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Review Article

Methylergometrine role in clinical practice

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Abstract

Postpartum haemorrhage (PPH) is a major cause of morbidity and mortality, with uterine atony accounting for 70-80% of all haemorrhages. According to the experts, the incidence of PPH ranges from 3% to 5%. The most common causes include uterine atony, laceration, accidental haemorrhage, and abnormal placentation. Factors that increase the risk of PPH include advanced age, assisted reproduction technology, and advanced age-associated co-morbidities. Even though guidelines recommend oxytocin as the first option, experts consider methylergometrine to be the ideal uterotonic in clinical practice in case of either normal vaginal or C-section delivery. The current consensus article aims to provide a collation of evidence-based literature and clinical insights from the experts on epidemiology, risk factors, and predictors of PPH. The article also provides a consensus on the role of methylergometrine (methylergonovine) in the management of PPH. Overall, methylergometrine alone or in combination with oxytocin is among the first-line drugs for the management of PPH with a favourable safety profile and cost-effectiveness.

Keywords: Postpartum haemorrhage, Placentation, Methylergometrine, Guidelines, Uterotonics.

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1. Introduction

Maternal mortality due to complications during and following pregnancy and childbirth is reported to be exceptionally high. In 2020, approximately 287,000 women died during and following pregnancy and childbirth according to World Health Organization (WHO). Data suggests that in 2020 most of the maternal deaths (95%) occurred in low and lower-middle-income countries, which could have been prevented.[1] The global maternal mortality rate (MMR) has decreased by 34%, equivalent to an average annual rate of reduction of 2.1% (from 342 deaths to 223 deaths per 100,000 live births) from 2000 to 2020. However, this proportion is one-third of the average annual rate (6.4%) needed to attain the sustainable development goal (SDG) of 70 maternal deaths per 100,000 by 2030.[2]

Approximately, 75% of all maternal deaths are attributed to severe bleeding and infections (mostly following childbirth), high blood pressure during pregnancy (pre-eclampsia and eclampsia), complications from delivery, and unsafe abortion.[1] Obstetric haemorrhage is responsible for nearly 47% of maternal deaths in India, followed by infections (12%), and hypertensive disorders (7%) due to pregnancy.[3]

2. Postpartum Haemorrhage: Epidemiology, Causes, Risk Factors and Predictors

2.1. Incidence of PPH

Postpartum haemorrhage (PPH) is defined as blood loss of more than 500 ml and 1000 ml after a vaginal delivery or C-section, respectively.[4] It also includes even a small amount of

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blood loss that can make women haemodynamically unstable. Globally, PPH is reported in 5% of all deliveries, with most deaths occurring within the first four hours, indicating that the consequence of labour at the third stage can cause PPH. The prevalence of PPH in India is reported to vary from 2-6% and 6% after vaginal delivery and C-section, respectively.[5]

2.2. Classification of PPH

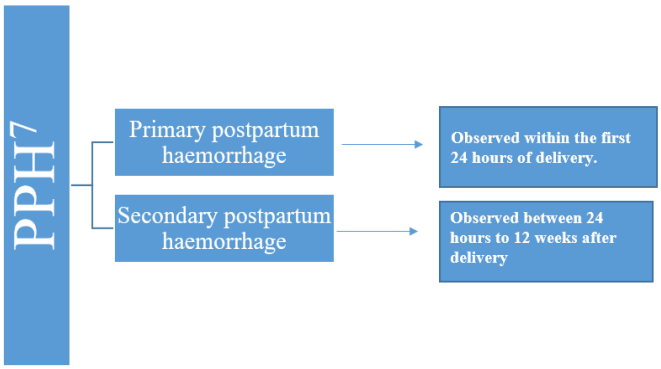

Figure 1: Classification of PPH

2.3. Causes of PPH

The primary causes of PPH include uterine atony, genital tract lacerations, retained placenta, uterine inversion, abnormal placentation, and coagulation disorders. Uterine atony, which includes an ineffective contraction of the uterus, is the most common cause of PPH, accounting for 70% to 80% of all haemorrhages.[6] In a recent study, researchers assessed the causes of early PPH; the findings suggested that up to 80% of PPH cases were attributed to uterine atony, while o causes include genital tract injuries, placenta accrete, and coagulopathies.[7]

