

## TREATMENT OF MENORRHAGIA

### Abdul-Rahim Haloob

MB,ChB, MFFP, FRCOG, Consultant Obstetricians and Gynaecologist, University of London Teacher (UCL), Royal College of Obstetricians and Gynaecologists District Tutor, Basildon University Hospital, Basildon, Essex United Kingdom

### Introduction

**H**eavy Menstrual Bleeding (HMB) is a significant cause of morbidity in premenopausal women in the UK. HMB is objectively defined as menstrual blood loss of more than 80ml/cycle, or menstrual bleeding lasting longer than 7 days, over several consecutive cycles. However the diagnosis is based on the women's subjective assessment of blood loss.

Excessive menorrhagia affects one in five women in the productive age, is contribute to about 20% of all referrals for specialist gynaecology services. The amount of blood lost in each period varies with the individual. Because of this wide variation it is impossible to define a 'normal' period in terms of the amount, length and frequency of bleeding. Generally speaking, variations were noticed because of age, and in relation to periods before and after pregnancy.

Menorrhagia is the term indicating heavy and regular periods. In about half the women with heavy periods, no cause can be found. However in others, menorrhagia could be due to:

1. Contraceptive device
2. Injectable Contraception such as Depoprovera.
3. Pelvis disorders such as: a fibroid; endometrial polyp; endometriosis and adenomyosis; endometrial hyperplasia; endometrial carcinoma. Haematological and hormonal

condition, a leading cause of HMB is what we called hormonal imbalances. Hypothroidism and blood coagulation defects and the use of anticoagulation drugs are contributing to large number of cases of HMB.

4. 80% of HMB due to Ovulation defects and unovulation .

### Implications of HMB

Heavy periods are restricting women activities at work and home directly by heavy menstrual flow and associated problems such as pain, feeling weak and indirectly by chronic tiredness and anaemia. HMB would impose some times severe restriction on sexual and marital life

### Treatment of HMB

Royal College of Obstetricians and Gynaecologists of the United Kingdom,(RCOG 1999) , National evidence-based clinical guidelines of menorrhagia in secondary care (Dec 2004), setting the standards in 2004 and the national NICE looked into the MAS for menorrhagia and evaluate individual procedures. However, medical treatment such as combined oral contraception, Tranexamic Acid and Mefenemic acid are effective for reducing HMB loss and the two later drugs are

effective in IUCD induced Menorrhagia. Medical treatment therefore must be tried in the primary care set-up before the woman referred to local gynaecologist.

After failure of medical treatment, patient should be offered:

1. Progestogen releasing I.U. C. D (Mirena I.U.S)
2. Endometrial resection or ablation
3. Hysterectomy
  - TAH
  - Laparoscopic assisted vaginal hysterectomy (LAVH) and total Laparoscopic Hysterectomy(LH)
  - Vaginal hysterectomy

Patients must be involved in the decision making process regarding their treatment and appropriate information should be provided. The discussion should involve the likely outcomes and complications.

Progestogen (levonorgestrel) Intra-uterine system, I.U.S (Mirena)

I.U.S is effective treatment for reducing heavy menstrual blood loss and should be considered an alternative to surgical treatment. Lahtenmaki P etal (BMJ1998) reported from Finland that women who were fitted with a Levonorgestrel releasing intrauterine system while on the waiting list for a hysterectomy for menorrhagia, were so pleased with the results that 60% of them refused hysterectomy when their names came up for admission. However, Mirena IUS not without problems such as water retention, weight gain, pain and irregular bleeding which some time forced women to demand removal after a short period of time.

#### MAS for Menorrhagia

Endometrial ablation techniques are now well established and the uptake of these alternative treatments of manorrhagia partly accounts for the fall

in the number of hysterectomies performed in Europe over the past decade.

Earlier techniques such as endometrial resection, rollerball coagulation and endometrial laser ablation (first generation methods), still regarded as gold standard in the MAS for menorrhagia. Second generation techniques aim to induce permanent thermal damage. Both first and second generation techniques aimed to inflict permanent damage or resection of basal endometrium by heated fluid directly or indirectly onto the endometrium or by radiofrequency (rf) or laser energy resection or ablation.

#### First Generation MAS

Endometrial resection by loop resection (resectoscopy) roller ball ablation of endometrium or laser ablation have been employed with the purpose of removing the entire thickness of the endometrium (Peninsula Technology Group 2003) . The benefits acclaimed to those therapies to reduce trauma and post operative complications to the women, reduced the need for a general anaesthetic and shifting the procedure from inpatient to day case treatment. Indirectly, these procedures have saved considerable amounts of money to the society. However, these procedures need intensive training and capital for equipment, and the financial advantage has been reduced by the need to perform additional surgical treatment in case of recurrence of heavy periods.

