

New surgical options in the management of menometrorrhagia: an overview

M Nisolle

Department of Gynecology and Obstetrics

CHR de la Citadelle

University of Liège, Belgium



*Pierre Fabre Symposium – October 9, 2012
Advances in the medical and surgical management of menometrorrhagia*



Pierre Fabre

Indications for endometrial ablation

- Dysfunctional uterine bleeding
- Failed traditional therapies (e.g. medical, dilatation and curettage)
- Contraindications to traditional therapies
- Poor surgical skills for anesthesia, hysteroscopic endometrial ablation, hysterectomy
- To preserve the uterus

Contraindications for endometrial ablation

- Genital tract malignancy (cervical, uterine, tubal, ovarian)
- Unresolved endometrial hyperplasia
- Women with anatomical or pathological uterine anomalies
- Women with history of previous classical caesarean section or transmural myomectomy
- Intra-uterine pregnancy
- Acute genital and/or urinary tract infection
- Women wishing to preserve their fertility
- Women expecting amenorrhoea as an outcome
- Women with an intra-uterine contraceptive device in place
- Failed previous endometrial ablation

Menometrorrhagia - Endometrial Ablation: 1st or 2nd generation?

First generation

- Video

Second generation

- Video

Menometrorrhagia - Endometrial Ablation: 1st or 2nd generation?

First generation

- Hysteroscopic vision
- Energy:
 - Monopolar energy
 - Bipolar energy
- General or locoregional anesthesia

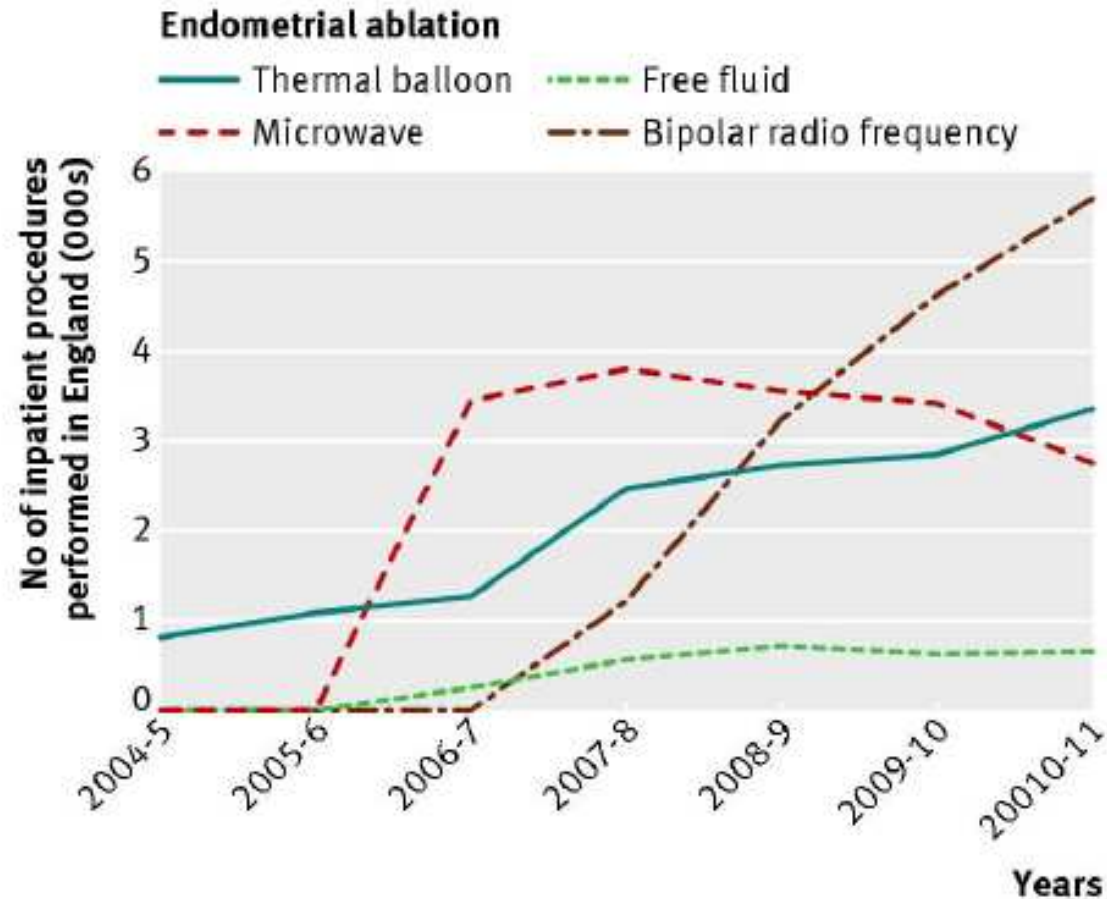
Second generation

- Blind technique
- Several energies
- Without general anesthesia

2nd generation endometrial ablation techniques

- Techniques
- Comparative studies
- Results
- Complications
- Cost effectiveness

