JAYPEE

Manual of Standard Drugs and Evidence-based Approach to Obstetrics & Gynecology

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SECTION A

Use of Drugs in Pregnancy

I: INTRODUCTION

The teratogenic period in the human—

By 10 weeks after the LMP all of the major systems have formed. Continued development and refinement of many systems continues in the second and third trimester of pregnancy and for brain into the first year of life.

a. The classic teratogenic period: The critical period for organogenesis or the classic teratogenic period is from 31–71 days after the last menstrual period in a normal 28 days menstrual cycle. Administration of drugs early in the period of organogenesis will lead to defects in the neural tube (CNS) or heart which form early, whereas exposure later in the period may lead to abnormalities such as cleft palate and defect in ear. Thus drug if not urgently needed should be postponed during 31–71 days (Fig. A.1).
b. Exposure to teratogens prior to day 31 produces all or none effect. This means the exposure leads to abortion and the conceptus does not survive, or there is survival without congenital anomalies.

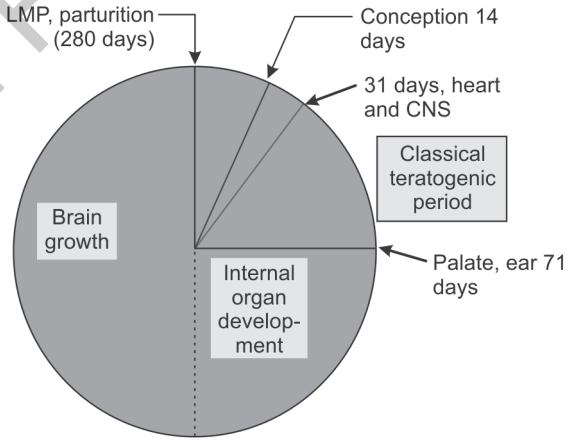

Fig. A.1: The classical teratogenic period in human

c. Fetal alcohol syndrome may occur in the later part of pregnancy due to alcohol exposure to mother or coumarin can lead to fetal intracranial hemorrhage that results in brain damage near the end of pregnancy.

US FDA categories of labeling of drugs in pregnancy

- A Controlled studies show no risk
- B No evidence of risk in human
- C Risk cannot be ruled out
- D Positive evidence of risk
- X Contraindicated in pregnancy.

Nutrition requirements in pregnancy and lactation (Table A.1).

Table A.1: Requirements of nutrients, minerals vitamins in pregnancy, and lactation

Requirements of nutrients, minerals and vitamins in pregnancy, and lactation
N= normal, P= pregnancy, L= lactation
a. **Protein**—N-50 gm (1gm/kg body weight), P-50+10=60 gm, L=50+20=70
b. gm
c. **Fat**—N-50 gm (1gm/kg body weight), P-50 gm, L-50+10=60 gm
d. **Carbohydrate**—395 gm, P-460 gm, L-550 gm
Minerals—
i. Calcium—N-400 mg, P-1,000 mg, L-1,500 mg
ii. Phosphorus—N-800 mg, P-1,200 mg, L-1,200 mg
iii. Iron—N-30 mg, P-40 mg, L-30 mg
iv. Zinc—N-12mg, P-15 mg, L-19mg
v. Iodine—N-150 mcg, P-175 mcg, L-200 mcg
vi. Magnesium—N-280 mg, P-320 mg, L-355 mg
e. **Fat-soluble vitamins**—
i. Vitamin-A—N-5000 IU, P-6,000 IU, L-8000 IU
ii. Vitamin-D—N-400 IU, P-400 IU, L-400 IU
f. **Water-soluble vitamins**—
i. Folic acid—N-0.5 mg, P-1 mg
ii. Niacin—N-15 mg, P-17 mg, L-20 mg
iii. Riboflavin—N-1.3 mg, P-1.6 mg, L-1.8 mg
iv. Thiamine (B_1)—N-1.1 mg, P-1.5 mg, L-1.6 mg
v. Pyridoxine (B_6)—N-1.6 mg, P-2.2 mg, L-2.1 mg
vi. Cobalamine (B_{12})—N-2.0 mcg, P-2.2 mcg, L-2.6 mcg
vii. Vitamin C—N-40 mg, P-40 mg, L-45 mg

II: DRUGS IN LOW-RISK PREGNANCY

1. In the first trimester folic acid only.
2. Iron and folic acid (60 mg of elemental iron + 500 mcg of folic acid)

should be prescribed after first 100 days of pregnancy and iron prophylaxis should be continued for last 100 days of pregnancy and is to be maintained for a minimum period of 3 months in puerperium.

