Principles, Protocols & Practices

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Newsletter Issue-1

Revisiting Induction of Labour

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CHAIRPERSONS MESSAGE...

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Dear Friends,

Fellows of ICOG and fellow FOGSIANS,

A very happy new year !

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 across the globe.

Induction of labour is one such 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. 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. This edition of the ICOG newsletter has been therefore dedicated to this important topic of “Protocols in Induction of labour” with the pros and cons, ifs and buts of IOL in every possible Obstetric Scenario covered over 8 topics by an erudite team. A good induction protocol will bring about a favourable outcome for everyone involved in child birth including obstetrician!

I hope the readers will enjoy reading the recent advancements in IOL and realise that this is a simple yet powerful technique in Obstetrics–most useful when used 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 practice applied to our procedures like IOL will help to reduce the burden of not only “unindicated” CS deliveries but also the maternal morbidity and mortality rates.

Happy reading!

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Dear Friends,

Season's Greetings and Wishing all my dear FOGSIANS a very happy new year 2018. As always, the advent of new year brings about new hopes, new horizons and renewed efforts and rededication towards our goals.

FOGSI and its academic wing ICOG have been instrumental in spreading knowledge, keeping the fraternity abreast the ever-expanding frontiers of our field and it gives me immense pleasure to say that the Team ICOG under the dynamic leadership of Dr. Shantha Kumari, Chairperson ICOG have spared no effort this year and brought out a very interesting, educative line up of topics with the tag line of Principles, Protocols and Practices. The first newsletter deals with the ever-enigmatic issue of Induction of labour in Indian women. IOL is the most common intervention done by the obstetricians all over and it poses a challenge with its where, when, and how in both low risk and high-risk populations, especially in this litigation ridden days of practice and amidst the serious concerns about the high cesarean rates too.

The present issue focuses extensively on all the aspects of IOL and hopefully will bring conclusions and consensus to form the ground work for development of GCPR guidelines /ICOG protocols for IOL and reducing Cesarean Rates in the nearest future.

I wish the Team all the very best in its untiring endeavors and all of you a happy and stimulating reading

Editor...

Dr. Ashok Kumar
MD, PhD
Director Professor,
Department of Obstetrics and Gynecology,
Maulana Azad Medical College & Associated Lok nayak Hospital, New Delhi.
ICOG Governing Council Member 2018–2020

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Dr. M. Krishna Kumari
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Dr. Niharika Dhiman
MS
Assistant Professor,
Department of Obstetrics and Gynecology,
Maulana Azad Medical College & Associated Lok Nayak Hospital, New Delhi.

Secretarys Message...

SECRETARYS MESSAGE...

Dr. Parag Biniwale

Secretary ICOG

Dear Friends,

ICOG, the academic wing of FOGSI has been proactively updating its members regarding the nuances in the field of Obstetrics & Gynaecology.

This year, Team ICOG 2018 under the leadership of President Dr. Jaideep Malhotra & Chairperson Dr. S. Shanthakumari shall bring ICOG campuses to you. The purpose of ICOG campus is to update members of FOGSI & ICOG current practices & latest recommendations in Obstetrics & Gynaeccology.

Labour has been an area close to every Obstetrician's heart. With changing scenario of maternal & foetal monitoring, induction of labour is gaining a lot of importance. It is imperative that obstetrician update themselves with the latest information in order to avoid overuse of caesarean section.

Induction of labour has seen a change in practise from castor oil to sweeping of membranes to amniotomy & use of prostaglandins in gel & tablet form. The new entrant prostaglandin insert has got its own place in induction of labour.

A lot needs to be discussed & understood with dos & dont's of labour inductions, counselling the pregnant woman regarding advantages & disadvantages and of course problems associated with induction & management of failed induction.

Our team will strive hard to give you best possible information on various subjects of Obstetrics & Gynaecology periodically. We assure you that these campuses will be of great help to you in your busy day to day schedule and will be ready reckoners available to you on your desk or desktop reminding you "to give best possible care to the pregnant woman & the unborn"

Happy reading!

