Good Clinical Practice Recommendations FOGSI- ICOG 2018

Induction of Labor:

Good Clinical Practice Recommendations

Chairperson, ICOG

President, FOGSI

Dr S. Shantha Kumari

Dr Jaideep Malhotra

Indian College of Obstetricians & Gynecologists The Federation of Obstetric & Gynecological Societies of India C-5,6,7,12,13, 1st Floor, Trade World, D-wing Entrance, S. B. Marg, Kamala City, Lower Parel (W), Mumbai-400013.

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Message from President, FOGSI

"The problems are solved, not by giving new information, but by arranging what we have known since long."

— Ludwig Wittgenstein

Dear Fogsians,

In this modern era of science and technology, we are flooded with information just at a click of one button; however such information cannot be used to treat our patients unless it is backed up with strong evidence. Developing Good Clinical practice guidelines that enlighten practitioners and patients is an exceptionally challenging task. It helps to improve methods of prevention, diagnosis, treatment, and clinical management. It also to reduce clinically significant variations among physicians in the particular management and procedures utilized in making diagnoses and providing treatment. These guidelines should be clinically valid and reliable and the content should be stated with clarity. One such field in obstetrics which requires revision and review of the available practices is induction of labour.

Over the past few decades, there has been an increase in the incidence of caesarean sections. With the increasing trend towards advanced gestational age, the increasing order of gestation and increasing number of elective inductions, the rates of a primi section has increased. There are different and newer methods of induction available, to choose the most suitable method is of utmost clinical relevance. The timing of induction is the second most important factor responsible for a favorable pregnancy outcome. With all these updates and evidences, there is a need to develop good clinical practice guidelines in Indian scenario. With the inputs from expert obstetricians across different parts of the country, 'Good clinical practice recommendations' (GCPR) on 'Induction of labor' have been formulated.

I hope the GCPR will be of clinical help to all and will eventually help in improving the maternal outcome.

Dr. Jaideep Malhotra

President, FOGSI – 2018

Message from Chairperson, ICOG



Dr S.SHANTHA KUMARI M.D. D.N.B.FICOG FRCPI (Ireland) FRCOG (UK) PROFESSOR OBGYN CHAIRPERSON ICOG 2018 CONSULTANT YASHODA HOSPITAL ICOG SECRETARY 2015 -2017 (Indian College of Obstetricians & Gynaecologists) Member FIGO working Group on Violence Against Women VICE PRESIDENT FOGSI 2013 ICOG GOVERNING COUNCIL MEMBER IAGE MANAGING COMMITTEE MEMBER NATIONAL CORRESPONDING EDITOR FOR JOGI ORGANIZING SECRETARY AICOG 2011 CHAIRPERSON MNNRRC 2008

The ultimate outcome of good Obstetric care is the delivery of a healthy baby with a healthy mother. A fact that sounds so simple is actually a coveted aim achieved only after meticulous planning of antenatal care and delivery. There are times when the benefits of delivery outweigh the continuation of pregnancy and the need for "induction of labour" arises. This process of induction of labour (IOL) requires a comprehensive assessment of the indication, appropriate choice of the method and skilful execution to attain the final goal of obstetrics. Over the years, as Obstetric techniques have advanced and the spectrum of obstetric services has increased there has been much debate and deliberation on the increasing interventions in Obstetrics and due concern has been raised about the alarming rise in caesarean deliveries almost all across the globe. Induction of labour is also one such potential technique which can be questioned for its appropriateness as an unnecessary interference with a natural process unless we can present a viable justification for it. This edition of the ICOG newsletter has been therefore dedicated to the important topic of "Protocols in Induction of labour" so that it summarily presents the pros and cons of Induction of labour and clarifies the need of this intervention to minimize the associated perinatal morbidity and mortality if the pregnancy continues. If a delivery has to be effected before the actual onset of natural labour, a good induction protocol will help avoiding the need for a caesarean section and hence reduce the CS rates in avoidable indications. The agents used for IOL have also seen paradigm shifts and despite the effectiveness of prostaglandins, there has been a resurgence in recent times of mechanical methods which have been refined with

better understanding of the physiology and biochemistry of the genital tract. I hope the readers will enjoy reading the recent advancements in IOL and realise that this is a powerful technique in Obstetrics – on the same note I wish to remind the young readers particularly that with power comes responsibility – so while you have a great technique at your disposal, it is in your best interests to use it justifiably ,in adherence to standard protocols and for the benefit of your patient in true earnest. The ICOG stands for developing Good Practice guidelines and I strongly believe that good clinical practices applied to procedures like IOL will make a difference to help reduce the burden of "unindicated" CS deliveries and reduce the maternal morbidity and mortality rates.