Different oral iron preparations are ferrous sulfate, ferrous fumerate, ferrous gluconate, carbonyl iron and ferrous ascorbate.

The rate of absorption of oral iron is 10% but the rate of absorption may be increased to 30–40% depending upon the severity of anemia.

3. Calcium (1000 mg)—Oral calcium is required.
4. Deworming—Deworming is required in India after 3 months of pregnancy. Albendazole — 400 mg single dose at bed time. Tablet mebendazole 100 mg bd for 3 days.
5. Injection tetanus toxoid—0.5 ml IM—Two doses at an interval of 4–6 weeks starting from 16–18 weeks of pregnancy. Only one booster injection of 0.5 ml is given IM when pregnancy occurs within 3 years of primary immunization.

Treatment of common ailments and diseases in pregnancy

Vomiting/morning sickness

- Get out of bed slowly in the morning, sit on the edge of the bed and take 1 or 2 biscuits as soon as you get up.
- Eat dry toast, crackers, or a peeled apple every few hours during the day and avoid fatty food and liquid in empty stomach.
- Drink plenty of beverages or soups throughout the day but avoid those that are either very hot or cold.
- Avoid odors that make you feel nauseous.
- Avoid high rich food that are fried, or seasoned with pepper, chillies and garlic.
- Doxylamine 20 mg PO 30 minutes prior to bed may be required.
- Nausea and vomiting usually passes after 3 months.

Acidity /Indigestion

- Eat several small meals during the day instead of three large ones.
- Avoid foods (like spicy foods or acidic foods such as citrus fruits) that cause gas or irritate your stomach.
- Do not lie down for at least 1 hour after you eat and don't exercise for at least 2 hours after your meal.
- Antacid may be offered whose heartburn remains troublesome despite lifestyle and diet modification.
- H_2 receptor antagonist (famotidine—20 mg bd; ranitidine—150 mg bd), proton pump inhibitors (omeprazole—20 mg od) are also helpful.

Constipation

- By high-fiber diet and drink plenty of liquids.
- Eat a bowl of high-fiber cereal such as bran flakes for breakfast and lots of fruits and vegetables throughout the day.
- Drink at least 8 glasses of water each day and in severe constipation use natural fiber laxative with water.
- Spend an ample of time for bowel clearance.

Diarrhea

- Boiled water and salt solution.
- Lomofen—1 tablet 6 hourly for watery diarrhea.
- Tablet metronidazole 200 mg/400 mg—1 tablet three times /day for 5–7 days.

Low back pain

- Do not use shoes with heels higher than 1 inch.
- Bend your knees when lifting; do not bend from the waist.
- Avoid lifting children and other heavy objects.
- Take rest on hard bed.
- Rest of foot on a stool if you have to stand for a long time.
- Sleep on your side with upper knee bent and supported by a pillow.
- Apply heating pad to the sore area.
- Simple exercise, massage therapy may ease backache during pregnancy.
- Analgesic like paracetamol 500 mg—1 tablet twice /thrice daily orally.

Leg cramps

- Stretching of your calf muscles before you go to bed.
- If cramping occurs in the middle of night, get up from the bed and walk around slowly until it passes away.
- Supplementation of calcium after the principal meal may be effective.

Hemorrhoids

- Relief of constipation by high-fiber diet and drinking of plenty of fluid including water may reduce the symptoms of hemorrhoids.
- Try not to strain during bowel movement or use laxative like isobgul husk (2tsf with water), cremaffin pink 4 tsf at bed time.
- Any kinds of surgical treatment is better to withheld during pregnancy as the condition sharply improves following delivery.

Simple swelling of ankles and feet

- Improving the circulation of blood in your legs by lying down and by putting your feet on a raised pillow several times throughout the day or sitting with your feet elevated as often as possible.
- Limitation of the amount of salt intake may also help.
- Wearing of support stockings.
- Don't use diuretic.

