APPROVED DOCUMENT

وزارة الصحة
Ministry of Health
المديرية العامة لمستشفى خولة
Directorate General of Khoula Hospital

Obstetrics and Gynecology Department

Document Title	Guideline for Management of Early and Second Trimester Pregnancy Loss
Document Type	Guideline
Directorate/Institution	Directorate General of Khoula Hospital
Targeted Group	All obstetrics and gynecology doctors, midwifes and nurses
Document Author	Dr Einas Al Ya'qoubi
Designation	Senior Specialist
Document Reviewer	Reviewer's name next page
Release Date	December 2024
Review Frequency	Three years

Validated by		**Approved by**	
Name	Ms. Huda Al Abri	Name	Dr. Rashid Al Alawi
Designation	Head of Accreditation Department	Designation	Director General
Signature		Signature	
Date	03/12/2024	Date	03/12 /2024

Acknowledgements:

1. Dr Rahma Al Ghabshi, Senior consultant, Head of Obstetrics and Gynecology Department &IV center.
2. Dr Mini Mammen Roy, Consultant, Obstetrics and Gynecology Department.
3. Dr.Sudha Krishnan, Specialist, Obstetrics and Gynecology Department.
4. Ms. Rashida Al Abused, Sr.staff nurse in-charge of Gynecology Ward
5. Ms. Rahma Al Manji, Sr.staff Nurse, Gynecology Ward.
6. Ms. Halima Al Zadjali,Sr.pharmacist in Clinical Pharmacy

Table of Contents

1. Definitions

1.1 Early pregnancy loss is defined as spontaneous loss of a pregnancy prior to 13 weeks of gestation. Common risk factors include maternal age and previous early pregnancy loss. The miscarriage can be divided into missed miscarriage which is defined as unrecognized intrauterine death of the embryo or fetus without expulsion of the products of conception, and incomplete miscarriage when some but not all the products of conceptions have been expelled.

Chapter 1

2. Introduction:

Early pregnancy loss is defined as spontaneous loss of a pregnancy before 13 weeks of gestation. This is commonly seen in the obstetrics and gynecology emergency room. These cases are managed medically or surgically.

3. Purpose:

The purpose for this guideline to:

3.1 Define the pregnancy loss and diagnostic features of different types of miscarriage.

3.2 Explain the medical management of Misoprostol.

3.3 Determine the cases in which the surgical management should be applied.

4. Scope:

The guideline applies to all obstetrics and gynecology doctors and nurses involved in caring for pregnant women.

Chapter 2

5. Structure:

This guideline should be implemented in patients seen by the medical staff (doctors and nurses) of the obstetrics and gynecology department at Khoula Hospital and diagnosed as early pregnancy loss.

5.1 Diagnosis by Transvaginal Ultrasound:

5.1.1.Definitive ultrasonographic diagnostic features of Early Pregnancy loss as the following:

a. Crown - rump Length (CRL) of 7 mms or greater and no fetal heart.

b. Mean sac diameter of 25 mms or greater and no embryo seen.

c. Absence of embryo with heartbeat 2 weeks or more after a scan that showed a gestational sac without a yolk sac.

d. Absence of embryo with heartbeat 11 days or more after a scan that showed a gestational sac with a yolk sac.

5.2 Findings suggestive, but not diagnostic of early pregnancy loss as the following :

a. CRL less than 7 mms and no fetal heart.

b. Mean sac diameter of 16-24 mms with no embryo seen.

c. Absence of embryo with a heartbeat 7-13 days after an ultrasound that showed gestational sac with/without a yolk sac.

d. Absence of embryo for 6 weeks or longer after the last menstrual period.

e. Enlarged yolk sac greater than 7 mms.

f. Small gestational sac in relation to the size of the embryo - less than 5 mms difference between the Mean Sac Diameter (MSD) and CRL.

5.3 Management:

a.When findings are suggestive, but not diagnostic, a follow up ultrasound should be done after 7-10 days to assess viability.

b. Once early pregnancy loss is diagnosed there are 3 accepted management options.

i. Expectant management
ii. Medical management
iii. Surgical evacuation

c.Important to document verbal consent in all management modalities.

d.Surgical and medical management, both have comparable efficacy.

e. Serious complications are rare with all modalities such as :
   i. Rate of hemorrhage related hospitalization with or without blood transfusion is 0.5 – 1% (same with all modalities of treatment).
   ii. Overall infection rate is low 1 – 2 % for all 3 modalities.

f. Patient's choice – risks and benefits of each option to be explained to patient.
g.Treatment modality is decided on the patient's preference.

