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## Ectopic Pregnancy, Including Methotrexate Administration Protocol Management Policy

### **Purpose**

To support clinicians in the management of women who have a diagnosis of ectopic pregnancy.

### **Principles**

Pregnant women should be offered evidence-based information and support to enable them to make informed decisions about management of their ectopic pregnancy. Addressing women's views and concerns should be recognised as being integral to the decision-making process.

### **Scope**

To all medical, and nursing staff in Women's Health Service, ED, Theatre and GSG

### **Definitions**

**Ectopic** – a pregnancy that is not in the endometrial cavity of the uterus. The fertilised egg has settled in a location other than the inner lining of the uterus. The large majority (95%) of ectopic pregnancies occur in the Fallopian tube. However they can occur in other locations, such as the ovary, cervix and abdominal cavity. An ectopic pregnancy occurs in 1 in 60 pregnancies.

**Early pregnancy** – all gestations up to 20 completed weeks (Note: Women with pregnancy of gestation >20 weeks should be referred to the maternity unit)

**ED** – Emergency Department

**POD** – Pouch of Douglas

### **Clinical Presentation**

Ectopic Pregnancy is suspected when a women presents with a combination of the following:

- **Clinical**
  - History of amenorrhoea
  - Pelvic pain and/or abnormal bleeding in the first trimester

- Shoulder tip pain
- Dizziness or spells of fainting
- Other evidence of blood in the peritoneum
- **Biochemical:**
  - Positive pregnancy test (urine or serum)
- **On Transvaginal Ultrasound**
  - Intrauterine gestational sac not seen
  - Ovarian / fallopian mass may be seen (not: an adnexal mass will not be found in 15 –35% of women with an ectopic pregnancy)
  - Fluid in the POD

### **Risk factors for ectopic pregnancy**

- Women with previous ectopic pregnancy
- Previous pelvic infection or pelvic inflammatory disease
- IUCD in situ
- Previous pelvic surgery – including caesarean section, tubal surgery, appendicectomy
- History of fertility problems – including assisted conception
- Progesterone only pill

Combination intra-uterine and extra-uterine pregnancy is rarely encountered (i.e. occurs in 1:40,000 natural pregnancies and 1:1,000 IVF pregnancies)

### **Selecting an appropriate management method**

- Two options for ongoing management are used most commonly:
  - **Medical management** (methotrexate)
  - **Surgical management**
- Women should participate fully in the selection of the most appropriate treatment
- *Provide women with written information concerning their treatment options and carefully advise of the advantages and disadvantages associated with each approach*
- **Decisions regarding management should take into account the following inclusion criteria**

**Management method****Inclusion criteria**

Medical management is most suitable for women who:

- Are haemodynamically stable
- Do not have pelvic pain
- Have  $\beta$ hCG <5000 IU/L
- On TVS have no foetal heart activity, an un-ruptured ectopic mass size <3.5cm and no fluid in the peritoneal cavity or pouch of Douglas
- Will be compliant with regular follow ups
- Agree to use reliable contraceptive for 3-4 months post treatment
- Desire future fertility

**Medical**

- Have no pre-existing severe medical condition or disorder
- Have no abnormality of LFT, U&E or FBC (liver, renal or bone marrow impairment)
- Have no known contraindications to methotrexate
- Are not currently taking non steroidal anti-inflammatory drugs (NSAID), diuretics, penicillin and tetracycline group drugs (this is not so critical for the single dose methotrexate regime).
- Do not have a co-existing intrauterine pregnancy
- Are not breastfeeding.