White discharge per vagina

- In the physiological vaginal discharge simple assurance is needed.
- A 7 day course of topical clortrimazole is an effective treatment and should be considered for vaginal candidal infection (associated with itch, soreness, offensive smell, or pain).

Cold and cough

- For cold antihistamines (like chlorpheniramine, dyphenhydrinate as a first line antihistamines and astemizole, cetirizine, loratadine, fexofenadine (allegra) as a second line, decongestants are also used.
- Cough suppressants—Codeine and dextromethorphan are commonly used.
- If fever persists introduce paracetamol 500 mg SOS when fever is > 100°F. If fever does not subside within 3 days use capsule amoxicillin 500 mg qid for 5 days.

Pruritus

- Lotion calamine is used on areas of itching twice daily for 7 days.
- Urosodeoxycholic acid (UDCA)—It improves maternal liver function by replacing more toxic bile acids in blood stream. It also improves bile acid transport across the placenta which may greatly reduce the risk of stillbirth.

  Dose of UDCA—500 mg bd until delivery.
- S-adenosyl methionine (S-AME)—Given IV (600–900 mg) also prevents preterm labor. Cholestasis reduce the fat-soluble vitamin K absorption.
- Vitamin K—Oral vitamin K reduces the risk of PPH. Vitamin K helps in synthesis of II, VII, IX and X.
- Steroids—Dexamethasone 12 mg orally for 7days with a reducing dose of 3 days will reduce the total bile acids and ALT. It also reduces the estrogen production by fetoplacental unit.

- Cholestyramine—Chelating agent, mixed with water taken in a dose of 4 gm, 2–3 times daily. It exacerbates vitamin K deficiency and associated with intracranial hemorrhage of child and maternal hemorrhage. It is not recommended for routine use.

III: DRUGS IN HIGH-RISK PREGNANCY

Early trimester bleeding

Ectopic pregnancy

- Unruptured ectopic pregnancy is treated by medically.
- Agents used for medical treatment: Methotrexate, mifepristone, potassium chloride, actinomycin, PGs, hyperosmolar glucose, anti-hCG antibodies.
- Criteria of medical treatment: (a) Patient is of good health, hemodynamically stable and able to follow up examination, (b) unruptured EP, (c) no evidence of intrauterine pregnancy, (d) ectopic mass is < 3.5 cm, (e) hCG <10,000 iu/l, (f) no yolk sac seen and (g) no fetal heart tone.
- Use of methotrexate (MTx)—
  a. Intra sac methotrexate by EVS guidance, where reduced dose is required.
  b. Systemic (Table A.2).

Table A.2: Use of methotrexate in different doses

Single dose	Measure β- hCG levels days 4 and 7 • If difference is ≥15% /repeat weekly, until detectable • If difference <15% between D4 and 7, repeat the methotrexate dose and begin new day 1 • If cardiac activity presents D7, repeat methotrexate dose, begin new day 1 • Surgical treatment if β-hCG level not decreasing or fetal cardiac activity persists after three doses of methotrexate
Two doses Methotrexate, 50 mg/m^2 IM/ days 0, 4	Follow up as for single dose method
Variable dose (upto 4 doses) Methotrexate 1mg/kg IM d1,3, 5,7. (leucovorin,0.1mg/kg IM d2, 4, 6 and 8	Measure β-hCG levels d1, 3,5 and 7. Continue alternate day injections until β-hCG level decreases ≥15% in 48 hours or four doses of methotrexate given. Then weekly β-hCG until undetectable

Hydatidiform mole

After evacuation of uterus continue IV drip with oxytocin. Injection methergin 0.2 mg is given by IV/IM route. Prophylactic antibiotics are also required. Blood transfusion may be necessary.

After evacuation follow up is essential for a minimum period of 1 year.

Abortion

Threatened abortion

a. Reassurance of continuation of pregnancy when bleeding settles.
b. Avoid strenuous activity and restrict normal daily activity.
c. For anxiety diazepam 5 mg is taken a bed time.
d. Duvadilan, gestin are not used recently and use of progesterone has doubtful role.