From Editors Pen...

FROM EDITORS PEN...

Dr. Ashok Kumar

MD, PhD

FAMS, FICOG, FICMCH

Director Professor, Department of Obstetrics and Gynecology

Maulana Azad Medical College & Lok Nayak Hospital.

Dear Friends,

Very warm greetings to all!

The rising rate of caesarean section worldwide has put into question the need for one to give a thought. We need to clearly define why, when and how to induce labour to achieve the optimum maternal and foetal outcome. This month's issue is dedicated to **"How to reduce caesarean rates; induction of labour for vaginal deliveries".**

Traditionally term pregnancy has been defined as delivery between 37 to 42 weeks. This nomenclature acknowledged that foetal maturation is a continuum, yet the use of the label "term" for pregnancies spanning 37 weeks 0 days through 41 weeks 6 days' gestation remained unchanged. Maternal and foetal outcome across the current spectrum of term is variable. Recent recommendations have redefined the nomenclature of term pregnancy and have suggested terminating pregnancy at full term (39–41 weeks). Pregnancies going beyond their expected date of delivery (EDD) require maternal and foetal surveillance as adverse outcomes have been associated with pregnancies crossing their EDD.

The timing of induction of labour in high risk and low risk pregnancy has been addressed separately in this issue. Induction of labour if timed appropriately can be the only intervention required during labour. Various methods of induction are available and choosing the most suitable one will be reflected as a favourable outcome. Decision of induction of labour should involve voluntary participation of the mother with a written informed consent regarding the benefits and risks associated with the process of induction.

There are various level of studies that have analysed practices in labour room which were being followed traditionally over so many years, we have highlighted the existing level of evidence for such procedures such as restrictive use of episiotomy, role of electronic foetal monitoring in labour, companionship during labour.

Clinical practice patterns during labour may vary according to the institutional protocols being followed in various centres, the decision for need of caesarean delivery thus needs to be monitored to bring down the rising caesarean section rate. Simple interventions such as standardised foetal heart rate monitoring, redefining the duration of labour, delivery support and regular audit of caesarean deliveries can bring the rate of primary caesarean section rate. Lastly we bring out the perception and experience of Indian women undergoing labour induction.

Dr. Ashok Kumar & Editorial Team

Index...

1. Redefining Term Pregnancy

Dr. Niharika Dhiman, Assistant Professor,
Dr. Ashok Kumar, Director Professor
Department of Obstetrics and Gynecology,
Maulana Azad Medical College & Associated Hospitals, New Delhi, India.

Gestation in a singleton pregnancy lasts an average of 280 days or 40 weeks. *The International Classification of Diseases* defines term pregnancy as delivery between 37 weeks 0 days and 41 weeks 6 days.[1] Previously it was assumed that the maternal and foetal outcome throughout these five weeks is uniform. A study by Reddy etal demonstrated that the period of term gestation (37–41 weeks of gestation) is more heterogeneous in mortality risk than previously recognized. Although births at 37 and 38 completed weeks are considered term, these early term births are consistently associated with significantly higher neonatal and infant mortality rates when compared to births at 39 through 41 weeks of gestation.[2] In fact, the frequency of adverse outcomes is U-shaped, with the nadir around 39 weeks 0 days through 40 weeks 6 days' gestation.[3]

Research shows that babies born before 39 weeks and after 41 weeks compared to babies born between 39–41 weeks are:

i. At greater risk of being admitted into the neonatal intensive care unit.[4]

ii. At a 20% greater risk of complications, including: breathing, feeding, and temperature problems; sepsis; and cerebral palsy.[4,5]

iii. 5% more likely to have an intellectual or developmental disability.[4,5]

iv. At a 50% greater risk for death within the first year of life.