In addition, endometritis, delayed placental bed involution, infection, subinvolution of the placental site, hereditary coagulation deficiencies, and retained products of conception are common causes of secondary PPH.[6,8] Congenital coagulopathies, cancer of the cervix, submucous fibroids, adherents of the placenta, dehiscence of C-section scar, uterine pseudoaneurysms, and rupture of the uterus are less common aetiologies.[8]

2.4. Factors precipitating PPH: Focus on late pregnancy and infertility

Literature suggests that multiple factors increase the risk of PPH, including history of PPH, multiple pregnancies, macrosomia, primiparity, multiple births, advanced age of mother, early delivery, illiteracy, caesarean delivery, and stillbirth.[9] Besides, antepartum haemorrhage, maternal anaemia, prolonged labour, and preeclampsia also increase the PPH risk.[10] In a recent study, Pubu ZM *et al.* assessed the risk factors for PPH and showed that maternal age >35 years, history of preterm birth, C-section, new-born weight >4 kg, and neonatal asphyxia were risk factors for PPH.[9]

Another cohort study including 64,886 pregnant women demonstrated a higher frequency of placenta previa, hypertension, gestational diabetes, and overweight or obesity in women aged ≥35 years.[11]

A cohort study by Fukami T *et al.* reported that foetal macrosomia (more than 4000 g), hypertension due to pregnancy, the pregnancy that results from assisted reproductive technology (ART), and severe vaginal and perineal lacerations are the risk factors for PPH.[12] The literature also suggests a 3.39-fold higher incidence of PPH for ART pregnancy in the patients with vaginal delivery (p <0.001) versus those without ART.[13]

2.5. Predictors for PPH

Identifying the predictors of PPH will help healthcare providers recognise patients who are at risk, which in turn, will help in planning adequate care and treatment. Among patients with PPH, the thoroughly combined predictors of PPH were identified as parity (particularly nulliparous), macrosomia, mode of delivery (such as operative vaginal delivery, including emergency and pre-labour C- section), and prior to PPH history.[14]

With the advancements in technology, magnetic resonance imaging (MRI) has been utilised for the diagnosis of placental diseases. Also, thinning of the myometrium, placenta penetration through the cervix, placenta accreta, and an irregular placental signal are associated risk factors for PPH in patients with placenta previa.[15]

3. Discussion

3.1. PPH and maternal mortality as a complication

Globally, the main cause of maternal morbidity and mortality is PPH. According to the WHO, in developing countries, 60% of deaths occur because of PPH, accounting for over 100,000 maternal deaths annually worldwide.[4]

3.2. Expert opinion

According to the experts, the incidence of PPH ranges from 3-5% in private practice and 5-10% in general hospitals and tertiary centres.

The common causes of PPH include uterine atony, laceration, accidental haemorrhage, abnormal placentation (placenta previa or placenta accreta), and prolonged labour.

The panelists agreed that pregnancy at an older age, and ART, hysteroscopic procedures, and biopsies performed during infertility treatment are risk factors for PPH.

Also, comorbidities associated with advanced-age pregnancy like pregnancy-induced hypertension, diabetes, hypertension, and thyroid gland abnormalities increase the risk of PPH.

PPH is a significant cause of maternal mortality, particularly in tertiary centres, accounting for 90% of the total cases.

Newer MRI technologies are beneficial in the prediction of PPH associated with placenta accreta and placenta previa in late pregnancy; however, the prediction of atonic PPH is complicated.