Techniques



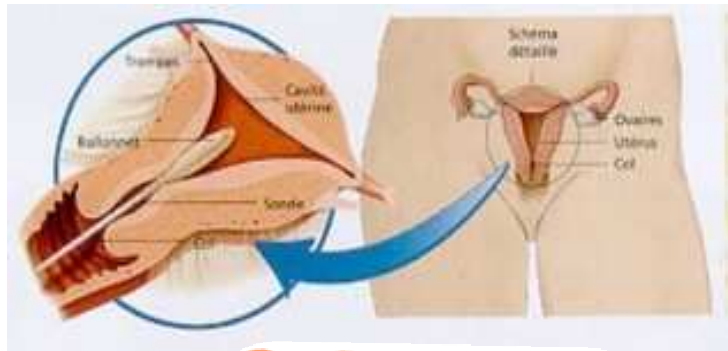
Daniels, BMJ 2012



Pierre Fabre Symposium – October 9, 2012
Advances in the medical and surgical management of menometrorrhagia

2nd generation Endometrial Ablation

- Thermal Balloon (TBA)



Insertion of a silicone balloon into the uterine cavity.

Hot liquid circulates inside the balloon.

Control of pressure and temperature by the computer.

Duration: 2 to 10 minutes.



Figure 1. The Cavaterm balloon and controller.

2nd generation Endometrial Ablation

- Thermal Balloon (TBA)
- Microwave (MEA)



- Insertion of a microwave probe into the uterine cavity to heat the endometrium
- Temperature is maintained at 75-80°C
- The probe is moved from side to side to destroy the endometrium

2nd generation Endometrial Ablation

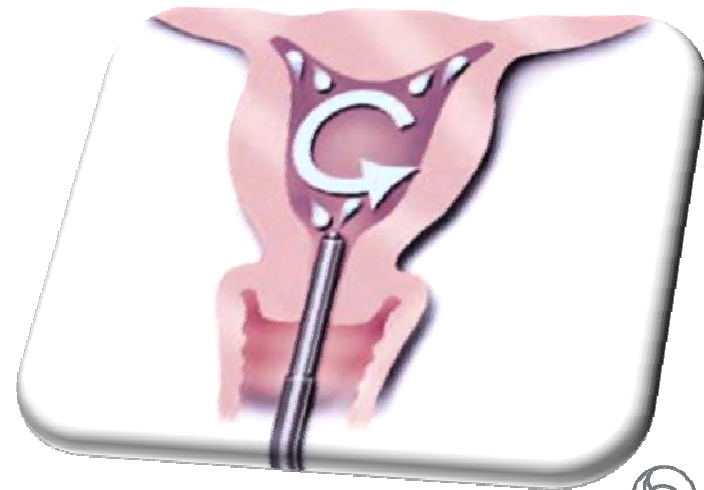
- Thermal Balloon (TBA)
- Microwave (MEA)
- Radiofrequency electro-surgery (RFA)



- Impedance-controlled bipolar radiofrequency ablation
- A triangular mesh electrode is expanded to fill the uterine cavity
- The electrode delivers electrical current and destroys the endometrial lining
- Temperature 45°C
- Duration of the procedure: max 15 minutes

2nd generation Endometrial Ablation

- Thermal Balloon (TBA)
- Microwave (MEA)
- Radiofrequency electrosurgery (RFA)
- Hydrothermal ablation (HTA)
 - Temperature: 90°C/194°F
 - Duration: 10 minutes