In the WHO multi-country survey on maternal and newborn health, gestational age at delivery averaged between 38.5 and 38.9 weeks for all countries; risks were elevated at 37 weeks 0 days through 38 weeks 6 days compared with 39 weeks 0 days through 40 weeks 6 days for early neonatal death (adjusted odds ratio, 1.21 [95% CI, 1.03-1.41]) and fresh (non-macerated) stillbirth (adjusted odds ratio, 1.31 [95% CI, 1.09-1.58]).[6]

In December 2012, a meeting of the Defining "Term" Pregnancy Workgroup was convened by the National Institute of Child Health and Human Development, the American Congress of Obstetricians and Gynecologists, the American Academy of Pediatrics, the Society for Maternal-Foetal Medicine, the March of Dimes, and the World Health Organization to refine the definition of term pregnancy. The workgroup[3] redefined term pregnancy as:

- **Early term:** 37 weeks through 38 weeks and 6 days
- **Full term:** 39 weeks through 40 weeks and 6 days
- **Late term:** 41 weeks through 41 weeks and 6 days
- **Post-term:** 42 weeks and beyond

This new classification has implications for counseling, management, and research. As already mentioned the known excess morbidity and mortality risk of delivery prior to 39 weeks and beyond 41 weeks, it is essential not to undertake non-medically indicated delivery before 39 weeks. However, for pregnancies between 37 weeks 0 days and 38 weeks 6 days gestation in which delivery is medically indicated or the onset of labour or rupture of membranes is spontaneous, delivery in the early-term period is appropriate.

The decision for termination of pregnancy depends upon accurate dating. For women with certain menstrual dates, dating should be done by last menstrual period (LMP) and reconfirmed along with the anatomical survey scan done at 18–20 weeks. The difference should be within 10 days to confirm LMP dating, and the estimated due date should be changed only if the calculated gestational age difference is 11 days or greater. For women with uncertain dates or an unknown LMP a first trimester scan at 11–13 weeks is recommended for dating. A crown rump length corresponding to a gestational age within 5 days confirms the estimated due date based on menstrual dates. However, if the difference between menstrual and ultrasound dates is 6 days or greater dating should be done by first trimester scan. Women who have conceived by artificial reproductive technique dating should be done from the day of embryo transfer.[3]

Thus, redefining of term pregnancy and its ramification into early term, full term and late term will help in decreasing maternal and neonatal morbidity and mortality. Non-medically indicated deliveries before 39 weeks is inappropriate and uncomplicated pregnancies should be allowed to deliver spontaneously at full term.

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2. Induction of labour in low risk term pregnant women: controversies about timing?...

Dr. C. P. Vijayan
Professor and Head of Obstetrics and Gynaecology
Government Medical College Hospital, Kottayam, Kerala.

In a pregnant woman the word 'term' is not a single entity. It is divided in to four categories. Early term, Full term, late term and post term.[1,5]

Early term: 37 0/7 weeks through 38 6/7 weeks

Full Term: 39 0/7 weeks through 40 6/7 weeks

Late term: 41 0/7 weeks through 41 6/7 weeks

Post term: 42 0/7 weeks and beyond

It is estimated that when no induction methods are adopted, 50% of women will deliver spontaneously in early term (37–39 weeks), 20% will deliver by Full term (39–41 weeks), 10% will deliver in late term and 7% will go for post term. These statistical estimates are when the proportion of spontaneous pre-term labour is 12%.

At what period of gestation the benefits of delivery are greater than the benefits of continuation of pregnancy? Probably at this point, the needs of the mother and the needs of the baby are conflicting each other. One consideration that is traditionally prevailing and proved by different studies is the concern that labour induction may increase the risk for caesarean sections, particularly among nulliparous women.[6] If the pregnancy is going for post term period, liquor volume may get reduced, placental insufficiency may set in, more of meconium staining of liquor, foetal heart rate variabilities, low Apgar score at birth and more admissions in to the NICU.[7] These factors may also in turn increase the caesarean section rate. What is the gestational period to strike a balance and minimise the need for caesarean section and foetal problems?

