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FOURTH EDITION

Drug Handbook in Obstetrics & Gynaecology



AK Debdas

JAYPEE

Drug Handbook in

Obstetrics and Gynaecology

FOURTH EDITION

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CHAPTER 14

Oxytocics and Tocolytics

14.1 FORMULA FOR OXYTOCIN USAGE

OXYTOCIN

Pharmacokinetics: It is a nonapeptide produced by posterior pituitary but now is synthetically prepared.

- *Half-life:* 5 minutes.
- *Duration of action:* Around 20 minutes.
- *Onset of action:* 2½ minutes given IM, about a minute given IV.
- *Availability:* Syntocinon (Novartis); Evatocin (Neon) 5 IU per ampoule.

Dosage and scope: This has been presented below indication wise:

- Dosage for induction and augmentation of labour.
- Dosage for cervical ripening—not used for this purpose nowadays, Prostaglandin is used instead.
- Dosage for oxytocin challenge test—not practiced.
- Dosage for prevention of postpartum haemorrhage (PPH).
- Dosage for control of PPH.

Dosage for Induction and Augmentation of Labour

Route: To be delivered either through infusion pump or through paediatric (micro) drip set for easier titration of dosage.

Diluent: 5% Dextrose solution may be used. However, since oxytocin has anti-diuretic action to avoid water intoxication, normal saline (0.9%) or Ringer lactate solution are the preferred fluid especially when high dose has to be used or it has to be given for a long period as in the case of missed abortion or intrauterine foetal death.

Dilution: Easiest formula here is to add'1 unit per100 mL of diluent fluid', e.g., for 500 mL bottle add 5 units in the bottle and for 1 L (1,000 mL) bottle add 10 units. This standard mixture will always deliver the standard amount of '10 milli unit (mU) of the medicine per mL of the fluid'.

Drip rate: For adjusting drip rate, the following facts must be remembered:

- 1 mL of the above standard mixture contains 10 mLU of Oxytocin
- In adult drip set—15 drops make 1 mL
- In micro drip set—60 drops make 1 mL (Paediatric set).

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Based on the above facts and for the standard dilution of Oxytocin (1 unit of oxytocin per 100 mL of drip fluid) as mentioned above—a 'ready to use' instant dose cum Drip Rate Chart has been prepared both for adult and micro drip set **(Table 14.1)**.

It is apparent from **Table 14.1** that giving low dose of oxytocin is quiet difficult by adult drip set and relatively easy by Paediatric drip set, for example, to give 2 mU/min by adult drip set the drip rate has to be (impossible) 3 drops/min whereas by micro drip set it will be (reasonable) 12 drops/min.

Dosage Protocol

- *Low dose protocol:* Start with 1–2 mU/min, increase by 1–2 mU/min at every 20–30 minutes interval until desired contraction pattern is established which is 5 contraction in 10 minutes at the maximum. Please note that mU/min can be instantly converted into drops/min from the chart **(Table 14.1)**. Usually dosage of not more than 10 mU/min is required for inducing labour in pregnancies near term. The maximum recommended dose for induction 20 mU/min.

Table 14.1: Dose cum drip rate chart.

Oxytocin	*Drip rate—drop/min*	
Dose to be given	*By adult drip set*	*By micro drip set*
2 mU/min	3	12
4 mU/min	6	24
6 mU/min	9	36
8 mU/min	12	48
10 mU/min	15	60

- *High dose protocol:* Start with 6 mU/min, increase by 6 mU/min every 40 minutes. With this high dose regime incidence of failed induction, prolonged labour, of operative delivery (of both forceps and caesarean section) and neonatal sepsis is significantly reduced.

However, in Indian situation with scanty monitoring facility, absence of cardiotocography (CTG)—it is best to use low dose protocol. In all these cases after delivery the oxytocin infusion should be continued at increased rate for the next 2–3 hours to prevent uterine relaxation.

Monitoring

Uterine contraction and foetal heart rate (FHR) monitoring are primary and should ideally be done by CTG machine. Digital doptone, where the FHR can be seen on the digital window, is a good alternative. It removes the need for physical counting which is not easy. Besides these, the following are also to be monitored—pulse, respiration, BP, intake, output and any abnormal symptoms.