"Gain new knowledge by reviewing old"-analects of Confucius

Knowledge is power and path to success and the best outcomes. Happy reading

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(3 June 2018)

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Good Clinical Practice Recommendations FOGSI- ICOG 2018 Induction of Labor

Methodology

- The President FOGSI and Chairperson ICOG, 2018 realized the need of evidence based guidelines for induction of labor for the country for uniform clinical practice to be used by obstetric care providers.
- FOGSI-ICOG GCPR (Good Clinical Practice Recommendation) development group was constituted.
- It included professors and clinicians from ICOG governing council and FOGSI.
- The priority areas were identified and a list of questions and component to answer induction of labor was prepared.
- Each member of the group performed published literature search for scientific and good quality evidences to draft a document based on each component of induction of labor.
- The documents were reviewed initially by Chairperson, Vice Chairperson, Secretary and Editor, ICOG for its uniformity and then peer reviewed by each member of the group.
- All members prepared their opinion and recommendations based on the draft document and their independent search for available evidences.
- A meeting was held on 3rd June 2018 at Gurugram. All members came prepared with their document and comments on the document prepared by other members.
- All members deliberated each component in detail and discussed comments and recommendations to arrive at a consensus.
- Prior to the meeting, the core group had prepared a preliminary document containing the draft recommendations. The statements were modified or added in the meeting itself, keeping in mind the vast and varied nature of the country and local available resources.
- The GCPR document was read again, finalized and approved by all the members of the development group in the meeting.
- After the meeting, the core group checked and edited the document.
- The document was finally approved by Chairperson, ICOG and President, FOGSI.

Good Clinical Practice Recommendations FOGSI- ICOG 2018

Induction of Labor: GCPR

The participants in the GCPR Development Group agreed on the following statements that apply to all recommendations contained in these guidelines:

1. <u>General Considerations</u>

- Induction of labor should be performed only for a specific medical and/or obstetric indication.
- Expected benefits of shortening the duration of pregnancy should outweigh the potential harms from continuation of pregnancy with no contraindications for vaginal delivery.
- The indication and process of induction of labor should be discussed with the patient.
- The profile of the patient, medical or surgical conditions, rupture of membranes, scar on the uterus, cervical status, the specific method of induction of labor and associated local resources in terms of health personnel, drugs and equipment should be taken into consideration.
- Induction of labor should be done after obtaining informed written consent.

2. <u>Setting for Induction of labor</u>

- All patients should be admitted for induction of labor in a health facility having facilities for caesarean section and management of complications.
- Induction of labor should be done under necessary supervision.
- Maternal and fetal monitoring should be done and the progress of labor should be documented.

3. Prerequisites & Preinduction Assessment

- Informed written consent
- Review of maternal history and profile
- Evaluation for indications and rule out any contraindications
- Reliable estimation of gestational age, presentation and fetal weight.
- Maternal pulse, blood pressure, temperature, respiratory rate and findings on abdominal palpation must be recorded.
- Evaluation of baseline fetal heart rate pattern by auscultation/electronic fetal monitoring.
- Maternal pelvis assessment and clinical evaluation for possible cephalopelvic or feto-pelvic disproportion.
- Assessment of cervical status using Modified Bishop scoring system to predict the likelihood of success and select appropriate method of induction of labor.
- Indication for induction and gestational age along with Modified Bishop Score should be documented at the time; the decision for induction of labor is made.

Cervix		Bishop Score Modifiers			
	0	1	2	3	woamers
Cervical	0	1 - 2	3 - 4	5+	Add
Dilation (cm)					1 point for:
Cervical	>4	2 - 4	1 - 2	<1	-Preeclampsia
Length (cm)					-Each previous
Station of	-3 or	-2	-1,0	+1, +2	vaginal delivery
Presenting	above				
Part (cms in					Subtract
relation to					1 point for :
ischial spine)					-Postdate
Consistency	Firm	Medium	Soft		pregnancy
					-Nulliparity
Position	Posterior	Midposition	Anterior		-PPROM