All observational studies published are comparing women who are undergoing induction at a particular gestational period with those women who had spontaneous labour.[5,8] The results of those studies may not be useful to select a time for induction of labour. This strategy will answer whether to do induction at that gestational period or to wait for spontaneous labour. How long to wait for spontaneous labour is not being answered by this strategy. For that purpose, there should be comparison between induction of labour done at different periods of gestation. For example, induction done at 40 weeks and at 42 weeks.

Induction of labour is not free from risk and different professional bodies are recommending induction of labour at different periods of gestation incorporating the available research evidences and the consensus between experts. WHO recommends at 41 weeks, NICE and RCOG Guidelines at 42 weeks, ACOG at 41 to 42 weeks and SOGC 41 weeks and beyond. WHO is admitting that this is a weak recommendation and is based on low quality evidences. FIGO is also upholding WHO recommendations. For all these decisions, a precise knowledge about the gestational age is absolutely necessary. Cycle duration, frequency, regularity, date of last menstrual period and first trimester dating scan are all important for this purpose.

Racial discrepancies exist in the behaviour of babies at term. It is reported that black race babies are getting mature earlier (by 39 weeks) and after 40 weeks, reduction in liquor volume and meconium staining are more. So, when we consider induction for black race babies, it is advisable to go for induction before 40 weeks.[2]

What about Indian babies? We are not having large trials among Indian women for bringing out optimum period for induction. The maturation of Indian babies may be different from that of Caucasian and black babies. We need large trials among Indian low risk pregnant women. We require comparative studies between groups of women getting induced at various period of gestations.

What is the option till the results of such studies are going to be published? We are free to follow the guidelines of any professional body. WHO guideline is most appropriate as it reflects a global view. WHO is stating that their recommendation is a weak one and not based on strong research evidences.[4] There is chance that Asian babies may be closer to black rather than Caucasians. So, it may not be very wise to go post term in Indian women. If this view is upheld low risk pregnancy has to be terminated within 40 weeks + 7 days. It does not mean that until 287 days of gestation are reached, we need to be idle. If at 40 weeks, the cervix is remaining long, uneffaced and / or thick, cervical priming should be done. Priming of the cervix and Induction of labour are to be dealt separately. If the cervix is well primed before Induction of labour, failure of induction are reduced. Mechanical methods and intracervical PGE2 gel are the methods for cervical ripening. It may take two or three days for the cervical ripening. After priming the cervix, if induction is started by oral PGE1, oxytocin, membrane sweeping or artificial rupture of membranes the success is more assured and the woman will be delivered by 40 weeks and 7 days. This prolonged method need special reference during antenatal classes. This will help to avoid fear and apprehension in primigravida. There is always a need for antenatal classes to pregnant women and their immediate relatives by the care giver himself/herself. The classes by the nursing students or nurses are not to replace the classes by the caring obstetrician. There are institutions where these classes are being taken at two levels. There is no harm in increasing the number and levels for these antenatal classes. A visit to labour suits and demonstration of instruments used to deliver babies are also welcome.

A general consensus about the failure of induction is also required for uniformity. If there are regular contractions and cervical changes fail to occur by 12–18 hours or if contractions are not generated after trying for 24 hours it can be considered as failure. This point also should be informed to the woman before starting the priming induction process. Patient should be allowed inside the labour room only in active labour.

A consensus meeting of senior consultants and teachers in Obstetrics of South India held for two days discussed the timing of induction of low risk pregnancies in detail (18th and 19th of November 2017). Majority opined that meconium staining and reduction in volume of liquor are more among our women even after 39 weeks. This view is also shared by some American experts as well. There are some experts in USA who are supporting the policy of starting cervical ripening-labour induction process at 39 weeks of gestation. It should be a planned process after a detailed discussion between the doctor and the pregnant woman including her immediate relatives. The process may last 4–5 days and the point of failure of the process may also be explained to them. Here the difference is that the process which we described at 40 weeks is intended to start at 39 weeks. Studies show that if we go meticulously and follow definite guidelines for the failure of induction, caesarean sections will not be increased. Some studies even show that elective induction at 39 weeks is associated with low caesarean section rates.[9,10]

Errol Raymond Norwitz, chair of the Department of Obstetrics and Gynecology at the Tufts University School of Medicine in Boston emphasized that continuing the pregnancy beyond 39 weeks is riskier than previously believed for the fetus. In addition, risks to the mother associated with routine induction are lower than appreciated. Charles Lockwood, dean of the Morsani College of Medicine at the University of South Florida in Tampa was opposed to the elective induction of labour at 39 weeks. Both of them expressed this opinion in the annual meeting of the American College of Obstetrics and Gynaecology in 2016.