4. Management of PPH: Preferred Drugs

4.1. Primary PPH

A multidisciplinary approach is warranted for the management of primary PPH (**Table 1**). Most cases of bleeding excluding lower genital tract tears are attributed to uterine atony. For atonic PPH, uterotonics are considered first-line drugs; in cases of failure, further interventions, including more uterotonics, haemostatic medications, surgical procedures, radiological embolisation, and/or devices for compression are required.[17]

Table 1: Multidisciplinary approach for the primary PPH management [17]

Approach for the management of primary PPH	Drugs/procedure/device
Uterotonics	Ergometrine, oxytocin, carbetocin, prostaglandin, misoprostol
Haemostatic drugs	Tranexamic acid (TXA) and recombinant activated factor VII (rFVIIa)
Surgical procedures	Uterine tamponade, ligation of an artery, and compression sutures of uterus
Radiological embolisation	Selective radiological embolisation of the bleeding vessel
Compression device	Non-pneumatic anti-shock garment (NASG) and aortic compression device

4.2. Secondary PPH

The underlying aetiology determines the treatment plan that should be used for secondary PPH. However, empirical treatment is started without a conclusive diagnostic test. Treatment strategies used for managing secondary PPH are mentioned in **Table 2**.[17]

Table 2: Treatment options for secondary PPH

Treatment option	Drugs/procedure
Medical management	Uterotonics, TXA or hormonal therapy, antibiotics
Surgical intervention	Evacuation of retained products
Radiological procedure	Embolism of uterine artery

4.3. Uterotonics for the management of PPH[18]

4.3.1. Oxytocin

It is a widely used uterotonic drug that enables rhythmic uterine contractions at low doses. The contractions are like those observed during spontaneous labour. Its half-life is roughly 3-5 minutes and can be administered as an infusion for maintaining uterine contractions. Intramuscular (IM) oxytocin demonstrates a latent phase lasting from 2-5 minutes; however, the uterine activity might continue for two to three hours. It cannot be used orally, needs to be transported and stored in a cold chain, and demonstrates a favourable safety profile.

4.3.2. Methylergometrine

It is an ergot alkaloid that facilitates sustained uterine contractions. The latent period begins two to five minutes after an IM injection. It exerts a vasoconstrictive effect and can cause hypertension.

4.3.3. Misoprostol

It is a prostaglandin E1 (PGE1) analogue and is used as a uterotonic. Sublingual misoprostol is absorbed after nine to fifteen minutes and has a half-life of about twenty to forty minutes. It shows various adverse effects like diarrhoea, pain in the abdomen, shivering, nausea, vomiting, and pyrexia.

4.3.4. Carbetocin

It is a synthetic, long-acting analogue of oxytocin. Sustained uterine contractions are produced within two minutes of carbetocin administration, lasting for about six minutes. The safety profile is similar to oxytocin.

5. Guideline and Scientific Association Recommendations for PPH Prevention and Treatment

5.1. WHO-recommended approach for managing PPH[19]

1. Uterotonics play a key role in the PPH treatment.
2. Uterotonics should be administered to all women giving birth to prevent PPH during the third stage of labour.
3. WHO recommends performing uterine massage and initiating resuscitation of fluid with isotonic crystalloids, as soon as PPH is diagnosed.
4. Tranexamic acid should be used for the management of refractory atonic bleeding or chronic trauma-related bleeding.
5. If uterotonics are unavailable or the patient suffers from refractory bleeding then intrauterine balloon tamponade is advised.
6. WHO recommends using bimanual uterine compression, non-pneumatic anti-shock garments, and external aortic compression until the patients have access to substantive care

7. If uterotonic medications and other conservative procedures fail, surgical interventions are recommended immediately.

5.2. WHO-recommended choice of uterotonics for the prevention of PPH[20]

1. Availability of multiple uterotonics: For the prevention of PPH in all births, oxytocin (10 IU, IM/IV) is recommended..
2. Unavailability of oxytocin: Carbetocin, or if appropriate, ergometrine fixed-dose combination, or oral misoprostol, ergometrine/methylergometrine, oxytocin, is recommended.
3. Absence of skilled healthcare personnel to inject uterotonics: Oral misoprostol (400 μg or 600 μg) is recommended.