There was a significant advantage in favour of hysterectomy in improving heavy menstrual bleeding (HMB). Satisfaction rates (upto 4 years post surgery) compared with endometrial destruction techniques. Although the quality of life scales reported no difference between surgery groups, there was some evidence of a great improvement in general health for hysterectomy patients.

Duration of surgery, hospital stay and recovery were all shorter following endometrial destruction.

Most adverse events, both major and minor, reported to be higher in the hysterectomy group compared to endometrial destruction.

#### Second generation MAS for menorrhagia

##### Thermal ablation:

A number of hydrothermal ablation devices were introduced to gynaecological practice in North America and Europe since 1994. These devices have undergone several modifications with variable results and outcomes.

##### 1. *Thermal balloon Ablation* (Thermachoice)(Ethicon,Somerville,N.J.)

5mm catheter with fixed length silicon balloon at the end. After dilation of the cervix, the balloon inserted into the uterus and distended gradually with 5% dextrose until the pressure reaches 160-180mmHg. Once the desired temperature has been reached the procedure takes eight minutes.

##### 2. *Cavaterm plus* (Walsten Medical,Morges Switzerland)

Hand piece with a diameter of 6mm, has a silicon balloon of adjustable length at the distal end designed to fit uterine cavities of variable lengths. Once in the uterine cavity, the balloon is inflated with 5% dextrose and the pressure is maintained at 220-240mmHg. The desired temperature (65-78°C) is maintained for 10minutes in order to achieve complete ablation.

##### 3. *Hydro ThermAblator* (HTA) (Boston Scientific Microvasive)

The HTA is designed to offer a new and simple alternative for menorrhagia- dysfunctional uterine bleeding. The HTA utilizes

circulation of heated saline, which fully conforms to the entire uterine endometrial lining, including the cervical area under direct hysteroscopic visualisation. The hysteroscopic sheath is 7.8mm in diameter. The pressure will be maintained electronically to less than 55mmHg in order to prevent flow through the uterine ostae. The treatment cycle is 10 minutes at a temperate of 80-90°C. At completion of the HTA treatment cycle, room temperature saline automatically flushes hot saline from the sheath and cools the uterine cavity.

##### 4-*Thermablate EAS* (MDMI Technologies, Richmond,BC,Canada)

This is the newest endometrial thermal balloon ablation system. Thermablate EAS consists of a light weight reusable hand held treatment control unit with a single use disposable catheter of 6 mm diameter. Following insertion of the prelubricated balloon into the endometrial cavity, the pressure automatically maintained at 180mmHg for the treatment cycle of 2min, and 8 second. Tissue necrosis to uniform depth of 4-5 mm has been demonstrated. Amenorrhoea rate of 20%, spotting 20%, hypomenorrhoea 37%, euomenorrhoea 16% and persisting menorrhagia 6% , has been reported.

##### Outcome of balloon ablation

The presence of submucous fibroids or endometrial polyps may increase the failure rates for balloon-based devices- this may be improved by using HTA.

However, MAS for menorrhagia proved to be associated lower complication rates, short hospital stay, and short periods of recovery and cost effective compared to TAH.

Compared with first generation techniques, HTA techniques are less

operator dependant, therefore easy to handle and shorter learning curve in addition to much lower complication rates. Thermal injury to the bowels and urinary bladder can occur when the procedure is complicated by uterine perforation. The new devices have in built mechanisms to check for perforation before initiation of the procedure.

Minor complications such as nausea and vomiting can occur in about 20-25% and postoperative cramping in up to 90%.

Reported amenorrhoea rates vary from 30 to 60% and 53% with HTA and a success rate of up to 94%, with patient satisfaction up to 98%.

Disposable devices cost between £250-400 per single use.

Other ablation devices using radiofrequency energy RF ( third generation)

a. Novasure (Cytac Surgical Products) Impedance controlled endometrial ablation system. The Novasure procedure is regarded to be one of the 21<sup>st</sup> century's best endometrial thermal ablation, being the fastest ablation technique. The average time is 90 seconds. The hard piece attached to the thermal electrode array expands to conform to the contours of the uterine cavity. It has inbuilt cavity integrity assessment using a small amount of CO<sub>2</sub>. The electrode array delivers bipolar RF energy until complete ablation after 90 seconds, and then the electrode array is retracted for easy removal. The bipolar electrode design provides a shallower ablation (2-3mm) in the cornus and lower uterine segment and a deeper ablation (5-7mm) in the fundus and main body of the uterus.

The system can alert the operator to a perforated uterine wall prior to treatment, this is an added safety

feature to minimise intra and postoperative complications.