Incomplete abortion—Medical management with 800 mcg of misoprostol every 4 hours. Curettage is necessary in 28% of cases.

Septic abortion

- Acronym 'ORDER': O—Oxygen; R—Replacement of fluid, D—Drugs; E—Evacuation of uterus; R—Re-evaluation of the condition.
- Drugs—IV antibiotics (give broad spectrum antibiotics like ampicillin 500 mg qid or cefotaxime 1gm bd IV route, gentamicin-60–80 mg IM tid plus metronidazole 500 mg/100 ml IV tid) for 5 days, tetanus toxoid, 250 U of tetanus immunoglobulin by deep IM.
- Additional—If bleeding disorder, assess DIC and laboratory test for CBC, BUN, serum urea, creatinine and electrolytes.

Missed abortion—The uterus is emptied by dilatation and evacuation. In the second trimester-induction of labor with high titer oxytocin drip, intra vaginal PGE2 gel or misoprostol. The cervix is first prepared by misoprostol or passively dilated with laminaria tent/PGE2 gel to avoid trauma before suction curettage.

Medical management by misoprostol 200 mcg is placed high in the vagina 4 hourly until delivery of the fetus and placenta, but possibility of retained products of conception is not uncommon. Evacuation is required later on.

If there is coagulation defect due to dead fetus blood transfusion, fibrinogen replacement might be of help before induction of abortion.

Drugs for recurrent abortion

For APLAS (Antiphospholipid antibody syndrome)

1. Aspirin—Aspirin in a dose of 75 mg once daily has been used as soon as pregnancy is diagnosed and should be given upto 34 weeks.
2. Heparin—It is potentially helpful for the treatment at present.

- **Mechanism of action of heparin**
  a. Anticoagulant effect
  b. It directly binds with APL
  c. Heparin activates complement activation.

  APLAS patients with no history of thromboembolic disease are treated with unfractionated heparin 5,000 IU BD or LMWH (enoxaparin 40 mg SC once daily or dalteparin 5000 IU SC once daily). Postpartum prophylactic warfarin and heparin is to be started 12 hours after vaginal delivery and 24 hours after cesarean section and continued till 6 weeks postpartum.

  Patient with history of thrombosis should receive a dose of heparin that will provide full anticoagulation as soon as fetal heart is documented and given throughout pregnancy. LMWH (Enoxaparin 1 mg/kg 12 hourly or dalteparin 200 IU/kg 12 hourly).The goal of therapy is to maintain the activated partial thromboplastin time (aPTT) 1.5–2 times normal when unfractioned heparin is used either SC 3 times daily or continuous infusion. If using LMWH antifactor Xa levels should be checked every trimester in order to maintain levels 0.5–1.1 u/ml. LMW heparin is stopped 24 hours before induction or as soon as patient feels labor pain. If patient is at a very risk of thromboembolism then LMWH can be switched over to unfractioned heparin at 36 weeks. Unfractioned heparin is to be stopped when patient is in active labor. Postpartum therapeutic anticoagulation with heparin is to be started 6 hours after vaginal delivery or 12 hours of cesarean delivery and simultaneously warfarin should be started orally. Once the prothrombin time (PTINR) of 2–3 times is achieved with warfarin, heparin should be discontinued and postpartum anticoagulation should be continued for at least 6 weeks.

  Important side effects unfractionated heparins include bleeding, thrombocytopenia and osteopenia.

3. Warfarin—It should be avoided in first trimester as it crosses the placenta and potentially teratogenic. It should be discontinued 2 weeks prior to planned delivery to allow clearance from maternal and fetal circulation and heparin or LMWH should be substituted.
4. Steroid—Steroids are not as efficient as heparin and aspirin also carry a high rate of maternal complications. Steroids are useful in patients with SLE (secondary APLAS) and when APLAS is associated with thrombocytopenia.
5. Immunoglobulin—Efficacy is doubtful.
   For SLE:
   (a) Glucocorticoid—Prednisolone is very much useful but glucocorticoid with fluorine at 9a position(dexa or betamethasone may cause

undesirable side effects as they are not metabolized well by placenta). (b) Antimalarial drugs like hydroxychloroquine may be used in pregnancy safely. (c) Cytotoxic agents like methotrexate, cyclophosphamide are rarely used in pregnancy for teratogenecity but azathioprine is not human teratogen and may be associated with growth impairment and impaired neonatal immunity. (d) High dose of IVIG. (e) NSAID—Indomethacin for short term is useful, but long term use may cause neonatal renal insufficiency

Drugs of medical termination of pregnancy (MTP)

- Methods of MTP in first trimester of pregnancy.
- Manual vacuum aspiration (upto 8 weeks), suction evacuation (from 6–12 weeks) and medical agents (upto 7 weeks).