5.4 Expectant management:

5.4.1 Success rate of expectant management for 7-14 days from the time of diagnosis is 90% and Effective and is first line option offered provided.

5.4.2 The obstetrics and gynecology doctors should ensure the following:

a. Patient is counselled well and agreed.

b. Patient is not at increased risk of bleeding e.g. coagulopathies.

c. There is no evidence of infection.

d. If a patient decides, she can switch from expectant care to medical management of evacuation any time.

5.5 **Medical management:**

a. Misoprostol is used in the medical management of early pregnancy loss, it is an analogue of Prostaglandin El.

b. It Interacts with Prostaglandin receptors and causes cervix to soften and uterus to contract resulting in expulsion of uterine contents.

c. It is Efficacy varies depending on gestational age and route of administration.

i. (Vaginal, oral, sublingual) dose and dosing schedule.

d.Vaginal bleeding and leaking negatively affect absorption through the vagina hence oral or sublingual route preferable.

e.Advantages - low cost, long shelf life, lack of need for refrigeration.

f.Available as 200 mcg tablets.

5.5 Surgical management:

5.2.1 Indications:

a. In women who do not want to wait for spontaneous expulsion.

b. Wish to avoid the pain and bleeding that accompanies the passage of the products of conception.

c. With heavy bleeding.

d. With evidence of sepsis.

e. With contraindications to Misoprostol.

f. With medical co-morbidity that need controlled evacuation in a hospital setting example – severe anemia, bleeding disorders, coagulopathy, or major cardiovascular disease.

5.2.2 Advantages:

a. Faster and more predictable complete evacuation (99%).

b. Lower risk of unplanned admission and unplanned evacuation as compared to medical or expectant management.

5.2.3 Disadvantages:

a. Need for anesthesia and inpatient care.

b. Rare complications – uterine perforation and its complications, cervical injury, intra-uterine synechiae, secondary subfertility.

5.6 Medical management of missed miscarriage:

5.6.1The obstetrics and gynecology doctors should ensure the following:

a. Electric Consent is taken - To state "Medical management of miscarriage with misoprostol", with suction evacuation if needed.

b. Remove IUCD if present.

c. Misoprostol doses is prescribe as the following :

i. Vaginal in the Posterior Fornix -800 mcg. Tablets should be moistened with normal saline or water and not with lubricant gel.

ii. The same dose of 800 mcg of misoprostol may be given orally if there is bleeding or leaking.

iii. The dose may be repeated after 3 hours (total 2 doses).

iv. Sublingual route - hold the pill under the tongue for 30 minutes. Any remaining fragments can be swallowed with water.

v. No routine dose adjustments needed in renal failure.

vi. Analgesia and antiemetic to be prescribed with Misoprostol.

d.Paracetamol 1000 mgs IV or oral with Misoprostol 1st and 2nd dose (Metoclopramide or Ondansetron with Misoprostol).

e. Mefenamic acid or Diclofenac as required.

f.Pre-treatment with nonsteroidal anti-inflammatory drugs before the misoprostol can be considered if needed.

g. If no response (no bleeding or passage of Product of Conception (POC).

i. After the first dose – second dose after 3 hours, 800 mcg vaginal or to be given as oral if there is bleeding. 600 mcg Sublingual (S/L) which is as effective as vaginal but has more side effects

ii. After the second dose:
keep the patient NPO and offer a suction evacuation. If the patient is not keen for a surgical intervention, after 1 week if no expulsion of POC, patient may be offered a date for suction evacuation.

h. The senior doctor should be involved in decision making and the patient should be consented accordingly.

i. Follow up Ultrasound- If bleeding or passage of POC after 1 st or 2nd dose.

5.7 Incomplete expulsion: (endometrial streak thickness > 15 mm – up to 25 mm):

a. Oral single dose Misoprostol 600 mcg.
   i. If given in Emergency room or outpatient clinic, it is advised to observe the patient for at least 2 hours (in general), however, individualization of cases should be considered.
b. Patient to be discharged and followed up after 3 weeks.
   i. No need to repeat ultrasound before discharge.
   ii. No indication to interfere or perform an evacuation before 3 weeks unless there is evidence of infection or significant bleeding.
   iii. Antibiotic prescription: Doxycycline.

5.8 Follow up:

a. Completeness of expulsion is confirmed by ultrasound findings and patient reported symptoms.
b. Endometrial thickness < 15 mm indicate complete expulsion.
c. Endometrial stripe thickness persists > 15 mm then advice a surgical evacuation.
d. If the patient is asymptomatic and if the endometrial streak thickness is 16-30 mm, there is a small role for expectant management for another 1 week or second dose Misoprostol could be considered. (To be decided after senior input from registrar and above).
e. If the patient chooses evacuation – the tissues obtained are to be sent for Histopathological examination.