Modified Bishop Score

Total score: 13; Favorable Score: 6 - 13; Unfavorable Score: 1 - 5

4. Indications & Contraindications and Timing

- 4.1. Induction of labor for a low risk pregnancy is recommended to be carried out only after 39 weeks.
 - At 39 weeks in low-risk nulliparous women, induction of labor results in a lower frequency of cesarean delivery without a statistically significant change in the frequency of a composite of adverse perinatal outcomes.¹
- 4.2. There could be some specific conditions in the mother or in the fetus which can mandate an induction of labor.
- 4.2.1. Term Prelabor Rupture of Membranes
 - Induction of labor is recommended if there is prelabor rupture of membranes (PROM) at more than 37 weeks.
 - Initial assessment of women presenting with term PROM involves confirmation of the diagnosis, gestation age, presentation and assessment of maternal and fetal well-being.
 - Active management of term PROM with induction is associated with reduced maternal infective morbidity and increased maternal satisfaction without increasing caesarean section or operative vaginal birth. Fewer infants are admitted to NICU and fewer infants require postnatal antibiotics^{. 2, 3}

4.2.2. Hypertensive Disorders in Pregnancy

- For women with preeclampsia, induction should be planned at 37 weeks or earlier if indicated for maternal or fetal compromise.
- For women with gestational hypertension at low risk of adverse outcomes, expectant management can be considered beyond 37 weeks.

 Induction of labor is associated with improved maternal outcome and should be advised for women with mild hypertensive disease beyond 37 weeks' gestation. In women with preeclampsia or gestational hypertension beyond 34 weeks gestation, elective delivery can decrease the incidence of complications, severe hypertension and the need for antihypertensive drug therapy.⁴⁻⁶

4.2.3. Diabetes in Pregnancy

- Induction of labor is not recommended before 39 weeks in a woman with gestational diabetes mellitus well controlled on diet.
- Induction of labor is recommended at 38 weeks of gestation if diabetes is controlled on insulin/oral hypoglycemics.
- Management of women with uncontrolled diabetes should be individualized.
- In women with gestational diabetes, without other maternal or fetal conditions, no difference was detected in birth outcomes regardless of the approach used (i.e. induction between 38 and 39 weeks versus expectant management).⁷⁻⁹

4.2.4. Fetal Growth Restriction

- Induction at labor at term is advisable for fetal growth restriction to prevent still birth
- The timing however, is guided by the severity of fetal growth restriction and any deterioration in the Doppler parameters during intensive fetal monitoring.

4.2.5. Twin Pregnancy

• In uncomplicated twin pregnancy, where there are no contraindications to vaginal delivery, induction of labor at 37 weeks is advisable.

- Contraindications of induction of labor in twin pregnancy are monoamniotic twins and first twin non cephalic.
- Early birth at 37 weeks' gestation compared with ongoing expectant management for women with an uncomplicated, dichorionic twin pregnancy does not appear to be associated with an increased risk of harms.¹⁰
- 4.2.6. Obstetric Cholestasis (Intrahepatic Cholestasis of Pregnancy)
 - Induction should be considered between 37-38 weeks to improve perinatal outcome.
 - An earlier induction (around 36 weeks) may be warranted in the presence of severe biochemical abnormalities especially severe derangements of bile acids levels.
- 4.2.7. Intrauterine Fetal Demise
 - The woman and her partner should be supported and counseled to cope with the situation.
 - Woman should be offered a choice of immediate induction of labor or expectant management. However in the presence of conditions like sepsis, preeclampsia or abruption, immediate delivery should be planned.
 - Although most patients will desire prompt delivery, immediate delivery is not critical. In more than 90% of the women, labor starts spontaneously in 3 weeks of diagnosis.¹¹
 - Disseminated intravascular coagulopathy has been reported in 25% of women who retain a dead fetus for more than 4 weeks.¹²
 - If induction is delayed for more than 48 hours, woman should have testing for disseminated coagulation failure twice a week.
 - For induction of labor, PGE2 and oxytocin can be used.
 - The use of misoprostol is off label (Appendix B).

4.2.8. Previous Cesarean Section

- The essential prerequisite for induction of labor in a woman with previous caesarean is the availability of facilities for maternal-fetal monitoring and emergency caesarean section.
- A detailed review of patient clinical profile should be done to ensure the eligibility for a vaginal delivery.
- Counseling should be done conveying the chances of vaginal delivery and the risk of uterine rupture with the use of various agents for induction of labor.
- In general, at least 60% of the inductions result in a vaginal delivery in women with previous caesareans¹³ and the number may be much higher in women with a favorable cervix and a prior vaginal delivery.
- Although the chances of uterine rupture are increased with induction of labor, the absolute risk is still reasonably low.
- In women with favorable cervix , amniotomy followed by oxytocin infusion is advisable
- In women with unfavorable cervix, use of mechanical methods like transcervical Foley catheter is the preferred method for induction of labor, followed by amniotomy and oxytocin.
- The use of prostaglandins is contraindicated for use in women with a scarred uterus because of a high risk of uterine rupture.