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Contraindication to Oxytocin Administration

Mechanical obstruction to vaginal delivery, scarred uterus, grand multiparity, multiple pregnancy (+/-), polyhydramnios, foetal distress, severe cardiovascular disease, etc.

Side effects: Besides uterine hyperstimulation and foetal distress, the possible serious side effects are—uterine rupture, placental abruption, amniotic fluid embolism and water intoxication.

Antidote of Oxytocin

If Oxytocin happens to cause hyperstimulation leading to tonic uterine contraction or too frequent contraction without adequate relaxation or too strong (high amplitude) contraction (all of which are invariably reflected by the occurrence of abnormal foetal heart rate pattern, i.e., foetal distress) injection Terbutaline (Bricanyl) 0.25 mg has to be given subcutaneously (1 mL ampoule contains 0.5 mg of the drug) to cause immediate uterine relaxation.

A direct antagonist of Oxytocin called Atosiban is now available very expensive.

However, the great thing about Oxytocin is its half-life is only 5 minutes and hence on simply stopping the drip plasma concentration falls rapidly (Williams Obstetrics, 2010).

Oxytocin Dosage for Prevention of Postpartum Haemorrhage

Dose

- For **'active'** management of 3rd stage of labour—5 units of the drug is to be given IM with the delivery of the anterior shoulder. It need not and should not be given IV for this purpose even if an IV drip is running.
- For **'physiological'** management of the third stage of labour—in vaginal delivery—5 units is to be given IM after expulsion of placenta. Not recommended.
- In caesarean section—10 units of the drug is to be added in the drip bottle immediately after the delivery of the baby and drip is run at 30 drops/min.
- In some units, after vaginal delivery, routinely, 20 units of the drug is given in the form of IV infusion over 1 to 2 hours following delivery but only to those mothers on IV drip.

Oxytocin Dosage for Control Postpartum Haemorrhage

- 5 units IV shot over 30 second (no faster).
- In addition, 20 units of it has to be given through IV infusion prepared by mixing it in 500 mL of normal saline or Ringer's lactate solution—at a rate sufficient to keep the uterus hard. Maximum rate—100 mU/min (*see* 'Dose Cum Drip Rate' chart given earlier in this chapter).

Caution: "Oxytocin should never be given as an undiluted bolus dose, because serious hypotension or cardiac arrhythmias may occur" (Williams Obstetrics, 2010).

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Note: It has been found that there is no benefit to start Oxytocin in infusion form (20 units in 500 mL of normal saline) before the delivery of placenta (Jackson, et al., 2001).

14.2 RECOMMENDATION FOR ERGOMETRINE USAGE

INSTANT PHARMACY

Methylergometrine; Syntometrine injection.
Methergine (Novartis); Utergin (Sigma) 0.2 mg in 1 mL ampoule.
Speed of action: 1 minute after intravenous (IV) injection and 7 minutes after intramuscular (IM) injection.

Indication of Use

- For active management of third stage of labour to promote seperation of placenta and reduce blood loss—both after vaginal delivery and caesarean section (*see* below for details)
- For control of primary postpartum haemorrhage (PPH)
- For control of secondary PPH
- Bleeding associated with abortion, e.g., inevitable or incomplete abortion
- During medical termination of pregnancy
- Subinvolution of uterus

Caution: It should not be given IV because it can cause severe hypertension. Nowadays, its IM administration is also avoided in favour of Oxytocin specially in cases of hypertension and heart disease.

Contraindication: Pregnancy, first and second stage of labour, hypertensive disorders, pre-eclampasia, eclampsia, heart disease, hepatic and renal impairment and after birth of first twin.
Relation with lactation: Reduces milk secretion and is excreted in milk.
Dosage:

- For active management of third stage of labour—0.2 mg (1 ampoule) to be given IM following delivery of the anterior shoulder or immediately after the birth of the baby.
- For control of atonic PPH—1 ampoule IV slowly over 60 seconds, may be repeated after 2 hours. This is a desperate situation.
- For excessive red lochia and subinvolution—1 tablet (0.125 mg) TDS for 3 days.