Amenorrhoea rate of 41-59% at 12months and 65% at 36 months has been reported. This increased to 70% in patients above 40 years old. Patients with type 1 and type 2 submucous fibroids from 1to 3 cm in diameter can be treated with successful control of bleeding of 96% (amenorrhoea rate of 71% and reduction in bleeding to normal levels or less of 25%), J AM Ass of Gynae Lapa.Nov 2002.

#### b- Microwave Endometrial Ablation MEA (Microsulis)

MEA system is a device designed to ablate the endometrial lining of the uterus using microwave energy at a fixed frequency . It consists of the MEA control unit that houses a control Module with an embedded microprocessor and user touch screen, microwave generator, applicator, a pneumatic footswitch, microwave and data transmission cables, a printer, a power cord and portable cart.

The MEA applicator is reusable instrument used to introduce microwave energy at 9.2GHZ into the uterus. The shaft of the applicator measures 8.5mm in diameter and graduated along its length in centimetre units, its ceramic tip is 7mm in length.

The depth of ablation is 5-6mm and the duration of the treatment is between 3and 5 minutes for the normal size uterus (75-85mm).

The ablation takes longer and become less effect when there is a submucous fibroid, due to absorption of microwave energy by the Fibroid, Nice Guidance 104 Dec 2004.

### Cryo Ablation of Endometrium Her Option, Office Cryoablation of Endometrium

This is the most recent second generation device introduced to gynaecological practice. Her Option is Cryoablation Therapy system aim to destroy the endometrium tissue through subzero temperature using ultrasound guidance to monitor the safety and extent of the treatment. The device comprised 5.5 mm probe and self contained unit. The depth of the ablation is up to 12mm. It was claimed by the manufacturing company (American Medical Systems) that 94% of evaluated patients were free of abnormal uterine bleeding after 2 years. The cryoablation can be achieved under oral analgesia and paracervical block., AM J Obstet. Gynecol 2003.

### Conclusion

Endometrial ablation is a suitable alternative to Hysterectomy for treatment of HMB

Systematic review of the first generation endometrial ablation techniques versus hysterectomy for HMB showed fewer complication rates and shorter recovery period.

Although there are some variations of the rates of amenorrhoea between different methods of second generations no studies found significant difference between 1<sup>st</sup> and 2<sup>nd</sup> generation techniques of Endometrial ablation. However, the second generation techniques resulted in significantly shorter operating and theatre times but not in post operative length of stay and recovery time. The perioperative and post operative complications rates are similar.

### Hysterectomy for benign conditions

TAH has been and for a long time regarded to be the operation of choice for heavy periods due to organic cause

and dysfunctional uterine bleeding (DUB). However, in the recent and advanced gynaecological practice this operation has been challenged for two reasons:

1. It was regarded as an operation performed by 'hyster-happy' mostly male surgeons. (BMJ June 2005)
2. Introduction of many minimal access procedures (MAS) and levonorgestrel I.U.C.D. (Mirena I.U.S).

The number of TAHs performed in the third world remains to be difficult to quantify. However, in the USA 600,000 hysterectomies are performed each year and in the UK, approximately 47000 hysterectomies were carried out annually. Women have a one in five chance of having a hysterectomy by the age of 55.

Nine of every 10 hysterectomies are performed for non-cancerous conditions. In many of these, no disease is present (DUB).

MAS procedure (endometrial ablation embolisation of fibroids and Minerva I.U.S) still of limited use due to the following reasons:

1. Availability of equipment and training
2. Long term safety of these procedures apart from transcervical endometrial resection (TCRE).

However, MAS for HMB proved to be associated with lower complications rate, short hospital stay, and short period of recovery and cost effective compared to hysterectomy. Hysterectomy rarely leads to perioperative death, but is it associated with a long term risk of death? Iversen et al 2005 concluded that long term study showed no significant increased risk of death and Johnson et al showed low rate of severe morbidity complicating hysterectomy.

The main types of Hysterectomy are now used Abdominal Hysterectomy, vaginal and Laparoscopic. Laparoscopic

hysterectomy has gradually increased and has advantages over other types;

- 1- Diagnose and treat other pelvic diseases
- 2- Carry out adnexial surgery
- 3- Ability to secure thorough intraperitoneal haemostasis
- 4- Associated with fewer abdominal wall infection or febrile episodes.
- 5- And rapid recovery time and shorter hospital stay
- 6- Rapid return to work and normal activities.

Laparoscopic assisted vaginal Hysterectomy (LAVH) and total Laparoscopic Hysterectomy (LH) both required the highest degree of surgical skills and currently done only in a very small proportion of units.

Although several studies showed longer operative time needed to perform LAVH and LH than vaginal hysterectomy, in an experience hands the operative time is comparable.

It is estimated that TAH cost in the region of £2275 compared to MAS procedures, which cost any thing between £1191 to £1614.

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