5.3. WHO-recommended choice of uterotonics for the treatment of PPH[19]

1. The recommended uterotonic agent is intravenous oxytocin.
2. In cases of unavailability or patients not responding to oxytocin, IV ergometrine, a prostaglandin drug (including sublingual misoprostol, 800 μg), or an oxytocin-ergometrine fixed dose is advised.

5.4. The International Federation of Gynaecology and Obstetrics (FIGO): Recommendations for the PPH prevention and treatment[21]

1. The FIGO advises using uterotonics for PPH prophylaxis during the third stage of labour in all births.
2. For uterine atony treatment, uterotonics are considered first-line agents
3. For the initial IV fluid resuscitation of PPH women, isotonic crystalloids are recommended

For women with clinically confirmed PPH after vaginal delivery or C-section, early intravenous tranexamic acid administration is advised within three hours after delivery.

1. Performing a uterine massage is advised for treating PPH
2. Uterine balloon tamponade is recommended when uterotonics are unavailable or patients do not respond to uterotonics
3. If uterotonic drugs and other conservative interventions fail, surgical interventions are recommended immediately

5.5. Federation of Obstetric and Gynaecological Societies of India (FOGSI): Recommendations for the PPH prevention and management

Prevention and management of PPH[22]

1. For women expecting to deliver, active treatment of the third stage of labour should be a part of routine management.
2. Procedures involved in the prevention of PPH include the administration of uterotonics after birth of the baby, delayed cord clamping, and controlled cord traction.
3. The uterotonics advised for the PPH prevention are given in **Table 3**.

Table 3: FOGSI recommended uterotonics for the PPH prevention and treatment

Drug	Dose	Route primary	Frequency of dose	Comments and contraindication
Oxytocin	10-40 units in 1000 ml of normal saline or lactated Ringer's	IV (IM, IMM)	Continuous infusion	No contraindications
Methylergonovine	0.2 mg	IM (IMM)	Every 2-4 hours	Contraindications include hypertension/ toxemia
15-methyl PGF2 (Hemabate)	0.25 mg	IM (IMM)	Every 15-90 minutes, not to exceed 8 doses	Contraindication include active cardiac pulmonary renal or hepatic disease
Dinoprostone (Prostin E2)	20 mg	PR	Every 2 hours	Should be avoided in hypotensive patient because of vasodilation. If available, 15 m PGF2 is preferable

Treatment of PPH

1. Fundal massage must be initiated and uterotonics must be administered on the diagnosis of excess vaginal bleeding. The uterotonics advised for the PPH treatment are given in **Table 3**.[23]

5.6. Expert opinion

The panelists opined that methylergometrine is good to use uterotonic, even in comparison to oxytocin. However, methylergometrine should not be used in patients with comorbidities such as hypertension and anaemia. According to the experts, 70-80% of patients in clinical practice do not suffer from hypertension, and hence, safe to administer. One expert suggested that an intravenous (IV) bolus ampoule of oxytocin is administered, followed by the addition of IM methylergometrine or repeated if the bleeding does not stop. In case of treatment failure, any prostaglandin, including sublingual mifepristone or carboprost can be used. One panellist also suggested that it should be available in the smallest centres to reduce cases of PPH.

6. Methylergometrine: Indications, Contraindications, and Pharmacology

For prophylaxis of PPH, the conventional treatments include methyl ergometrine, oxytocin, and 15-methyl prostaglandin F2α.[24]

6.1. Indications[25]

1. Delivery of the placenta
2. Routine treatment of uterine atony
3. Haemorrhage and uterine subinvolution
4. Control of uterine haemorrhage in the second stage of labour after delivery of the infant's anterior shoulder

6.2. Clinical pharmacology[25]

Methylergometrine causes a rise in the tone, amplitude, and rate, of rhythmic contractions by acting directly on the uterine smooth muscles. Thus, it shortens the third stage of labour and reduces blood loss by inducing a fast, and sustained tetanic uterotonic effect. It has a rapid onset of action after administration by IV (immediate), IM (2-5 minutes), and after oral (5-10 minutes).