William A Grobman as Principal investigator of a clinical trial (trial number NCT 01990612) for making recommendations about timing of induction of low risk term pregnancies, aims to enrol 6000 women.[3] The results of this study also may not answer all our queries due to reservation about generalisation and likely differences in the behaviour of Indian babies. But let us wait for its result.

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3. When to induce labour in high risk pregnancy

Dr. Muralidhar V. Pai
Professor & Head,
Department of Obstetrics & Gynecology,
Kasturba Medical College, Manipal Academy of Higher Education, Manipal–576104.

Introduction

Induction is indicated when the benefits to either the mother or the fetus or both, outweigh those of continuing the pregnancy. High risk pregnancy is a common indication for induction of labour before due date, in view of maternal and foetal health. When to induce labour depends upon the type of high risk factor and fetomaternal health. In some high risk pregnancies induction is controversial if not contraindicated for example twins, heart disease complicating pregnancy, breech and scarred uterus. This chapter addresses the issues regarding the indications, methods and timing of induction in high risk pregnancies.

High risk factors that indicate induction[1]

1. Prolonged pregnancy
2. Pre-labour rupture of membranes
3. Foetal growth restriction
4. Foetal compromise as a result of placental insufficiency due to any condition
5. Rhesus iso-immunization
6. Medical diseases complicating pregnancy such as hypertension, diabetes and their complications like eclampsia
7. Abruption
8. Oligo / Polyhydramnios
9. Bad obstetric history / unexplained Intra Uterine foetal Death (IUFD) in the past
10. IUFD in current pregnancy

Counseling before induction

Women should be explained the following points before offering induction of labour:

- The reason for induction
- Method and success rate of each method
- Use of one or more methods/change of plan of induction (ARM + Oxytocin after Misoprostol induction)
- Risk and benefits of induction to the mother and baby
- Need of continuous foetal monitoring with cardiotocograph
- Possibility of foetal distress
- Need of emergency LSCS in case of failure to respond or foetal distress

Factors influencing successful induction

- Gestational age (higher the better)
- Bishop score (higher the better)
- Presence of infection (poor outcome)
- Foetal fibronectin (increases just before delivery) – a positive test suggests reduced induction delivery interval
- Ultrasound assessment of cervix (<2 cm is favorable)

Methods of induction[2]

Mechanical methods

- Insertion of Foley catheter through an undilated cervix
- Sweeping/Stripping of membranes
- Artificial rupture of membranes (ARM). This is followed up with oxytocin infusion

Pharmacological methods

- Dinoprostone (PGE2) gel is commonly used for cervical ripening prior to induction. This may also induce labour in some. It is administered in the dose of 0.5 mg. every 8 hours and should not exceed 3 doses in 24 hours.
- Misoprostol (synthetic analogue of PGE1) is the commonly used drug for induction in the dose of 25 mcg administered vaginally or orally every 6 hours and should not exceed 4 doses in 24 hours.

- Oxytocin infusion-The physiological dose is 2 mIU/min. This is achieved by adding 2 IU of oxytocin in 500 mL of Ringer's lactate. This should be preceded by ARM.
- Mifepristone-This antiprogesterone is not used alone for the induction of labour. A single oral tablet of 200 mg is used 24 hours prior to using PGE2 gel / PGE1.

When to induce?

When to deliver is the most important decision that an obstetrician has to make and if the considered mode of delivery is vaginal the timing of induction is of paramount importance.

