problem in performing EA as a first line therapy. However medical treatment should always be offered.
Pre-operative counselling

- Not a guarantee of amenorrhea
- Not a method of sterilization; discussion on sterilization is paramount
- Address long term recurrence /failure rate, particularly of age < 40.

35 years of technical evolution in Endometrial Ablation

- 1981 Endometrial ablation using Nd:Yag laser
- 1989: Monopolar resection/ablation with loop-rollerball
- 1997: First Non-resectoscopic (2^{nd} generation) EA

- Vancaillie TG, Obstet Gynecol 1989
Evolution of technology to perform EA: decrease use of resectoscope? Yes and No.

- **YES**: Now progressively replaced by *non-resectoscopic* ablation technologies (second generation, global ablation GEA) for normal cavities
- **NO**: *Resectoscope still essential* for:
  - sub-mucosal fibroids,  
  - adenomyoma,  
  - large polyps,  
  - mullerian anomaly,  
  - limited excision in case of fertility preservation;  
  - previous myometrial surgery including previous ablation.
Progressive adoption of global endometrial ablation (GEA) over hysteroscopic resection

- For normal cavities, endometrial ablation should be performed using a global, non-resectoscopic technique, because of its greater safety, easy of use and outcome is comparable to resection.
  - SOGC AUB Guideline # 292, 2013; CNGOF Guideline 2010; NICE 2015

- Newer techniques compare favorably with hysteroscopic resection in terms of ease of use, patient satisfaction, complication rate and success rate.
  - Cochrane Database Systematic review 2013
  - Laberge, Fortin et al. A Randomized Controlled Multi-Center FDA Trial of the Safety and Efficacy of the Minerva Endometrial Ablation System. One-Year Follow-Up Results. JMIG 2016 (accepted for publication-in press)
Currently available GEA technologies

- Thermal Balloon therapy (dextrose, glycerin)
- Bipolar mesh
- Free circulating hot saline
- Cryotherapy
- Argon-bipolar (available in US only)
Any global technique superior?

• Equally safe
• Comparable ease-of-use
• Higher amenorrhea rates with Bipolar RF (Novasure)
• Equal overall patient satisfaction long term up to 10 years
• Microwave and Thermachoice no longer available
• Minerva may be superior in the short term

NICE Surveillance report 2015
Lethaby et al. Cochrane review 2013
Kroft et Liu, JOGC 2013
Laberge et al. JMIG 2017
Newer technologies

- **Minerva**: Argon-bipolar technology (available in US)
- **Lina Librata**: glycerine-filled balloon
- **Cerene** by Channel Medsystems: cryotherapy
- **Aegea**: low pressure vapor
Endometrial ablation vs other treatment modalities

• Vs Levonorgestrel IUD

• Vs Hysterectomy
EA vs Lng-IUD: 6 RCTs

- Similar efficacy at 2 years
- Lng-IUD is more cost-effective
- Progestogenic side effects with Lng-IUD
- Better amenorrhea rate with EA

EA vs Hysterectomy: 9 RCTs

• Higher satisfaction rate with hysterectomy (98% vs 85%)
• Lower rate of serious adverse events with EA
• Lower rate of hospitalisation with EA
• Lower cost initially and up to 4 years with EA

EA vs Hysterectomy

• For a normal uterine cavity and a normal size uterus, *EA is the preferred surgical method* to treat AUB of benign origin in women who have completed their family.

• Patient should be counselled about:
  • lack of guarantee of amenorrhea after EA,
  • lack of contraceptive effect
  • and the possibility of recurrence
Trends and challenges in 2017

1. Increase treatment access
2. Improve physician training
3. Reduce failure rates
Challenge #1: How can we increase treatment access?

a. EA as first line therapy

b. GEA in ambulatory setting

c. Industry to make GEA devices more affordable
1a) EA as first line therapy

- «Woman of 42., completed her family, with moderate to severe menorrhagia secondary to DUB»:
  - Why submit this lady to a prolonged hormonal treatment if she does not wish to?
  - Is medical trial mandatory or is medical option discussion mandatory before EA?

- ACOG and SOGC guidelines: EA can be offered as first line therapy for women with DUB who have completed childbearing

ACOG practice guideline no. 81, Obstet gynecol May 2007;109 (5)
1b) Ambulatory setting: features

- Outside the operative room
- Without anesthetist support
- Quicker, cheaper, more efficient
- Not for every patient
- Need for strict protocol and adequate treatment room
1c) Industry to offer affordable devices

✓ Competition between manufacturers
✓ Hospitals and governments to negotiate collective deals on larger volume of GEA devices:
✓ more volume = more bargaining power
✓ Experience is conclusive in other areas (cardiac pacemakers, laparoscopic energy sources and instruments) up to 40% cost reduction in Quebec
Challenge #2) Improve physician training

Yes. Most complications reported are secondary to poor counselling (need for contraception) or protocol deviation, i.e. non respect of the product manufacturer’s manual « IFU »

Yes. Bowel perforation, although rare, has been reported with all EA systems

Yes. Some studies seem to promote the use of GEA in patients with myoma, large polyps...but there is NO high quality data to support safety and efficacy; use the resectoscope instead.

Yes. GEA should not be used in patients with previous myometrial surgery except low transverse c-section; it should not be used for a « redo » procedure.
Challenge #3) reduce failure rate

- Failure = need for additional surgery (redo, hysterectomy) or medical therapy
- Symptoms: recurrent HMB, dysmenorrhea, pelvic pain
- Risk factors: age < 40, previous tubal ligation, pre-operative dysmenorrhea
- Significant reintervention rate 16%-24% long term
- Caution! Re-intervention rate in RCTs is very low because patients are counseled extensively, surgery performed by very experienced surgeons, and because follow-up is relatively short (1 year)

Solutions to improve long term effectiveness

- Rigorous patient selection:
  - Age above 30 (despite RCT with women < 30)
  - Adequate imaging pre-op (SIS, 3-D U/S, HSC,MRI)
  - GEA is to be used only for normal cavities
  - Avoid GEA in cases of suspected significant adenomyosis

- Use of immediate post-op progestins:
  - Depot Medroxyprogesterone acetate
  - Insertion of Lng-IUD

- Repeat EA by experienced surgeons under direct visualisation (4-fold increase in complications)

*El-Nashar J Min Invas Gynecol 2010*
Conclusion

1. Endometrial ablation should be proposed as first line therapy along with medical treatment in women who no longer wish to become pregnant, especially after 40.

2. EA should definitely be offered before hysterectomy in women with HMB of benign origin with a normal size uterus.

3. A Global technique should be preferred in cases of normal uterine cavity.

4. Be cautious with new technologies that have not been the subject of rigorous randomised clinical trials published in peer-review journals or provide only short term data.

5. Outpatient treatment should be promoted because it lowers costs and provides a simpler set-up for a simple procedure in healthy women.