2nd generation Endometrial Ablation

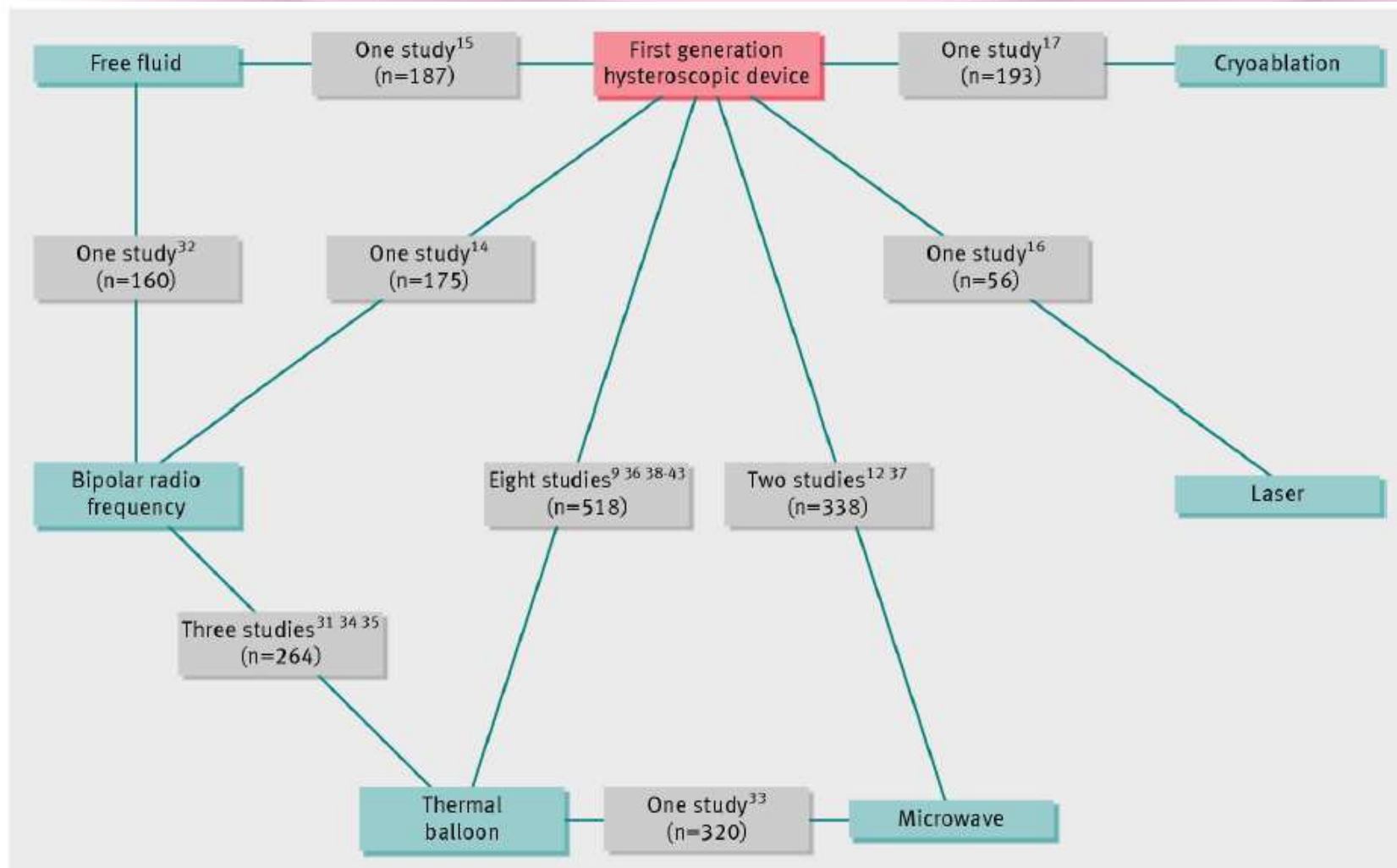
- Thermal Balloon (TBA)
- Microwave (MEA)
- Radiofrequency electrosurgery (RFA)
- Hydrothermal ablation (HTA)
- Cryoablation

A slender single-use probe is inserted into the uterus.