Medical agents (7 weeks)

- Standard dose is mifepristone 200 mg orally followed by 400 mcg misoprostol oral/vaginal.
- First day (day1): Tablet mifepristone (antiprogestin) 200 mg orally.
- Second day (day 2–3): Two tablets of misoprostol (2 × 200 mcg = 400 mcg) orally/vaginally.
- Third visit (day 15): To ensure the abortion complete.

Note: Miferine kit contains one tablet of mifepristone 200 mg and 4 tablets of misoprostol (200 mcg each, i.e. two tablet for oral and two tablets for per vaginal use at the same sitting). Chances of incomplete abortion is high. It is not generally used in patients with severe anemia as prolonged per vaginal bleeding may occur.

Drugs for MTP (13–20 weeks)

- Intra-amniotic hypertonic saline infusion, extra-amniotic instillation of 0.1% ethacridine lactate (yellow dye with acridine derivative), intra and extra-amniotic prostaglandin, but vaginal insertion of 400 mcg of misoprostol followed by D/E at 13–14 weeks. Alternatively cerviprime gel (PGE2) 0.5 mg gel is introduced into cervical canal to ripen the cervix; this can be repeated after 6 hours if cervix does not ripe. Injection prostodin (carboprost tromethamine)–250 mcg is given IM 3 hourly till maximum 6–8 doses.
- Hypertonic saline infusion causes hypernatremia, endotoxic shock, DIC, cerebral hemorrhage and hysterotomy causes scar endometriosis (1%). So both are not recommended nowadays.

Extra-amniotic ethacridine lactate insertion

- Foley catheter (16 size) is introduced transcervically into the extra amniotic space above the internal os and the bulb is inflated with 10–20 ml distilled water to seal off the internal os. Ethacridine lactate (0.1%) is instilled through the catheter in dose of 10 ml per week (maximum 150 ml). Catheter is left in situ for 6 hours and then removed after deflating the bulb if not spontaneously expelled out. Uterine contraction starts by 12–18 hours .Oxytocin augmentation is done. Induction-abortion interval is 24–36 hours, if no abortion occurs after 48 hours, reinstillation of the drug or some other technique may be adopted.
- Complications: Renal failure may occur in a very few percent of cases.

Note: MTP is not mandatory in pregnancy following intake of COCPs.

Hyperemesis gravidarum

A. Admit the patient in hospital.
B. Counsel the woman and family regarding the harmless nature of the condition.
C. Nutritious support—Start IV fluid, either R/L or dextrose saline.
   Dehydrated patient generally losses 6% of the fluid per kg of body weight, e.g. in 60 kg body weight the fluid loss is 6/100 × 60= 3.6 liters.
   So, total amount of fluid = 3.5–4 liter /day.
   Drip rate/minute = Desired number of liters to be given per day × 12.
   Pharmacology—Injectable antiemetics are used in acute case:
   a. Metaclopramide 5–10 mgq 8 hour IV
   b. Ondansetron 8 mgq 8–12 hour IV or PO
   c. Additional MVI infusion daily.
   Others are:
   i. Antihistamines (doxylamine, diphenhydramine, prométhazine, meclizine).
   ii. Phenothiazine (prochlorperazine, chlorpromazine).
   iii. Benzamides (metaclopramide).
   iv. 5-HT_3 antagonists (ondansetron, granisetron).
   v. Corticosteroids—Prednisolone, droperidol, methylprednisolone (16 mg tid for 3days taper over 2 weeks to lowest effective dose and total duration of therapy 6 weeks).
D. Repeat urine examination every 4 hours till it becomes negative for ketone bodies.
E. Once the vomiting stops and dehydration is corrected, discharge the patient.
F. Advise the woman to take small, frequent carbohydrate meal.