Prolonged pregnancy

Before allowing the pregnancy to go beyond expected date of delivery (EDD), one must rule out cephalopelvic disproportion and other co-morbidities that necessitate delivery before EDD. The timing of delivery/induction after EDD depends upon the amniotic fluid index (AFI) and biophysical profile. Doppler indices won't be of much help in this situation. Once the AFI and / or BPP goes below 5 it is better to induce labour. Irrespective of foetal status it is prudent to plan induction between 41 0/7 and 41 6/7 week as the placental reserve drastically comes down beyond 42 weeks and the incidence of foetal death will be high.[1]

Pre-labour rupture of membranes (PROM)

The chances of women going into labour following preterm PROM is lesser (40%) compared to term PROM (70%).[2] If a woman has preterm PROM induction of labour should not be carried out before 34 weeks unless there are additional obstetric indications (for example, infection or foetal compromise due to comorbidities). If preterm PROM occurs after 34 weeks one may consider induction of labour after ensuring that steroids have been given for lung maturity.[3] A rescue dose may be considered if it was given 2 weeks prior in the absence of infection. However one should discuss the risk of sepsis, need for caesarean section in the event of foetal distress in labour and NICU care. Term PROM may be either managed expectantly (not more than 12 hours) or induction may be offered.[1]

Induction for foetal indications

If the induction is for foetal reasons such as growth restriction or intrauterine compromise as a result of placental insufficiency then the timing depends upon the results of foetal well-being tests.[4] It is prudent to consider induction when anyone of the following is noted during foetal well-being tests:

- The umbilical artery Doppler shows reversal of flow
- Cerebroplacental (CP) ratio is less than one
- Aortic Isthmus Doppler shows reversal of flow
- Ductus venosus shows reversal of 'a' wave (It is better not to wait till this happens, as this is the last change in the chain of events due to hypoxia and the foetal death will be imminent)
- Biophysiscal profile score is less than 5
- Amniotic Fluid index is less than 5
- Abdominal Circumference is less than 5th percentile

In Rhesus isoimmunisation, it is better to consider induction once the baby is deemed to have achieved lung maturity as it is easier to perform neonatal exchange transfusion than repeated intrauterine transfusions. One should monitor the uterine contractions closely and it is advised to avoid hypertonic contractions to avoid massive fetomaternal bleed.

Induction in medical diseases

Preeclampsia

The definitive management of preeclampsia is delivery and the mode is decided by the urgency to deliver. If vaginal delivery is contemplated it is better to induce when any of the following is noted [5]

- Features of imminent eclampsia such as headache, blurring of vision, epigastric pain, persistent high blood pressure (160/110 mmHg), papilledema, pulmonary edema, serum creatinine >1.1 mg/dL, doubled AST/ALT, platelet <100 thousand/cmm
- Eclampsia
- HELLP syndrome
- Renal / Liver failure
- Abruption
- Completion of 37 weeks of gestation

Diabetes complicating pregnancy

If vaginal delivery is planned it is better to consider induction between 38^0 and 39^6 weeks in well controlled women,[6] as chances of sudden IUD increases after that. If the sugars are not under control, earlier induction should be considered depending on foetal wellbeing tests and NICU availability.

Other medical diseases

In other medical diseases such as anaemia, heart diseases, asthma, usually the need of induction doesn't arise as preterm labour is more common with these conditions. However it is better not to go beyond 40 weeks in these situations and preferably once the underlying condition is optimized for delivery.

Induction is relatively contraindicated with ARM and oxytocin in heart diseases and with PGE1 or 2 in Asthma.

Abruption

Abruption is a progressively deteriorating condition which may end up in fetomaternal mortality or at least morbidity, hence there is no role for expectant management at any gestation in current practice.[2] Many prefer immediate caesarean delivery if the fetus is alive and in distress. If the fetus is not in distress, however one should consider induction of labour with ARM+oxytocin. ARM, in addition to inducing labour, relieves intra uterine pressure and reveals possibility of foetal distress. Abruption is the only situation where immediate induction with ARM+Oxytocin is indicated in IUFD.