From the tip of the probe subzero temperatures are applied symmetrically to the uterine lining

Duration: 20 to 30 minutes

Network of studies evaluating 2nd generation endometrial destruction devices for treatment of heavy menstrual bleeding

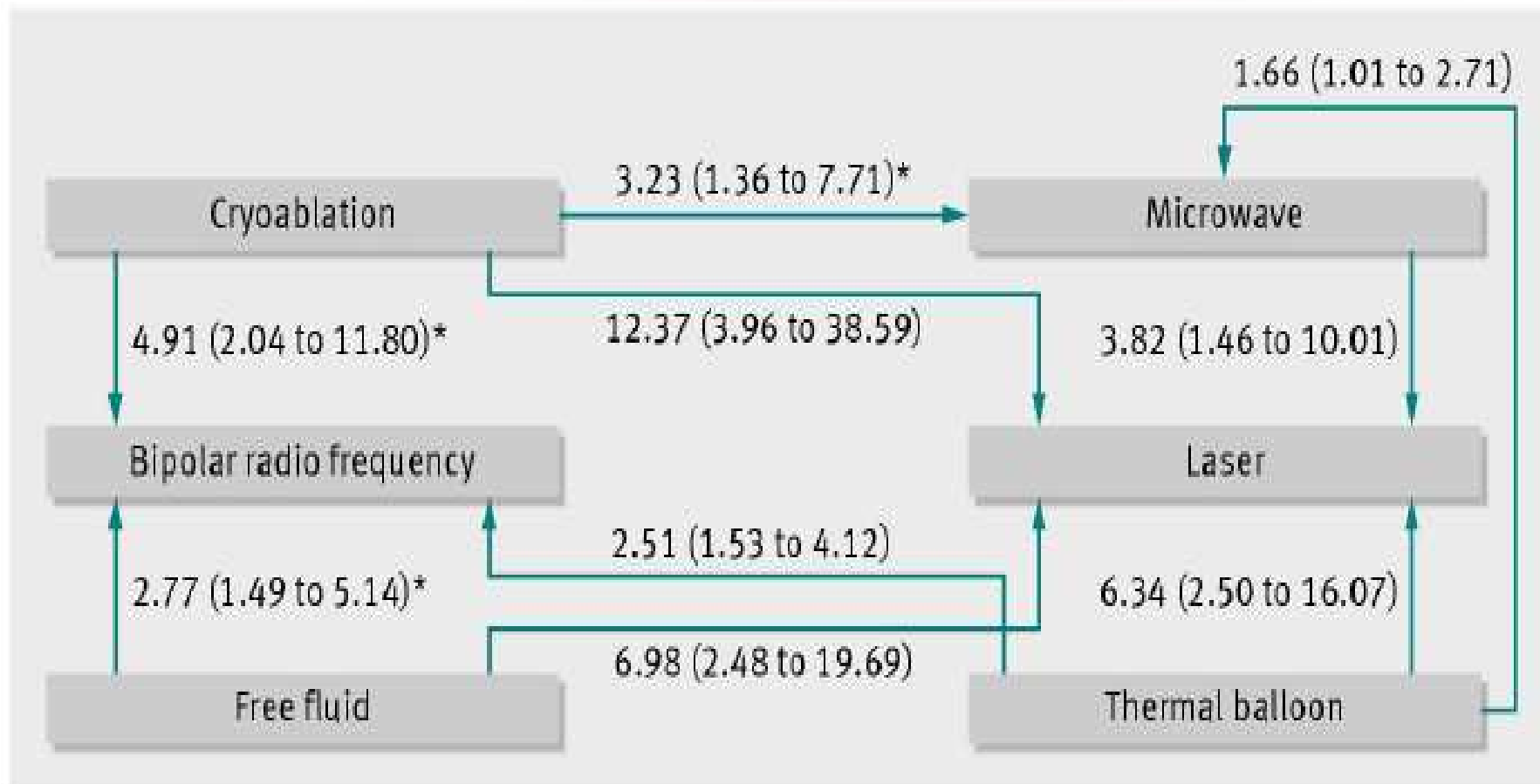


Daniels, BMJ 2012 

Pierre Fabre Symposium – October 9, 2012
 Advances in the medical and surgical management of menometrorrhagia