6.3. Contraindications [25]

Methylergometrine is contraindicated in the following conditions:

1. Hypertension
2. Toxaemia
3. Pregnancy
4. Hypersensitivity

6.4. Efficacy of methylergometrine in PPH: Clinical evidence

In a study, researchers compared oxytocin and methylergometrine efficacy in reducing the risk of PPH (N = 150 in each group) for the active treatment of the third stage of labour. Women who were administered methylergometrine demonstrated significantly less meantime of the third stage of labour, post-delivery fall in haematocrit, mean blood loss, and need for more uterotonics. [26]

The effects of methylergonovine and oxytocin on haemodynamic stability and bleeding volume in C-sections were compared by Anvaripour A *et al*. Patients who were candidates for elective spinal anaesthesia C-sections were included in the study. In comparison to the methylergonovine group, the oxytocin group experienced a considerably larger fall in mean arterial blood pressure in minutes 1, 3, 5, 10, and 15. Between minutes 1 and 5, the oxytocin group saw a substantial rise in heart rate compared to the methylergonovine group. Compared to the oxytocin group, the methylergonovine group required a statistically lower concentration of the vasoconstrictor medication ($p<0.0001$).[27]

In another research, researchers evaluated the administration of the role of prophylactic methylergonovine along with oxytocin in patients (in labour) who are undergoing an intrapartum C- section (N = 160). The patients in the prophylactic methylergonovine plus oxytocin group needed significantly fewer additional uterotonic agents versus oxytocin alone (20% versus 55%), were likely to have an improved uterine tone (80% versus 41.2%), had a lower incidence of post-partum haemorrhage (35% versus 58.8%) and decreased requirement of blood transfusion (5% versus 22.5%), and demonstrated less mean quantitative blood loss (996 ml versus 1315 ml, P = 0.004).[1]

Amant F *et al.* compared the efficacy and adverse effects of misoprostol versus methylergometrine for PPH prevention. Women with plausibly normal pregnancies were administered misoprostol or methylergometrine/placebo (N = 200) after childbirth. The need for further oxytocic drugs was lower after methylergometrine (4.4%) versus misoprostol (12.8%) (P = 0.065). No difference was observed in the mean systolic and diastolic blood pressure an hour after childbirth, in both the groups. Fever and shivering were significantly more common in the misoprostol group versus (fever: 34% versus 3%, P <0.0001; shivering: 42% versus. 8.5%, P <0.0001). On the third day post-partum, the haemoglobin level (g/dL) was similar in both groups.[29]

In a study, patients undergoing non-elective C- sections were administered either methylergometrine or no methylergometrine during the post-partum period. Methylergometrine (0.2 mg) was administered orally every 6 hours until hospital discharge, with the first dose given within the first 6 hours after C- section (N = 80). A notable reduction in the rate of postoperative endometritis was observed in

patients receiving methylergometrine versus no methylergometrine (10% versus 36%, p <0.005). Besides, the mean postoperative haemoglobin was notably higher in the methylergometrine-treated group versus the control group (p <0.001).[30]

Gilad O *et al.* assessed the outcomes in breastfed infants exposed to methylergonovine. The study demonstrated that post-partum maternal use of methylergonovine did not affect lactation, rate of neonatal complications, and differences in the growth or adverse neurodevelopment results at the time of follow-up (p = 0.26).[32] (**Table 4**)