Combination of Oxytocin and Ergometrine (Syntometrine Injection)

Composition: Oxytocin 5 units and Ergometrine maleate 0.5 unit

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Dose:

- For prevention of PPH: 1 ampoule to be given IM (not IV) after delivery of placenta.
- For active management of third stage of labor: To be given IM with the delivery of the anterior shoulder.

Note: This drug is not available in India.

In any case, this is no longer favoured because it contains Ergometrine which may cause hypertention. Plain Oxytocin is favoured instead.

14.3 RECOMMENDATION FOR PROSTAGLANDIN USAGE

INSTANT PHARMACY

Dinoprostone tablet; Dinoprostone gel; Misoprostol tablet—oral and vaginal; Carboprost injection.

Dinoprostone Tablet (E2)

Prostaglandin (PG) tablet (DRL) 0.5 mg.

Dinoprostone Gel (E2)

Cerviprime gel (Astra); Dinoripe gel (DRL).
0.5 mg E2 in 2.5 mL gel—comes in pre-loaded syringe.

Misoprostol Tablet (E1)

Misoprost tablet (Cipla) 25, 100 μg; 200 μg and 600 μg.
Zitotec (Sun) 200 μg.

Carboprost Injection (F2 Alpha)

Prostodin injection (Astra) 125 μg and 250 μg.
Deviprost (DRL) 250 μg.

Preparation and usage at a glance

Route of administration	*Preparation*	*Indication of use*
Oral	Dinoprostone (E2) tablet Primiprost; PG tablet 0.5 mg tablet	➢ Induction of labour around term ➢ Augmentation of slow labour ➢ Induction and termination of pregnancy in cases of: – Intrauterine death – Malformed foetus ➢ Induction in a cardiac case where fluid over loading is to be avoided

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Route of administration	*Preparation*	*Indication of use*
Oral	Misoprostol (E1) tablet Misoprost; 25, 100, 200, 600 μg	➢ 1st and early 2nd trimester termination (MTP) ➢ 1st and 2nd trimester missed abortion ➢ Cases of leaking membrane at term (contraindicated in scarred uterus in 2nd trimester)
Intracervical	Dinoprostone (E2) gel Cerviprime; Dinoripe: 0.5 mg E2 in 2.5 mL of gel in preloaded syringe	Ripening of cervix specially near term but can be used even in 2nd trimester
Intramuscular	Carboprost (F2 alpha) Prostodin; Deviprost injection – 125 μg ampoules – 250 μg ampoules	Refractory atonic PPH—250 μg Active management of third stage—125 μg
	For cervical softening prior to suction termination in 1st trimester specially in nulliparae; vaginal Misoprostol tablet has practically replaced this indication	
Vaginal	Misoprostol (E1) tablet (see above)	1st and 2nd trimester termination—MTP 1st and 2nd trimester missed abortion
	The same tablet can be used vaginally	Ripening of cervix prior to induction of labour at or around term
	These now come in retrieval system, i.e., the drug can be taken out in case of hyperstimulation	Induction of labour near term (contraindicated in scarred uterus in 2nd and 3rd trimester)

(MTP: medical termination of pregnancy; PPH: postpartum haemorrhage)

CHOICE OF PROSTAGLANDIN INDICATION-WISE

For Ripening of Cervix around Term

Two choices—Intracervical gel and vaginal tablet.

Dinoprostone Intracervical Gel 0.5 mg

It comes in pre-loaded syringe.

Attach the plastic cannula that comes in the pack to the nozzle of the syringe and deliver slowly the whole content into the cervical canal "just below" the level of internal os under aseptic precaution.

This may be used for inducing both live and dead foetus.

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Misoprostol Vaginal Tablet 25 μg (Cipla)

Application: Moisten it with a bit of antiseptic, and insert it high up in the vagina in the posterior fornix.

Caution: If Prostaglandin has been used to ripen cervix Oxytocin infusion should not be used for 6–12 hours to avoid the risk of hyperstimulation.