4.2.9. Preterm Prelabor Rupture of Membranes

- If preterm prelabor rupture of membranes occurs after 34 weeks, the plan for induction should be made after discussing with the women the risks of sepsis to the woman and to the baby, complications of preterm birth and availability of neonatal intensive care facilities.
- If preterm prelabor rupture of membranes occurs after the period of viability, induction of labor should not be carried out before 34 weeks, unless there are additional obstetric indications (chorioamnionitis or fetal compromise).
- Antenatal steroids and antibiotics should be administered as appropriate.

- Magnesium sulphate for neuroprotection should be considered if delivery happens before 32 weeks.
- Tocolysis is not recommended as it does not significantly improve outcome. It may be given to delay delivery till the effects of steroids occur.
- 4.3. Contraindications of Induction of labor
 - Induction should be avoided if there are any contraindications to labour or vaginal delivery which can be because of :
 - Placenta or vasa previa
 - Umbilical cord presentation
 - Transverse lie or footling breech
 - Prior classical or inverted T uterine incision
 - Significant prior uterine surgery (e.g. full thickness myomectomy, transfundal uterine surgery)
 - Active genital herpes
 - Pelvic structural deformities associated with cephalopelvic disproportion
 - Invasive cervical carcinoma
 - Previous uterine rupture
 - Previous pelvic surgeries like vesicovaginal fistula/rectovaginal fistula/pelvic floor repair (third or fourth degree perineal tears repair), trachelorrhaphy.

5. <u>Methods of cervical ripening and induction of labor in unfavorable</u> <u>cervix</u>

5.1. **Prostaglandins E2**

• Prostaglandins (PG) E2 (dinoprostone) is available in two forms in India for cervical ripening.

- i) Dinoprostone gel (3 g gel/0.5 mg dinoprostone) is placed inside the cervix, but not above the internal os. The application can be repeated after 6-8 hours, not to exceed 3 doses in 24 hours.
- ii) Dinoprostone vaginal pessary (10 mg embedded in a mesh) is placed in the posterior fornix of the vagina for 24 hours.
- PGE2 has an associated risk of uterine tachysystole and higher rates of chorioamnionitis in the setting of ruptured membranes.
- The use of vaginal and intracervical dinoprostone may not be very effective in women with ruptured membranes.
- Both forms are found to have equal efficacy. Both result in a significantly lower cesarean delivery rate and an increased proportion of vaginal deliveries within 24 hours.^{14,15}
- Vaginal preparations are easier to administer than the intracervical preparation.

5.1.1 Intracervical Dinoprostone gel

- The gel should be stored in a refrigerator at '2 to 8°C'.
- The application (3 g gel/0.5 mg dinoprostone) can be repeated in 6 hours, not to exceed 3 doses in 24 hours.
- Ambulation of the patient is allowed after 30 minutes of insertion
- Temperature, pulse, respiratory rate, blood pressure, uterine activity and vaginal bleeding should are examined immediately after insertion then hourly for 4 6 hours.
- If necessary oxytocin for augmentation of labor is started only 6 hours after the last dose.

5.1.2. Dinoprostone vaginal pessary

- The pessary should be stored in a freezer at '-10 to -25°C'.
- The dinoprostone pessary (10 mg), placed transversely in posterior fornix, releases PGE2 at a constant rate of approximately 0.3 mg/hour over the 24-hour dosing period.
- Ambulation of the patient is allowed after 30 minutes of insertion
- Monitoring at frequent intervals for uterine contractions and fetal condition should begin after administration of the drug.

- It is removed at the end of the 24-hour dosing period OR once the onset of active labor is achieved whichever is earlier.
- Rupture of membranes after the insertion of pessary, does not necessitate removal of the pessary.
- It can be easily administered and quickly removed in case of uterine hyperstimulation.
- Oxytocin for augmentation of labor, if necessary is started 30 minutes after removal of the pessary.

5.1.3. Prostaglandin PGE1 (Misoprostol)

• Misoprostol is not yet approved for induction of labor by Drug Controller General of India.

5.2. Balloon Devices: Foley Catheter

- Transcervical Foley catheter is safe, cheap, easy to store and preferred in cases of scarred uterus and unfavorable cervix provided there are no signs of infection.
- It causes less uterine hyperstimulation as compared to prostaglandins but does not reduce cesarean rates.^{16,17}
- Balloon catheter and vaginal prostaglandins may have similar effectiveness.
- A small degree of traction on the catheter by taping it to the inside of the leg.
- The catheter is left in place until it falls out spontaneously or for 24 hours.
- Foley catheter followed by oxytocin infusion is recommended as an alternative method for induction of labor.
- It is contraindicated in placenta previa and should be avoided in women with ruptured membranes and undiagnosed vaginal bleeding.