Table 4: Safety profile of methylergometrine versus other uterotonics

Uterotonics	Side effects
Methylergometrine	Major: hypertension[32] Others: nausea (2%), vomiting (2.8%), diarrhoea (0%), fever (0%), shivering (0%), PPH (0%)[33]
Oxytocin	Major: hypotension, NSTEMI, STEMI, acute lung oedema [32] Others: nausea (0.8%), vomiting (0.4%), diarrhoea (0.4%), fever (0%), shivering (0%), PPH (0%),[33] chest pain (0.04%), flushing (0.03%), and abdominal pain (0.38%)[34]
Carbetocin	Major: hypotension, NSTEMI, STEMI, acute lung oedema[32] Others: chest pain (0.09%), flushing (0.03%),[34] nausea (21%-27%), pain of abdomen (40%), itching (10%), flushing (26%), vomiting (7%-9%), warmth feeling (20%), headache (3%-14%), and tremor (11%)[35]
Misoprostol	Major: Dysrhythmia[32] Other: nausea (0.8%), vomiting (0.08%), diarrhoea (0.4%), fever (10.4%), shivering (0.4%), and PPH (1.2%)[33]
Carboprost	Major: pulmonary oedema, bronchospasm, dystonia[32] Others: nausea, vomiting, diarrhoea[33]
Tranexamic acid	Thrombotic complications[36]

NSTEMI: Non-ST-elevation myocardial infarction, STEMI: ST-elevation myocardial infarction

6.5. Expert opinion

Methylergometrine for different patient profiles

1. First choice in an uncomplicated pregnancy without co-morbidities
2. Use in patients with mild anaemia
3. First choice for atonic uterus
4. Prior to choosing surgical treatment for PPH

Methylergometrine is among the first-line drugs for the PPH management after both normal or C-section delivery. Patients with hypertension, cardiovascular disease, or medication hypersensitivity shouldn't take methylergometrine. It demonstrates few side-effects or contraindications compared to the other drugs.

Some experts prefer IV methylergometrine, while a few of them prefer IM methylergometrine; adding IV methylergometrine with IM methylergometrine also provides good results. Nausea and vomiting are usually seen after 3-4 minutes of methylergometrine administration in C-section patients. This suggests that methylergometrine may not be the only cause of nausea and vomiting and that other factors may also contribute to it during the C-section.

An expert opined that although FOGSI does not recommend using IV methylergometrine, the use of diluted IV has an immediate action in clinical practice among C-section patients. Diluted methylergometrine does not cause hypertension and is the best choice. Experts suggest that IV methylergometrine works faster (42 seconds) versus IM methylergometrine (7 minutes). The panellists agreed that no drug provides prolonged contraction and good tone when compared to methylergometrine. The experts also favoured using oxytocin along with IM methylergometrine.

Experts opined that new-generation practitioners should use methylergometrine for managing PPH.

In clinical practice, experts use oral methylergometrine in the following conditions:

1. Subinvolution of the uterus
2. After medical termination of pregnancy, oral methylergometrine can be used for 2-4 days, especially in the second-trimester abortion, where chances of bleeding are high
3. Oral methylergometrine can be given for 3-4 days to patients who were treated for PPH and complained of some bleeding during follow-up
4. For a couple of days to women who give birth to twins and was found to be effective
5. Risk of endometriosis.

Experts also agree that methylergometrine is a cost-effective medication for PPH treatment.

7. Conclusion

Globally, the major reason for maternal morbidity and mortality is PPH. However, adequate care and treatment can help reduce the mortality rate. The most common cause of PPH is uterine atony. Experts suggest that uterotonics are the first-line treatment for PPH prevention and treatment. Guidelines suggest oxytocin as the first-line medication,

experts consider methylergometrine to be used for preventing PPH. Methylergometrine can be given in the IV but is limited to IM form. It has proven to have a superior safety profile in routine practice as compared to other uterotonics. Methylergometrine should only be avoided in patients (20–25% of the population) who have both anaemia and hypertension. Consequently, methylergometrine is the preferred uterotonic for the vast majority of people. It can be administered either individually or in conjunction with oxytocin to treat PPH. Therefore, the current article suggests that methylergometrine is an efficacious, safe, and cost-effective treatment for PPH management.

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9. Conflict of Interest

None.

10. Ethical Approval

Not required.

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