5.9 Instructions to patients after expectant management of successful medical management:

a. Advice to visit the local health institutes if
   i. Any signs of infection
   ii. Heavy bleeding (if she soaks more than 2 large pads per hour for 2 consecutive hours)
b. Abstinence for 1-2 weeks after complete expulsion (to reduce risk of infection)
c. Address issues on breast feeding — No known adverse effects on nursing infants and no known consequences of exposure.

5.10 Common side effects:

a. Pain and cramping, stronger than menstrual cramp.
b. Bleeding – typically heavier than menses, will start within an hour of Misoprostol.
c. Chills and fever.
d. Nausea, vomiting and diarrhea.

5.11 Potential complications:

a. Heavy bleeding with hemodynamic instability and significant drop in hemoglobin are rare after Misoprostol.
b. Rate of hemorrhage related hospitalization with or without blood transfusion is 0.5-1%.
c. Infection – overall rate of infection is very low 1-2%. Misoprostol does not increase the rate of infection. Fever persisting for more than 24 hours, uterine tenderness, and foul smelling discharge are the clinical features suggestive of infection.

5.12 Contraindications to Misoprostol in first trimester pregnancy loss:

a. Molar pregnancy
b. Heavy bleeding, hemodynamic instability.
c. Presence of infection.
d. Medical co-morbidities – significant anemia, hemorrhagic diseases, patient on anticoagulants, coagulopathy, uncontrolled asthma, major cardiac and cardiovascular diseases, to be evaluated on case-by-case basis.
e. Known allergy to Misoprostol.

5.13 Medical termination of pregnancy in 1st trimester (less than 13 weeks) of a viable fetus as the following:

a.

Misoprostol 800 mcg vaginally/orally every 3-12 hours with a maximum of 2-3 doses.

b. Incomplete Miscarriage: Misoprostol 600 mcg oral single dose.
c. Management of incomplete miscarriage in first trimester (can be done on an-outpatient basis after approval by a senior registrar/consultant).
d. Ultrasound characteristics – heterogenous and/or echogenic material along the endometrial stripe or in the cervical canal.

5.14. Medical management with Misoprostol:

a. Patient information – same as in missed miscarriage – procedure, success rates, common side effects that are limiting, what to expect after Misoprostol and potential complications.
b. Address issues on breast feeding.
c. Complete Blood Count (CBC), save serum, Haemoglobinopathy and coagulation profile (to be sent if indicated).
d. Blood group and Rhesus if not known before.
e. Blood to be arranged on admission.
f. Consent to be taken — to state — (Medical management of miscarriage with Misoprostol)+ consent for SOS medical
g. Inserted G 20 cannula.
h. Analgesia/Painkiller and antiemetic, non-steroids medication.
i. **Dose:** Single dose Misoprostol 600 mcg oral to be given.
j. Sublingual 400 mcg is just as effective, but side effects are more. Both oral and sublingual work equally well in incomplete miscarriage with efficacy of more than 90 %
k. Oral route is better accepted and has less side effects than sublingual route.
l. Repeat doses do not improve efficacy and are not routinely used.
m.
n. Analgesia and Antiemetic's to be prescribed as in missed miscarriage.
o. If admitted the patient can be discharged after 3 hours if all is well.
p. No need to rescan before discharge.
q. Broad spectrum antibiotic - oral Doxycycline and Metronidazole.
r. Follow Up to confirm completeness of expulsion after 3 weeks. As per patient's symptoms and ultrasound findings:

i. If retained Products of Conception (RPOC): (endometrial thickness more than 15 mms) and patient is symptomatic offer a surgical evacuation.

ii. If RPOC < 30 mms and patient is asymptomatic options are:
   - **Evacuation**, if that is the patient's choice.

Or

- **Expectant management** for 1 more week – decision is to be taken by seniors (registrars and above) after appropriate counseling of the patient.

Or

- **The second dose of Misoprostol** can be considered after senior input – the patient needs to be clearly explained about the marginal benefit of second dose in incomplete miscarriage.

5.14.1 Medical termination of pregnancy in Second trimester

a. Misoprostol is always given in a hospital setting.
b. Surgical evacuation is best reserved for retained products of conception.
c. Dose is decided according to the ultrasound assessment of the gestational age of fetus and not by the period of gestation.