Pierre Fabre

Amenorrhea rate at 12 months



Daniels, BMJ 2012

HTA

Outcomes in patients who underwent office endometrial ablation using the HTA system according to myoma status

| Variable | Patients With Myomas | | Patients Without Myomas | | p Value ^a |
|---|----------------------|-----------|-------------------------|-------------|----------------------|
| | No. (%) | 95% CI | No. (%) | 95% CI | |
| Outcome | | | | | |
| Amenorrhea | 37 (38.9) | 29.1–48.8 | 84 (61.8) | 53.6–69.9 | <.001 |
| Oligomenorrhea | 27 (28.4) | 19.4–37.5 | 35 (25.7) | 18.4–33.1 | |
| Eumenorrhea | 9 (9.5) | 3.6–15.4 | 12 (8.8) | 4.1–13.6 | |
| Menorrhagia | 11 (11.6) | 5.1–18.0 | 4 (2.9) | 0.1–5.8 | |
| Hysterectomy because of bleeding | 11 (11.6) | 5.1–18.0) | 1 | 0.7 (0–2.2) | |
| Total | 95 (100) | | 136 (100) | | |
| | | | | | RR (95% CI) |
| Menorrhagia or hysterectomy because of bleeding | 22 (23.2) | 14.7–31.6 | 5 (3.7) | 0.1–6.8 | 6.3 (2.5–16.0) |
| Hysterectomy because of bleeding | 11 (11.6) | 5.1–18.0 | 1 (0.7) | 0–2.2 | 15.7 (2.1–119.9) |

CI = confidence interval; HTA = HydroThermAblator (Boston Scientific Corp, Natick, Massachusetts) RR = relative risk.

^a χ^2 test.

Glasser et al, 2009



Pierre Fabre Symposium – October 9, 2012
 Advances in the medical and surgical management of menometrorrhagia



TBA and RFA

- Results: 23% amenorrhea
- Predictor of amenorrhea:
 - Age ≥ 45 years
 - Uterine length < 9 cm
 - Endometrial thickness < 4 mm
- RFA $>$ TBA
- 5-year cumulative failure rate: 16%

El Nashar et al Obstet Gynecol 2009



Pierre Fabre Symposium – October 9, 2012
Advances in the medical and surgical management of menometrorrhagia