5.3. Low dose oxytocin infusion

• The low-dose regimen for cervical ripening begins with 1 to 2 mU/min, increased incrementally by 1 to 4 mU at every 30 minute intervals. It can be used in patients where prostaglandins are not available.

- Infusions pump, wherever available should be used.
- Oxytocin should be stored in refrigerator at '2 to 8°C'.

5.4. Membranes Sweeping

- It solely improves rate of entering spontaneous labor. It does not improve maternal or neonatal outcome improvements.¹⁸
- It is suitable for non-urgent indications for term pregnancy termination because interval between sweeping membranes and initiation of labor can be longer than other methods of cervical ripening.
- It can be done simultaneously at the time of assessing the cervix after informing the patient.
- It can be repeated if labor does not start spontaneously.

5.5. Other Methods

• Hygroscopic dilators (laminaria tents), mifepristone, nitric oxide donors, relaxin, hyaluronidase or breast nipple stimulation are presently not recommended for induction of labor in view of the availability of low quality evidence for their use.

6. Induction of Labor with a favorable cervix

6.1. Oxytocin

- Intravenous oxytocin is the most commonly used method of induction for women with a favorable cervix (Modified Bishop Score >6).
- Oxytocin can be used alone, in combination with amniotomy, or following cervical ripening. It can be used for induction as well as augmentation of labor.

- It should be used with caution in women with previous cesarean delivery and grand multiparous women because of the risk of uterine rupture.
- Intravenous oxytocin and amniotomy is most likely to achieve vaginal delivery in 24 hours.
- Oxytocin should be administered intravenously as a infusion to allow continuous, precise control of the dose administered.
- The low-dose regimen begins with 1 to 2 mU/min, increased incrementally by 1 to 2 mU at every 30 minute intervals.
- The high-dose regimen starts with 4 to 6 mU/min with dose increments of 4 to 6 mU/min every 15 to 30 minutes.
- High dose protocols reduce the induction delivery interval and are associated with higher rates of tachysystole than low dose protocols. Maternal and fetal complication rates are similar with both protocols.
- Infusion of oxytocin should be documented in mU/minute or drops/min with the dilution being mentioned.
- The oxytocin infusion can be increased until labor progress is normal or uterine activity reaches 200 to 250 Montevideo units (ie, good regular uterine contractions, each lasting for 40-45 seconds duration and minimum of 3 contractions in 10 minutes).
- Upper limit of the oxytocin infusion during labor with a live fetus in the third trimester is 40 mU/minute.
- Monitoring for infusion rate of oxytocin and uterine contractions and fetal heart rate by continuous cardiotocography is preferable.
- In facilities where cardiotocography is not available, fetal monitoring should be done by intermittent auscultation every 15 min in first stage and 5 minutes in second stage.
- Blood pressure and pulse should be assessed every hour. Intake and output should be assessed every 4 hours. The frequency, intensity and duration of uterine contractions should be assessed every 30 minutes and with each incremental increase in oxytocin.
- Cervical status should be assessed prior to administration of oxytocin and repeated after at least four hours of moderate contractions.
- A vaginal examination may also be repeated in situation of a nonreassuring fetal heart pattern to rule out the presence of meconium, abruption or a cord accident.
- Close watch is kept for clinical features of maternal hyponatremia, uterine hyperstimulation and uterine rupture.

Preparation of oxytocin infusion & dose calculation

- Oxytocin is administered as dilute solution by intravenous route. Isotonic solutions such as ringer lactate or normal saline are preferred over dextrose solution for fluid selection to minimize the risk of electrolyte imbalance (eg. hyponatremia) and volume overload.
- Each ampoule (1 ml) of oxytocin contains 5 units.
- Two ml of oxytocin (two ampoules) is taken in a 10 ml syringe and diluted with 8 ml of normal saline. It makes 10 ml of saline solution having 10 units of oxytocin. One ml of this saline solution contains 1unit of oxytocin. To make a bottle of 2 units of oxytocin infusion, 2 ml of this solution is added in 500 ml of Ringer Lactate.