Oligo / Polyhydramnios

The timing of delivery in oligohydramnios has already been discussed, ie when AFI is less than 5 (or single vertical pocket is less than 2).[4] Doppler parameters can also be considered for deciding the timing of termination of pregnancy.

The timing of delivery in polyhydraminos depends upon presence of both maternal and foetal distress. If there is evidence of foetal compromise or in the presence of maternal respiratory embarrassment with a mature fetus, it is better to induce by controlled ARM and oxytocin.

Bad obstetric history with unexplained IUFD in the past

Whenever there is a history of unexplained IUFD in the past the consensus is to deliver at least one week prior to the time of previous IUFD.[2] The method of induction depends upon the favorability of the cervix.

Intrauterine death of fetus in current pregnancy

In the event of an intrauterine foetal death, if there is evidence of ruptured membranes, infection or bleeding, immediate induction of labour is the preferred management option1. In the absence of infection and bleeding (coagulopathy) one may choose expectant management, with frequent total count and coagulation studies, upto 2–3 weeks and then consider induction. Oral Mifepristone 200 mg may be given prior to inducing with vaginal Misoprostol. ARM is usually avoided.

Controversial indications

Induction of labour in situations like twins, scarred uterus is controversial if not contraindicated. Those against induction argue that, necessity of induction suggests presence of additional problems (in addition to original high risk factor) hence vaginal delivery is not suitable. However, those who would like to induce labour prefer PGE2 gel to misoprostol in cases of twins and scarred uterus to avoid hyper stimulation of uterus and imminent rupture of uterus.[2] Induction of labour is generally not recommended if the fetus is in the breech presentation.[1]

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4. Methods of induction of labour

Dr. Swati Rathore
Associate Professor,
Christian Medical College
Vellore, Tamil Nadu, India.

Induction of labour (IOL): is defined as an artificial initiation of labour with intent to achieve a vaginal delivery.

It is indicated when benefits to mother or fetus outweighs those of continuing the pregnancy. Success of induction depends on both, correct patient selection and appropriate selection of the induction method. Successful labour induction is clearly related to the state of the cervix. Various methods or techniques are used for pre-labour cervical ripening and to stimulate uterine contractions. Most of the drugs commonly used for IOL are Food and Drug Administration (FDA) approved but a few that are not included in the list of approved medicines for IOL are also used (off label use).

Goals of IOL:

- To achieve vaginal delivery within 24 hours
- To reduce cesarean delivery without compromising maternal and neonatal outcomes
- To reduce perinatal morbidity and mortality.

Good practice points:

- Success of IOL depends on favorability of cervix
- High bishop score prior to IOL predicts greater success rate and increased chances of vaginal delivery.
- Clinician should individualize the patient and select the best available method for IOL.
- Women should be given detailed information regarding advantages and disadvantages of IOL.
- Verbal and written information should be provided.
- Consent should be obtained.
- Possibility of need for re-induction or operative delivery should be discussed.
- Expected length of process and duration of hospital stay should be informed.

Points to be discussed with preinduction counselling

- Discuss indication and need for IOL
- Maternal and foetal benefits vs risk
- Individual preferences and institutional protocols
- Proposed IOL methods, agent and labour stimulation or augmentation
- Type of agent, frequency of dosing, total dosage and route of administration
- Options if IOL is unsuccessful
- If unsuccessful: Re-plan for induction after 24–48 hours or attempt re-induction with other method or combination of methods.

The choice of IOL depends on obstetric and medical risks as well as on emergency and elective indications.