Anemia in pregnancy

A. **In anemia**—Different routes of iron therapy (Table A.3).

Table A.3: Different routes of iron intake

Oral iron*	• Water-soluble—Best Ferrous better than ferric • Ferrous acerbate—Best	• More bioavailable • Less free radicals • Envelops the free radicals—less tissue damage
Parental iron	• Iron dextran complex, sodium ferric gluconate complex (SFGC) • Iron sucrose(IV)	IM, painful, anaphylaxis total iron infusion not possible Very safe
Other than iron preparation	Human recombinant erythropoietin Folic acid	Useful in renal failure and severe anemia Very safe
Blood transfusion	PCV	To avoid volume load to prevent CCF

* Oral iron should be taken in between meals for better absorption.

- Pregnancy of less than 30 weeks (correction of anemia)
  a. Iron deficiency—Oral iron (side effects—constipation, GI upset, black stool, abdomen discomfort)—60 mg elemental iron.
  b. Intolerance or noncompliance to oral iron—IM iron or IV iron administration.
  c. Folic acid deficiency—Oral folic acid.
  d. Albendazole 400 mg by mouth once or mebendazole 500 mg by mouth once or 100 mg twice /day for 3 days.
- Pregnancy 30–36 weeks
  a. Iron deficiency—Oral /parenteral iron (IM or IV).
  b. Folic acid deficiency—Oral folic acid.
- Pregnancy > 36 weeks
  a. Blood transfusion.

Parenteral iron

i. Intramuscular (IM) iron—Injection jectofer (iron sorbitol citrate) is given deep gluteal region daily—10 injections (side effect—Muscle pain, staining of skin, and abscess formation). It has no added advantage over oral iron therapy.

ii. IM and IV
   1. Injection imferon—(iron dextran) 2 ml (50 mg elemental iron per ml) can be injected like jectofer.

iii. IV route:
   2. Total dose imferon (TDI) by IV route.

- TDI—Elemental iron (mg) = (Normal Hb – patient's Hb) × weight (kg) × 2.21 + 1000
- If the calculated dose is >2500 mg give it in two divided doses.

3. Iron sucrose—2.5 ml of iron sucrose (2ampule) diluted in a maximum of 100 ml of 0.9% of NaCl solution, immediately prior to infusion. The infusion must be at a rate of 100 mg/15 minute.100 mg IV three times weekly (day-1, day-3, and day-5) (2.5 ml = 50 mg of Fe).
4. Ferric carboxy maltose injection equivalent to elemental iron 500 mg/10 ml.
   - Ferric carboxy maltose (not recommended in pregnancy but can be used in puerperium)—By IV infusion. It can cross the placenta and may affect the skeletal development of fetus in animal study. Extensive report in pregnant mother is not yet achieved.
   - Ferric carboxy maltose, a new IV preparation comprises of a macromolecular iron-hydroxy complex of polynuclear iron (III) hydroxide in the carbohydrate shell. From this stable complex, iron is released slowly, avoiding toxicity and oxidative stress. Upto 1000 mg of ferric carboxy maltose can be given in a single administration over 15 minutes without the need of the test dose. Single dose administration offers convenience to patients and is cost-effective (Table A.4).

Table A.4: Calculation of the cumulative iron dose

Hb (gm/dl)	Patient with body weight ≥ 35 kg and < 70 kg	Patient with body weight ≥ 70 kg
<10	1500 mg	2000 mg
≥ 10	1000 mg	1500 mg

A single ferric carboxy maltose injection should not exceed 1000 mg of iron (20 ml) per day or 15 mg of iron (0.3 ml) per kg body weight. Do not administer 1000 mg of iron (20 ml) more than once a week.

In case of drip infusion, ferric carboxy maltose injection must be diluted only in sterile 0.9% sodium chloride solution as follows (Table A.5).

Table A.5: Administration of ferric carboxy maltose

Ferric carboxy maltose	Iron	Maximum amount of sterile 0.9% NaCl solution	Minimum administration time
4 –<10 ml injection	200 – <500 mg	100 ml	6 minutes
10–20 ml injection	500 – 1000 mg	250 ml	15 minutes

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