Units of Oxytocin added in 500 ml of Ringer Lactate	Oxytocin infusion in Drops per minute & equivalent dose in mU/minute (One mI is equal to 16 drops)							
1 Unit	8 Drops	16 Drops	24 Drops	32 Drops	40 Drops	48 Drops	56 Drops	64 Drops
1 Onit		-	-	-	-	-	-	
	1 mU	2 mU	3 mU	4 mU	5 mU	6 mU	7 mU	8 mU
	8	16	24	32	40	48	56	64
2 Units	Drops	Drops	Drops	Drops	Drops	Drops	Drops	Drops
	2 mU	4 mU	6 mU	8 mU	10mU	12mU	14mU	16mU

The dose of oxytocin in drops/minute and mU/minute is shown below:-

6.2. Amniotomy

- A simple and effective method when the membranes are accessible and the cervix is favorable. It creates a commitment to delivery.
- Flow of amniotic fluid should be controlled with vaginal fingers. The liquor should be drained slowly because sudden decompression of uterus can lead to placenta abruption.

- Care should be taken when amniotomy is done in unengaged presentation because there is a risk of cord prolapse. The vaginal fingers should not be removed until presenting part rests against the cervix.
- Amount and color (meconium or blood stained) of the liquor is observed.
- Monitoring of fetal heart should be done during and after the procedure
- Amniotomy alone is not recommended for induction of labor.
- Oxytocin should be commenced immediately after amniotomy or after two hours depending on the intensity of uterine contractions.

7. Monitoring during induction of labor

- Maternal and fetal monitoring is a must.
- Before induction of labor, a nonstress test is recommended.
- Intermittent maternal and fetal (fetal heart rate) monitoring should be done every hour initially.
- Continuous electronic/more frequent intermittent fetal heart rate monitoring should be started in active labor
- Progress of labor is monitored using partogram.
- Close watch is kept for temperature, pulse rate, blood pressure, fetal heart pattern, vaginal bleeding, uterine hyperstimulation, uterine rupture and scar dehiscence in women with previous cesarean delivery.

8. Pain relief

- Women should be informed of the availability of pain relief options.
- Women should be provided pain relief appropriate for them after counseling. This can range from simple analgesics to epidural analgesia.
- Women should be encouraged to use breathing and relaxation techniques in labor.
- There is no need to wait for labor analgesia arbitrarily till the cervical dilation has reached 4–5 cm.^{19,20}
- If given early in labor, it does not affect the progress of labor.²¹
- Pethidine and opioid analgesia can be used for short term pain relief, preferably in early labor.

• If regional analgesia is planned, the woman should be informed about the risks and benefits and the implications for her in labor.

9. <u>Complications of Induction of Labor</u>

9.1. Uterine Hyperstimulation

- First step is to discontinue oxytocin infusion or withdraw dinoprostone vaginal pessary.
- Tocolytics preferably betamimetics are recommended for women with uterine hyperstimulation during induction of labour. Contraindications of betamimetics especially cardiac disease should be kept in mind.
- If associated with abnormal fetal heart pattern, delivery should be accomplished.

9.2. Uterine Rupture

- Rupture can occur in both scarred and unscarred uterus and is associated with multiparity, malpresentation, unsupervised or aggressive use of uterotonics.
- Woman with previous cesarean undergoing induction of labor should be counseled.
- A close watch is kept on maternal signs and monitoring is done for fetal heart rate abnormality.
- In suspected case of uterine rupture or scar dehiscence, delivery is by emergency cesarean section.

9.3. Failed Induction

• Failed induction of labor must be differentiated from failure of labor progress.(Appendix)

- Maternal and fetal wellbeing should be reassessed.
- Subsequent management options are:
 - i. Another attempt to induce labor with a different method can be considered after discussion with the patient but it depends on the nature and urgency of the clinical situation (indication of the induction of labor)
 - ii. Cesarean delivery.

10. Counseling of women planned for induction of labor

- The information should be provided to the patient and her partner before the process of induction is planned (Appendix C)
- The woman should be given enough time to discuss and ask any questions.
- It should include the following:
 - i. Indication of induction of labor
 - ii. Risks vs benefit of induction of labor
 - iii. Method of induction of labor and its advantages and disadvantages
 - iv. Any alternatives available
 - v. Use of electronic equipment for monitoring
 - vi. Expected duration of labor
 - vii. Support system available during labor
 - viii. Pain relief
 - ix. Option available if induction of labor fails

11. Maternal request for induction of labor

• The maternal request for induction of labor at term for nonmedical reasons should not be entertained as it is an unnecessary intervention except under exceptional circumstances.

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Definitions

Induction of labor: Artificial initiation of contractions in a pregnant woman who is not in labor to help her achieve a vaginal birth within 24 to 48 hours.