Pierre Fabre

Cumulative failure rate

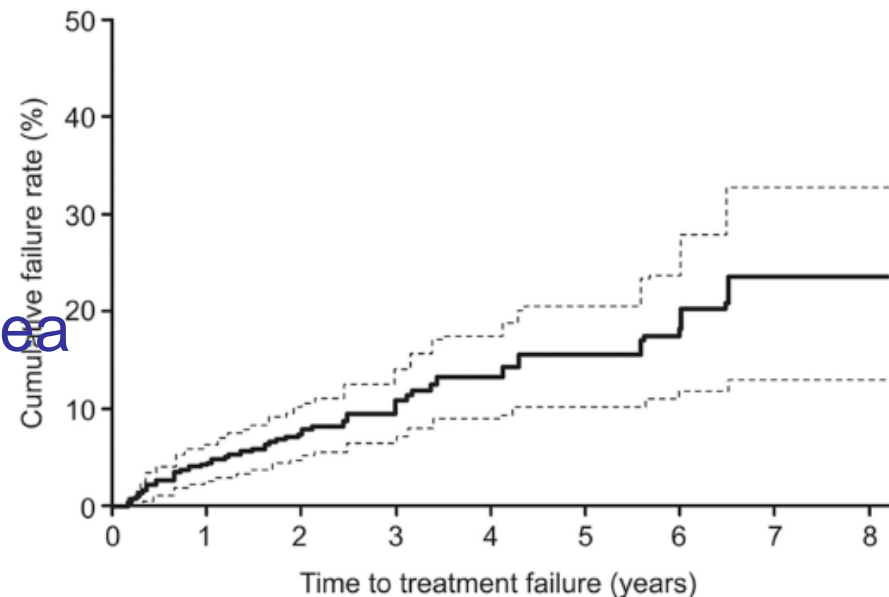
Predictors of treatment failure

Age <45 years

Parity ≥ 5

Prior tubal ligation

History of dysmenorrhea



El Nashar et al Obstet Gynecol 2009



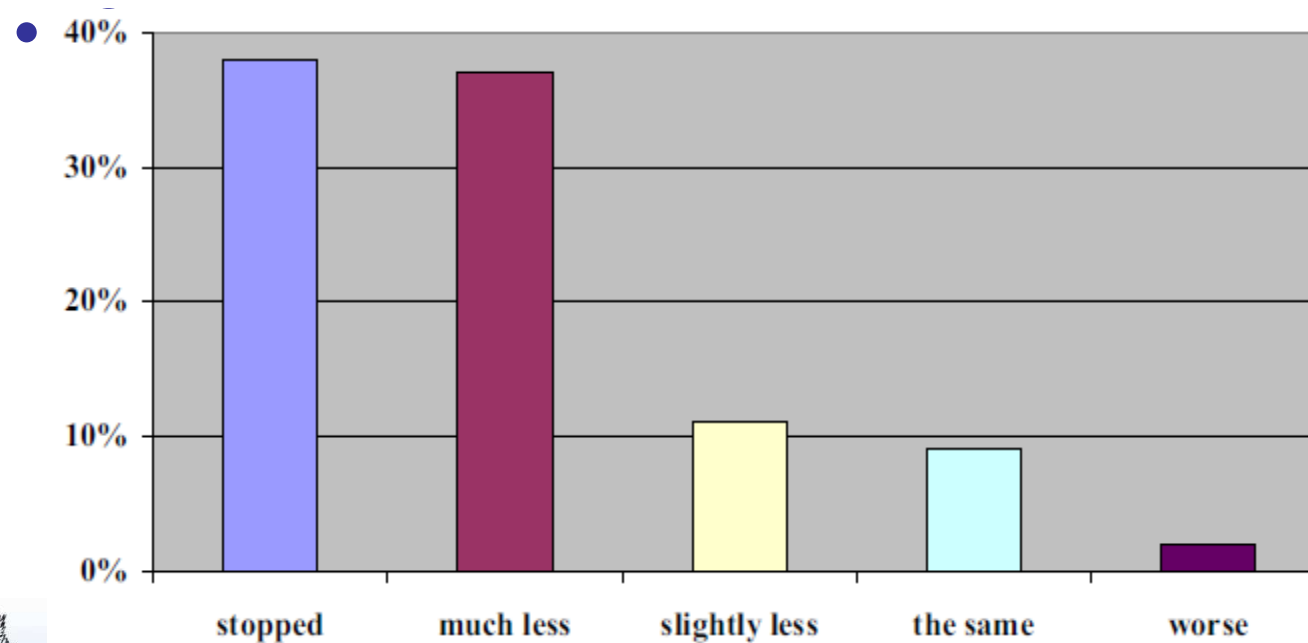
Pierre Fabre Symposium – October 9, 2012
Advances in the medical and surgical management of menometrorrhagia



Pierre Fabre

TBA

- Retrospective cohort study after TBA for menorrhagia
- Follow up: 8 years
- Amenorrhea rate: 38% and substantial decrease in bleeding in 37%



Kopeika et al, Am J Obstet Gynecol 2011

Complications

- Perforation of the uterus
- Minor secondary haemorrhage
- Burning of the vagina, cervix and small bowel
- Serious complications occurring with an incidence of less than 1%

Recommendations

- In cases of suspected uterine displacement, clinicians should verify the correct placement using ultrasound before the device is activated
- As well as the use of ultrasound for all devices, the use of hysteroscopy prior to the insertion of the ablation device is recommended if the device is not a balloon. This enables a check to be made that sounding and dilation of the cervix has not caused a perforation or false passage

Cost-effectiveness: MEA vs TBA

- MEA is likely to be more cost-effective than TBA at 1 year
 - The mean cost of TBALL (10 years equipment life, 100 uses annually) of reusable equipment was £181 (95% confidence interval [CI] £70-434) greater than MEA
 - No statistically significant differences between the total nonhealth costs and health benefits of the two arms
 - On average, MEA provided more Quality-adjusted life-years (QALYs)
 - MEA was, on average, dominant (less costly and at least as effective) and there was over a 90% chance that MEA would be considered cost-effective at a £20,000 threshold of cost per QALY
- Kilozo, *Value Health* 2010

Conclusions

- Technically easier
- Success rate and complication profiles compare favourably with TRE
- Less complication with 2nd generation procedure for TEA
 - Fluid overload
 - Uterine perforation
 - Cervical laceration
 - Hematometra
- More side effects: nausea, vomiting, uterine cramping
- Less effective than hysterectomy in stopping bleeding but is not invasive
- Hysterectomy is associated with a higher risk for pelvic floor repair and surgery for SUI

Lethaby, Cochrane Data Base 2005
Cooper et al, BJOG 2011



Pierre Fabre Symposium – October 9, 2012
Advances in the medical and surgical management of menometrorrhagia



Pierre Fabre

Therapeutic options for Heavy Menstrual Bleeding