For Induction of Labour

Two choices—oral tablet, vaginal tablet.

Dinoprostone (Oral) Tablet 0.5 mg

One tablet hourly for 3 doses, if no response then 2 tablets hourly into 3 doses (maximum).

Once the labour is established dose may be reduced to 1 tablet hourly or 2 hourly or even be omitted.

Misoprostol (Vaginal) Tablet 25 μg

One tablet of 25 μg to be placed in the posterior fornix.

Oral and vaginal routes are more suitable for the cases of intrauterine death because these do not involve putting up IV drip which is distressing.

Caution: Use of Misoprostol for induction of labour is an 'off label' use (manufacturers do not approve) though American College of Obstetrics and Gynaecology has approved its use for this purpose in December 2000 (Williams Obstetrics, 2005).

For Augmentation of Labour

Dinoprostone (Oral) Tablet

Dose: One tablet hourly or 2 hourly for 2–3 doses depending on the uterine response, foetal heart rate (FHR) behaviour and progress of labour. Very close monitoring by cardiotocography is required.

For Termination of Pregnancy with Intrauterine Death

There are two choices:

- Dinoprostone tablet orally—*see* under induction of labour.
- Misoprostol tablet vaginally—*see* under induction of labour.

For Induction of Midtrimester Abortion

Vaginal Misoprostol Only

Initial dose—Misoprostol—600 μg vaginally. Then 400 μg 4 hourly.

Complete abortion in 95%.

Contraindicated in scarred uterus (Williams Obstetrics, 2010).

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For Facilitating 1st Trimester Abortion

Before suction evacuation procedure to avoid injury to the cervix from rapid dilatation which is injurious.

Misoprostol Tablet

Insert 2 tablets of 200 μg high up in the vagina in posterior fornix after moistening these in some antiseptic solution about 8 hours before the proposed time of operation. This not only causes dilatation of cervix but also often partial expulsion of the product.

For Active Management of Third Stage of Labour (For Prevention of PPH)

Two choices (1) carboprost and (2) misoprotol tablet.

Carboprost

Injection Prostodin 125 μg 1 ampoule IM with the birth of anterior shoulder.

Misoprotol Tablet

600 μg inserted rectally.

For Control of Refractory Atonic PPH

Two alternatives and three routes of administration.

Carboprost Injection 250 μg

- Intramuscular—1 ampoule deep IM instantly. If the bleeding is not controlled the injection may be repeated every 15–90 minutes up to maximum 8 doses (Cunningham et al., 2005).
- Intramyometrial injection—1 ampoule may be given suprapubically (unlicensed).

Misoprostol Tablet Rectally

A total of 1000 μg to be inserted rectally (Williams Obstetrics, 2005).

CONTRAINDICATION TO PROSTAGLANDIN THERAPY

- All obstetric contraindications for uterine stimulation apply, e.g., cephalopelvic disproportion, grand multiparity, foetal distress, scarred uterus, etc. Risk of rupture is 16 times greater if used in labour in a post caesarean case.
- Active-cardiac, pulmonary (specially asthma), renal and hepatic disease, epilepsy, glaucoma, etc.
- Acute pelvic inflammatory disease
- Hypersensitivity to Prostaglandin

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ADVERSE REACTIONS

Vomiting, diarrhoea, elevation of temperature, headache, dizziness, hypotension, uterine hypertonicity and its consequent problems including foetal distress, rupture uterus.

14.4 PRACTICAL TOCOLYSIS

INSTANT PHARMACY

Ritodrine (withdrawn), Isoxsuprine, Terbutaline.
Note: Tocolytic therapy do not markedly prolong gestation but may delay delivery in some women up to 48 hours which offers the following benefits:
a. Transfer patient to a higher centre with good neonatal unit
b. Permits time for the corticosteroid therapy to work

POSSIBLE INDICATION OF TOCOLYSIS

- Actual or threatened premature onset of labour
- History of one or more premature labour in the past
- History of recurrent late midtrimester abortion
- Short cervix
- Irritable uterus
- To cover long journey by the mother during pregnancy
- During amniocentesis, cordocentesis, cervical cerclage, foetal surgery
- As a temporary measure to control exaggerated uterine contraction during labour causing foetal distress
- In cases of cord prolapse in labour to prevent cord compression by uterine contraction while arranging delivery.