Successful induction: A vaginal delivery within 24 to 48 hours of induction of labor.

Elective induction: Induction of labor in the absence of acceptable fetal or maternal indications.

Cervical ripening: Use of pharmacological or other methods to soften, efface, or dilate the cervix to increase the likelihood of a vaginal delivery.

Tachysystole: More than 5 uterine contractions in 10 minute period averaged over 30 minutes. This is further subdivided into two categories, one with and one without fetal heart rate changes.

Hypertonus: Excessive uterine contractions lasting more than 120 seconds without fetal heart rate changes.

Hyperstimulation: Excessive uterine contractions (tachysystole or hypertonus) as a result of induction of labor with nonreassuring fetal heart rate changes.

Amniotomy: Artificial rupture of the membranes to initiate or speed up labor.

Analgesia: Pain relief without loss of consciousness.

Failed induction: Failure to achieve regular uterine contractions (every 3 minutes) after one cycle of completion of cervical ripening consisting of a) Insertion of three intracervical PGE2 gel (3gm) at 6-hourly intervals, and 12-24 hours of oxytocin administration after rupture of membranes, if feasible, or b) One PGE2 pessary (10 mg) within 24 hours

Appendix B

MISOPROSTOL-ONLY RECOMMENDED REGIMENS 2017 <13 weeks' gestation >26 weeks' gestation8 13-26 weeks' gestation Postpartum use Postpartum hemorrhage (PPH) prophylaxis^{i,2,10} Pregnancy termination^{a,b,1} Pregnancy termination^{1,5,6} Pregnancy termination^{1,5,9} 600µg po (x1) 13-24 weeks: 400µg pv*/sl/bucc every 3 hours^{a,e} 27-28 weeks: 200µg pv*/sl/bucc every 4 hours^{f,g} 800µg sl every 3 hours or pv*/bucc every 3-12 hours (2-3 doses) 25-26 weeks: 200µg pv*/sl/bucc every 4 hours^f >28 weeks: 100µg pv*/sl/bucc every 6 hours or PPH secondary prevention j.11 (approx. ≥350ml blood loss) 800µg sl (x1) Fetal death^{2,9} Missed abortion^{c,2} Fetal death^{f,g,1,5,6} 27-28 weeks: 100µg pv*/sl/bucc every 4 hours1 PPH treatment^{k,2,10} 800µg pv* every 3 hours (x2) 200µg pv*/sl/bucc every 4-6 hours >28 weeks: 25µg pv* every 6 hours 800µg sl (x1) or 600µg sl every 3 hours (x2) or 25µg po every 2 hoursh Incomplete abortion^{a,2,3,4} Induction of labor^{h,2,9} 600µg po (x1) Inevitable abortion^{9,2,3,5,6,7} 25µg pv* every 6 hours <u>or</u> 400µg sl (x1) 200µg pv*/sl/bucc every 6 hours or 25µg po every 2 hours or 400-800µg pv* (x1) Cervical preparation for surgical abortion^a Cervical preparation for surgical abortion^d 13-19 weeks: 400µg pv 3-4 hours before procedure 400µg sl 1 hour before procedure >19 weeks: needs to be combined or pv* 3 hours before procedure with other modalities References a WHO Clinical practice handbook for safe abortion. 2014 by on Herzten et al. Lancet. 2007. Sheldon et al. 2016 FIAPAC abstract c Gemzell-Danielsson et al. IJG0. 2007 d Säv et al. Human Reproduction, 2015, Kapp et al. Cochrane Database of Systematic Reviews, 2010 Perritt et al. Contraception, 2013 g Mark et al. LIGO, 2015 h WHO recommendations for induction of labour, 2011 i FIGO Subies. Prevention of PPH with misoprostol, 2012 j Raghavan et al. BJOG, 2015 k FIGO Guidelines. Treatment of PPH with misoprostol, 2012 Route of Administration pv – vaginal administration sl – sublingual (under the tongue) Notes 1 If mitpristone is available (preferable), follow the regimen prescribed for mitpristone + misoprostol^a 2 Included in the WHO Model List of Essential Medicines 3 For incomplete/inevitable abortion women should be treated based on their uterine size rather than last menstrual period (LMP) 4 Leave to take effect over 1-2 weeks unless excessive bleding or infection 5 An additional dose can be offered if the placenta has not been expelled 30 minutes after fetal expulsion 6 Several studies limited dosing to 5 times, most women have complete explicits in before use of 5 doses, but other studies continued beyond 5 and achieved a higher total success rate with no safety issues 1 Including ruptured membranes where delivery indicated 8 Follow local protocol if previous cesarean or transmural uterine scar 9 If only 200pg tablets are available, smaller doses can be made by dissolving in water (see www.misoprostol.org) 10 Where exprision is not available or storage conditions are inadequate 11 Option for community based programs po – orai bucc – buccal (in the cheek) Avoid pv (vaginal route) if bleedir nd/or signs of infection Rectal route is not included as a recommended route because the pharmacokinetic profile is not associated with the best efficacy

