Guidance on the responsibilities of manufacturers, the regulator and clinicians with respect to endometrial ablation

The recommendations of a joint workshop

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Medicines and Healthcare products Regulatory Agency
Royal College of Obstetricians and Gynaecologists
British Society for Gynaecological Endoscopy

Endometrial ablation

This leaflet contains the conclusions of a workshop organised by the Medicines and Healthcare products Regulatory Agency (MHRA). The workshop was arranged in response to concerns in relation to the significant number of adverse events reported to the MHRA Adverse Incident Centre associated with endometrial ablation.

The workshop brought together representatives of The Royal College of Obstetricians and Gynaecologists (RCOG), the British Society for Gynaecological Endoscopy (BSGE), relevant manufacturers and members of the MHRA.

This leaflet sets out the responsibilities of the three parties involved: gynaecological clinicians, manufacturers, and the regulator. We hope you will find this guidance helpful.

Gynaecological clinicians

1. Patient selection

i. Indications

- needs treatment, i.e. heavy menstrual bleeding not responding to medical treatment
- family complete
- healthy endometrium
- hysterectomy not essential

ii. Bearing in mind the following patients do best

- older age
- shorter uterine length (6-10 cm)
- smaller uterine volumes (less than 15 ml)
- higher intrauterine pressures where applicable
- no previous uterine surgery
- no intrauterine pathology, e.g. fibroids
- no previous pelvic inflammatory disease/abdominal surgery

iii. Generic contra-indications

- classical caesarean section
- other open mid-line uterine surgery
- current pelvic infection
- malignant or pre-malignant endometrial changes

iv. Device specific contra-indications

- previous endometrial ablation
- myometrial thickness at level of caesarian scar of less than 8 mm or 10 mm
- uterine cavity size less than 4 cm
- uterine length (cervix to fundus) of greater than 12 cm
- abnormal uterine shape

2. Training

- Ensure that all clinicians being trained for endometrial ablation have adequate experience in endoscopic and ablative procedures
- Ensure all clinicians are subjected to adequate training/mentoring programmes, professional organisations having laid out criteria of competence
- Ensure all participating clinicians take part in refresher courses to update technique and review any updated changes in the instructions for use

3. Before treatment

- Ensure patients have given adequate consent and been provided with the full facts including the possibility of post-procedural complications and with understanding of symptoms, particularly following uterine perforation (consider preparation of patient booklet)
- Ensure clinician is trained to undertake the procedure and is familiar with the instructions for use
- Adhere to NICE guidelines for patient selection if previous caesarean section
- Carry out pre-operative procedures including uterine assessment using hysteroscopy and/or ultrasound and ensure the endometrium is healthy
- Consider cervical softening agents if dilatation is anticipated to be difficult

4. Treatment

- Examine patient to assess uterine size and axis
- Consider laparoscopic control in selected patients, e.g. repeat ablation
- Immediately after dilatation of the cervix and prior to positioning the device for treatment, assess cavity for perforation, false passage or even trauma to the uterine wall, using hysteroscopy
- Ultrasonography following insertion of the device, and before activation, may be used by those fully trained in its use to help ensure that the myometrium has not been partially penetrated or even perforated
- Perform procedure in accordance with procedure protocols
- If an operator has any doubts that the device is not correctly positioned, remove the device and re-check the cavity with the hysteroscope, if any evidence of myometrial trauma the procedure must be abandoned
- If there is any concern about damage to internal organs then assess by laparoscopy, proceeding to laparotomy if appropriate
- Consider post-procedure hysteroscopy to allow assessment of cavity and treatment

5. Post-procedure assessment

- Ensure adequate post-procedure analgesia
- Inform patients to expect rapid recovery to normal and to report early if they begin to deteriorate
- Early diagnosis and treatment of complications (particularly perforation)
- Report all adverse events to manufacturer and/or MHRA

Manufacturers

- Production of safe devices with upgrades and modifications as necessary
- Production of maintenance schedules
- Initiation of training programmes and refresher courses for clinicians
- Production of user-friendly instructions for use (IFU)
- Notification of all relevant clinicians if there are changes in instructions for use
- Reminding clinicians of importance of reporting adverse events (to manufacturer and/or MHRA as relevant)
- Ensuring an appropriate post-market surveillance system is in place and relevant conclusions are brought to the attention of clinicians

MHRA (Regulator)

- Promotion of the use of the specific obstetrics and gynaecology reporting form on the MHRA website
- Establishing links to RCOG/BSGE websites
- Promotion of adverse event reporting by clinicians
- Designing a questionnaire so that all necessary details of all endometrial ablation related adverse events reported to the MHRA Devices Adverse Incident Centre are recorded
- Feedback to clinicians through means of Royal Colleges and professional bodies about adverse events and their outcomes at suitable time intervals (6-monthly)
- Feedback to clinicians about any changes in the instructions for use particularly those involving safety issues

For further information, visit the following websites:

www.mhra.gov.uk

Medicines and Healthcare products Regulatory Agency

To report adverse incidents to the regulator go to:

http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/index.htm

www.rcog.org.uk

Royal College of Obstetricians and Gynaecolgists

www.bsge.org.uk

British Society for Gynaecological Endoscopy

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