Approach towards tocolysis has been presented here under three clinical headings:

I. Tocolysis for stoppage of pre-term labour
II. Tocolysis to avert foetal distress
III. Cold tocolysis to 'prevent' premature labour.

Present position of practical tocolysis: Though many new tocolytics are in pipeline, since at the present time mostly beta-mimetics are used and has been researched most widely, only this group has been presented in detail.

Tocolysis for Stoppage of Pre-term Labour

Three choices—Ritodrine, Isoxsuprine and Terbutaline all of which are beta-mimetics.

Ritodrine

This drug has been withdrawn from USA market because it has been reported to cause very serious side effects including mortality.

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Isoxsuprine

Duvadilan (Duphar).
Tablet—10 mg/tablet; Injection—10 mg/ampoule.

Route of Administration

- *Oral:* 20 mg 3–4 times a day after meals, following improvement 10 mg 2–3 times a day.
- *Intramuscular:* 10–20 mg 3 times daily depending upon uterine activity *and side effects*. Once the contraction ceases the drug should be switched to oral route.

But, recently maintenance tocolysis after acute therapy is not being recommended (William's Obstetrics, 2018).

Terbutaline

This is for acute tocolysis only (see below).

Tocolysis to Avert Foetal Distress

It is required for:

- *Exaggerated uterine contraction (usually due to hyper-stimulation) causing foetal distress*
- *For stoppage of normal uterine contraction in the event of cord compression*

*Beta-mimetic drug of choice here is Terbutaline (Warren and Arulkuma*ran, 2009).

Terbutaline Injection

Bricanyl (AstraZeneca)
1 mL ampoule contains 0.5 mg of the drug.

Dose: 0.25 mg subcutaneously.
Alternative drugs for acute Tocolysis.
Nitroglycerin

Dose: To be given sublingually 400 μg.

Duration of action: 2–3 minutes.

Special indication: To aid delivery of foetus during caesarean section where all the liquor have drained away, e.g., transverse lie who has been in labour for long.

Cold Tocolysis to Prevent Premature Labour

These include:

a. Cases with past history of premature labour or recurrent premature labour
b. Those who have irritable uterus (specially when proved by external tocography)
c. Patient proposing to take long journey

Isoxsuprine tablet: Some practioners use it but its use is debatable.

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For indication (a) and (b) the tocolytics are usually given up to 34 weeks, i.e., when lung maturity is expected to occur.

For cold tocolysis pulse count should be done 4 times a day specially if the patient complains of palpitation.

Foetal Safety of Beta-mimetics

It is safe for foetus.

Maternal Safety—Many Side Effects

There is the rare risk of postpartum haemorrhage due to uterine atony specially after caesarean section (Ingemarason et al., 1993).

Antidote to Beta-mimetics

Propranolol (a non-selective beta blocker) promptly reverses the effect of the beta-mimetic drugs and allow the uterus to contract. Injection Inderal (1 mg/mL in 1 mL ampoule) to be given IV over one minute. In order to prevent its entry into the neonate, it should be given only after clamping the cord.

A New Approach for Preventive Tocolysis

Ultra Omega-3 capsule (Meyer Vitabiotics)
Composition

- Omega-3 fish oil : 600 mg
- Docosahexaenoic acid : 300 mg
- Eicosapentaenoic acid : 60 mg

Dose 1 capsule twice daily from 12th week of pregnancy up to delivery.

Contraindication to Tocolysis

Cardiac disease, eclampsia, severe pre-eclampsia, intrauterine infection, intrauterine foetal death, placenta previa and abruption of placenta. Steroid and tocolytics, if at all used in a pregnant diabetic (better not), they should be used with great caution and under very close monitoring of blood glucose.

Benefit of Tocolysis

No significant effect on perinatal mortality, frequency of prolongation of pregnancy to term have been found (Williams Obstetrics, 2018).

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