Source: https://www.figo.org

Appendix C

Good Clinical Practice Guidelines FOGSI- ICOG 2018 Induction of Labor: GCPR

Patient information sheet

Name of patient: _____w/o: _____

ID No._____

This information sheet provides you with the details of the procedure. You are requested to go through the document carefully. In case of any query/ doubt, you should talk to your doctor for further explanation. After reading and understanding the document, you will need to sign the document.

What does Induction of Labor mean?

Induction of labor is a process where the uterine contractions are artificially initiated to start the procedure of childbirth to achieve a vaginal delivery

Why is it needed?

Induction of labor may be offered for various reasons where your doctor feels that delivering the baby would be more beneficial for the mother and child than continuing the pregnancy.

In your case, induction of labor is being done for:

Diagnosis: _____

Indication:_____

What are the success rates?

Induction of labor does not necessarily mean that the patient will have vaginal delivery. Success of induction depends upon many factors including a previous normal delivery, condition of the cervix and position of the head of the baby. If unsuccessful, a reevaluation would be done to decide if a further trial can be given or it is better to go for a cesarean section.

Preparation:

Induction of labor is done after admission to the hospital where both the mother and the baby can be monitored.

Complications:

- Failed induction: Induction of labor may not result in the initiation of the labor or the labor might get initiated but does not result in vaginal birth and might need cesarean delivery.
- **Hyperstimulation :** Prostaglandins and oxytocin may lead to hyperstimulation of uterus (excessive uterine contractions)
- Nausea, vomiting and diarrhea: Some women tend to have gastrointestinal side effects with the prostaglandins.
- Uterine Rupture: There is an occasional chance of uterine rupture, although very rare, especially in women who have had previous uterine surgery or cesarean section.
- **Infection:** Mechanical methods are associated with the risk of maternal infection. Women who undergo induction of labor after the membranes have ruptured are at increased risk of infection.
- **Cord accident :** Amniotomy has be associated with the risk of cord prolapse and need for emergency Caesarean section
- Fetal heart rate abnormalities: Induction of labor can be associated with fetal heart rate changes and need for emergency caesarean section.

Consent Form

I (<u>Name of the patient</u>) wife of Sh. (<u>Name of the Husband</u>)

ID No: _____

have read the above document and have understood the need for the proposed procedure. The indication, possible complications and need for further procedure in case of failure of the induction of labor have been explained to us by our doctor <u>(Name of the doctor).</u> I have been given the opportunity to ask questions and clarify my doubts.

I hearby give my full consent to undergo the procedure. I understand the risk involved.

Procedure (specify the method of induction of labor):

Indication:

Time and date:

Place:

Name & signature of the patient

Name and signature of the attendant

Name & signature of the doctor

Name & signature of the witness

Appendix D

Good Clinical Practice Guidelines FOGSI- ICOG 2018 Induction of Labor: GCPR

Check List

Method used for the patient:				
Name of patient:	w/o:			
ID No	; Date:	; Time:		
• Age (Date of birth):	•			
 LMP (last menstrual period) : Expected date of delivery : 				
Corrected Expected date of deliv				
• Gestational age by LMP :				
• Gestational age by first ultrasour	nd (done before 20 w	eeks of gestation) :		
• History of any allergies, medical	l condition, special no	eed: Yes/ No		
• High Risk Review: Yes/No				
Indication for Induction Reviewe	ed : Yes/ No			
• Planned Method of Induction: Ye	es/ No			
• Consent form signed by the patie	ent and her attendant :	Yes/ No		

- Fetal Heart Rate Assessment : Yes/ No
- Pre-Induction Modified Bishop's Score:

Score	Cervical dilatation (cm)	Position of cervix	Cervical consistency	Cervical Length (cm)	Station
0	Closed	Posterior	Firm	>4	-3
1	1-2	Central	Medium	3-4	-2
2	3-4	Anterior	Soft	1-2	-1,0
3	5-6	-	-	<1	+1.+2

Total Score of the patient: _____; (Favorable Score: 6-13 & Unfavorable Score: 0-5)

- Signature of the Doctor:______; Date and time:______;
- Name of the Doctor:______