**Surgical**

**Women who are NOT haemodynamically stable, or who cannot be managed medically, as per criteria above, or have already had failed medical management, should be offered surgical management.**

- The psychological impact of early pregnancy loss may seriously affect women and their partners
- Time should be given for women to make decisions, and counselling should be made available
- Evidence shows that there may be little difference in psychological outcomes when comparing surgical and medical methods of managing ectopic pregnancy

- Plans for management and follow-up should be clearly recorded in notes and discharge summary

### **Medical management (Methotrexate)**

#### **Treatment schedule**

- Explain treatment to the woman (and partner) and provide written information)
- Collect pre-treatment bloods (i.e.  $\beta$ hCG, U & E, LFT, FBC) Administer Anti-D to Rhesus negative women
- Obtain woman's weight and height and calculate body surface area
- Obtain written consent
- Single methotrexate dose calculated based on 50mg/m<sup>2</sup> surface area
- Consider a multi-dose regime of methotrexate for women with cervical or cornual ectopic pregnancies.

#### **On discharge**

- Complete discharge summary
- Arrange appropriate blood tests with patient
- Put in MAU diary for follow up as appropriate
- Provide contact numbers / appointments for support services (eg: Social Work)
- Advise the woman of the following:
  - That she may experience some pain in the abdomen as the pregnancy resolves. She may take simple analgesia
  - To avoid vaginal intercourse until follow up is complete, contraception should be recommended for 3 months
  - To avoid alcohol for 7 days
  - To avoid herbal remedies and vitamin preparations containing folate
  - To contact local General Practitioner after hours if concerns regarding pain or bleeding

#### **Follow up and monitoring**

- Day 1: day on which methotrexate is given
- Day 4:  $\beta$ hCG
- Day 7: FBC,  $\beta$ hCG, LFT, U & E
- Day 14: FBC,  $\beta$ hCG
- Weekly follow up until  $\beta$ hCG is <5IU/L -  $\beta$ hCG can take several weeks to fall
- If  $\beta$ hCG does not fall by >15% between days 4 –7
  - Discuss with consultant Gynaecologist
  - Administer second dose (required in ~ 15% of cases)

(If these fall on a Sat – bloods should be requested on the Friday. If these fall on a Sunday – bloods should be requested on the Monday)

#### **If second dose is administered:**

- Day 7: confirm normal LFT. Injection should be given in opposite gluteal

- Day 11:  $\beta$ hCG
- Day 14: FBC,  $\beta$ hCG, LFT's and U & E
- Women with evidence of rupture or significant pelvic/abdominal tenderness should be discussed with Consultant Gynaecologist and are likely to require surgical treatment.
- On completion of treatment, discharge women to GP

### **Surgical management**

#### **Treatment schedule**

- Explain treatment to woman (and partner)
- Obtain written informed consent
- Collect pre-treatment bloods (i.e.  $\beta$ hCG group and hold, FBC) and administer Anti D to women who are Rhesus negative
- If the woman is **haemodynamically stable**, a laparoscopic approach is preferable to an open approach
- If the woman is **not haemodynamically stable**, the most expedient method of surgical management should be chosen – in most cases this will be laparotomy.

<b>For women who are <u>not</u> haemodynamically stable:</b>
<ul style="list-style-type: none"> <li>• Resuscitate</li> <li>• Secure immediate IV access</li> <li>• Send bloods for FBC and cross match 4 units</li> <li>• Inform: Theatres, Anaesthetics and on-call Gynaecology Consultant</li> </ul>



**The urgency of the situation must be stressed to all concerned. Surgery should be performed even before blood and fluid losses have been replaced**

- Salpingectomy is often performed, particularly if:
  - The tube is severely damaged
  - There is uncontrolled bleeding
  - There is a recurrent ectopic pregnancy in the same tube
  - There is a large tubal pregnancy of >5cm
  - The woman has completed her family

Laparoscopic salpingotomy should be considered as the primary treatment if the woman has contralateral tube disease and desires future fertility

#### **On discharge after surgery**

- GSG or DPU to arrange follow up in 6 weeks in Gynaecology Clinic
- Complete discharge summary
- Provide contact numbers / appointments for support services (eg: Social Work)
- Advise women of the following:
  - To see GP in one week for removal of sutures

- What to expect (in terms of pain, bleeding etc)
- She may take simple analgesia for pain
- To contact? after hours if concerns regarding pain or bleeding