5.14.2 Recommended doses of Misoprostol for Second trimester induced miscarriage of a viable fetus as the following:

a. Between 13 to 24 weeks of gestation.
    i. Vaginal or sub-lingual 400 mcg, 3-4 hourly – 5 doses maximum.
b. Between 25 to 27 weeks of gestation.
    i. 200 mcg vaginally/sublingually or oral every 4 hours, maximum 5 doses.

5.14.3 Recommended doses of Misoprostol for second trimester induced miscarriage of anon viable fetus as the following:

a. 13 to 24 weeks of gestation.
    i. Vaginal 400 mcg, every 3 hours, until expulsion.

b.25 to 27 weeks of gestation.
    i. Vaginal 200 mcg, every 4 hours, until expulsion.

c. After expulsion of fetus – scan to be done in the ward to assess the completeness. If there are retailed products measuring ≥ 15 m, evacuation to be arranged.
    i. Misoprostol is safe < 28 weeks even with history of cesarean section.
    Misoprostol is not recommended in women ≥ 28 weeks of gestation with a prior cesarean section delivery

5.15 Outpatient department (OPD) management of incomplete miscarriage - under supervision of Senior Registrar or Consultant:

a. Blood investigations should be: complete blood Count, save serum, Haemoglobinopathy and coagulation profile (to be sent, only if indicated). Blood group and Rhesus if not known before.

b. Describe for the patient the Misoprostol 600 mcg oral or 400mcg sublingual or 400 to 800 mcg vaginal.
c. Follow up should be within one week- to be arranged by treating team. Pros and cons should be explained to the patient with advice to attend to the ER in case of signs of infection or bleeding.
d. Antibiotics (Doxycycline & Metronidazole) if not given earlier.

5.16 Anti-D rhesus prophylaxis

a. Offer anti-D rhesus prophylaxis at a dose of 250 IU (50 micrograms) to all rhesus-negative women who have a surgical procedure to manage an ectopic pregnancy or a miscarriage.
b. Anti-D Ig is no longer necessary in women with threatened miscarriage with a viable fetus and cessation of bleeding before 12 weeks' gestation or spontaneous miscarriage before 12 weeks of gestation.
c. It may be prudent to administer anti-D Ig where bleeding is heavy or repeated or where there is associated abdominal pain particularly if these events occur as gestation approaches 12 weeks. The period of gestation should be confirmed by ultrasound.
d. **Do not offer anti-D rhesus prophylaxis** to women who:
    i. Receive solely medical management for an ectopic pregnancy or miscarriage.
    ii. Or have a threatened miscarriage < 12 weeks of gestation.
    iii. Or have a complete miscarriage < 12 weeks of gestation.
    iv. Or have a pregnancy of unknown location.

c.Do not use a Keilhauer test for quantifying feto-maternal hemorrhage.

5.17 Thromboprophylaxis:

a. Venous thromboembolism risk assessment to be done for all women undergoing surgical evacuation and thromboprohylaxis to be given accordingly as per protocol.

Chapter 3

6. Responsibilities:

6.1The Head of Obstetrics and Gynecology Department Shall:

6.1.1 Ensure that all the doctors are aware and adhere the this guideline

6.1.2 Ensure that all doctors are implement the guideline appropriately.

6.2. The Director of Nursing Affairs shall:

6..1 Emphasize to all Head of sections and Unit supervisors the implement of adhering to the guideline.

- **The Head of Section /MCH unit supervisor / shift supervisor shall**

6..1 Reinforce all nursing to adhere to the guideline

- **The MCH department Incharges shall:**

6..1 Implement the guideline within the MCH department

6..2 Ensure proper supervision is given to all staff particularly new nurses regarding the guideline

- **All MCH nursing shall:**

6..1 Adhere to the guideline

6..2 Educate and support patients in the MCH department.

6..3 Document all the details about the patient's condition

6..4 Report any adverse incident involving the patient in the Al Shifa system and inform the Incharges and Unit supervisor

Chapter 4:

7. Document history and version control table

Version	Description	authors	Review Date
1	Initial release	Dr Einas Rashid Al Ya'qoubi	2024

APPROVED DOCUMENT

8. Related document:

8.1 Guideline for Management of Spontaneous Abortion

8.2 guideline of management of thrombosis and thromboprohylaxis in pregnancy and postpartum.

9. References:

- ACOG new recommendation on Early pregnancy loss April 2015
- NICE guidelines, April 2019
- Misoprostol dosage guidelines by FIGO and WHO based on recommendations by the Bellagio group, published in the Int J Gynecologist supplement, 2023
- Guidelines on miscarriage by The Royal Australian and NZ college of Obs & Gyn.
- Guidelines on Management of early pregnancy loss by the Institute of Obstetrician and Gynecologists – Royal College of physicians of Ireland.