### **Follow up and monitoring**

For women undergoing salpingotomy:

- Day 3  $\beta$ hCG
- Day 7  $\beta$ hCG
- If  $\beta$ hCG plateaus or rises, arrange ultrasound scan. If this is negative consider medical treatment
- Where a sub-optimal fall precedes a negative laparoscopy, consider managing expectantly
- On completion of treatment, discharge woman to GP

### **References**

*Guidelines on the Management of Ectopic Pregnancy, Royal Oldham hospital 2001*

*Management of Tubal Pregnancy, Royal College of Obstetricians & Gynaecologists 2004*

*Ectopic Pregnancy: Management, The Royal Women's Hospital, Victoria, Australia*

## APPENDIX 1:

# Procedure for Administration of I'm Methotrexate in Ectopic Pregnancy Management

### Purpose

The purpose of this policy is to provide clear procedural guidelines for the administration of IM Methotrexate in ectopic pregnancy management. Methotrexate is a cytotoxic therapy and effects the growth and development of fetal cells. Precautions must be taken to reduce the risk associated with the handling and disposal of cytotoxic drugs for the benefit of staff and patients.

### Scope

All midwifery, nursing and medical staff in the Maternity Assessment Unit.

### Related Policy

Ectopic Pregnancy Management policy.

### Procedure

Once written medical directive, including; the date, Patient's name and date of birth, drug, dose, route of administration, frequency of administration, and legible signature of the medical practitioner are available:-

- The drug chart is to be taken to Pharmacy for dispensing. Pharmacy will be able to dispense this immediately
- Methotrexate comes in vials. You will need to work out the amount to be given.

$$\frac{\text{What you want}}{\text{What you have}} \times \frac{\text{Quantity it comes in}}{1}$$

- As per the Ectopic Pregnancy Management Policy all patients should have baseline BhCG, U&Es, LFTs, FBC prior to administration – check this has been done.

Dosage calculation is in the Ectopic Pregnancy Management Policy

The aim is to avoid all spillage, excess exposure to Methotrexate for both the administrator and patient receiving injection.

### **Equipment**

Grey Latex Free Gloves,  
Syringe  
18 gauge Blunt Fill Needle  
22 g needle  
Purple sharps disposal bin  
Gauze squares  
Water  
Plaster

### **Method**

Gloves should be worn during the procedure.

Draw up correct amount of Methotrexate (**DO NOT PUSH AIR INTO VIAL**)

- this is to avoid methotrexate being sprayed out from vial)

Do not allow Methotrexate to be released from needle when expelling air from Syringe, a filter connector placed over needle is a safety precaution to Prevent spray and can be used

When giving, **use Z track technique, deep IM Injection**

**Wipe injection area clean with water when finished**

### **Disposal of Equipment**

Careful disposal of needle, syringe, vial and gloves is necessary due to the cytotoxic capacity of this medication.

Use the purple sharps disposal bin. When it is full call orderlies for collection and disposal.

### **Documentation**

Alongside usual documentation of administration the site of the injection should be recorded in the patient notes

### **Spillage:**

1. If methotrexate comes in contact with the skin, or following a needle stick incident, the area should be washed copiously with water for at least 10 minutes.
2. If methotrexate enters the eyes, they should be irrigated thoroughly with water for at least 10 minutes and medical advice sought.
3. Always double glove when dealing with spillages.
4. Wipe up any spillage with absorbent wipes provided in spillage pack, place in yellow bag and dispose of directly into cytotoxic sharps bin (Purple lid) (Guidelines are provided within spillage pack).

### **References**

Ectopic Pregnancy – Management Policy, O&G Dept HVDHB  
Administration of Methotrexate, Rheumatology Dept HVDHB  
Manufacturers Guidelines. [www.medsafe.govt.nz](http://www.medsafe.govt.nz)

## CHS Handling of Cytotoxic Infusions, CHS HVDHB