Table 1: Indications of IOL

Obstetrical risks	Maternal medical risks	Labour risks
Post-dated pregnancy	Diabetes mellitus	Intra uterine growth restriction (IUGR)
Pre labour rupture of membranes (PROM)	Chronic hypertension	RH iso-immunization
Gestational hypertension	Chronic kidney disease	Oligohydramnios
Gestational diabetes mellitus	Antiphospholipid syndrome	
Preeclampsia	SLE	
Eclampsia		
Abruption		

Elective IOL: This mode of induction may be planned for:

- Non-medical or social and financial reasons
- On patient demand or on maternal request
- Risk of rapid labour anticipated (history of precipitate labour)
- Patient stays far from hospital

Problems associated with elective IOL

- Increased chances of cesarean delivery
- Increased duration of labour
- Increased need for monitoring (both maternal and foetal)
- Imposes financial burden

Mechanism of action

Cervical ripening is a process that consists of certain biochemical events. These changes further result in cellular and molecular disorganization and remodeling of cervical extracellular matrix. Increase in hyaluronidase and glycosaminases helps in collagen dispersal and solubility which causes cervical softening and ripening. Nitric oxide synthetase, protease activation, increase in IL-8 and cytokines promote vascular permeability, collagen degradation and results in cervical distensibility.[1,2]

Pre IOL assessment checklist

- Confirm maternal history, gestational age and indication for induction.
- Rule out any contraindication for vaginal delivery or IOL
- Assess maternal and foetal wellbeing (Hemoglobin%/ Temperature/Blood Pressure/foetal Heart Rate)
- Perform abdominal examination [confirm foetal presentation, position, lie and engagement]
- Commence cardiotocography [CTG] prior to induction in high risk woman
- For assessment of Bishop's score perform per vaginal examination.

Bishop score [BS]

Bishop's score is a widely used pre induction digital examination for cervical assessment which takes five factors into account. It is a very cost effective and an easy method of assessment. However, it is subjective to inter observer variability. In Bishop's scoring system, a total score of 13 is given. A score between 6 and 13 is considered as a favorable cervix.

The original Bishop score was introduced in 1964 and Calder modified the same in 1974.

In BS cervical effacement was noted in terms of percentages [%] while in Modified Bishop score(MBS) this cervical feature is replaced and documented in terms of cervical length. The modified feature documentation is more objective.[3,4]

Table 2: Preinduction cervical score assessment (MBS):

Cervical feature	Score			
	0	1	2	3
Dilatation	<1	1-2	3-4	>4
Length of cervix (cm)*	>3	2	1	<1
Station (relative of ischial spine)	-3	-2	-1/0	+1/+2
Consistency	Firm	Medium	Soft	
Position	Posterior	Mid	Anterior	

*** In the BS, effacement (%) used in place of cervical length. Score 0 – 0-30%, 1 – 40-50%, 2 – 60-70%, 3 – 80%**

Methods of induction: Can be broadly classified depending on the type of agent used

Table 3 : Methods of induction: according to the type of agent used

Pharmacological Cervical ripening agents	Prostaglandin E2 (PGE2): Vaginal gel Timed releasing pessary Prostaglandin E1 (PGE1): Tablets (oral, buccal, sublingual) Oxytocin: Low dose infusion High dose infusion
Non pharmacological methods	Membrane stretching and sweeping Mechanical Method: Specifically designed balloon devices i) Single balloon [Foley's] ii) Double balloon catheter [Cook's] Hygroscopic or osmotic dilator: Laminaria tent, Dilapan EASI: Extra amniotic saline infusion
Surgical method	Amniotomy or artificial rupture of membrane (ARM)
Other methods	Hyaluronidase injections Hypnotic relaxation Homeopathy and herbs Hot bath Acupuncture Breast and nipple stimulation Sexual intercourse Castor oil

1. Membrane stretch and sweep:

Sweeping of membrane constitutes separating the foetal membranes from the lower uterine segment digitally thereby leading to release of Prostaglandins (PG) from the membranes. This stimulates oxytocin release from the posterior pituitary by Ferguson's reflex and leads to onset of labour.

The woman can be offered the option of membrane sweeping commencing at 38 to 41 weeks. As per NICE guidelines membrane sweeping is recommended to nulliparous at 40 and 41 weeks and for multiparous at 41 weeks. It reduces frequency of postdated pregnancy and also minimizes need for formal induction. There is no increase in maternal and foetal infection. This can be offered on OPD basis.

Cochrane reviewed 22 trials involving sweeping of membrane at term [38–41 weeks] which reduced the frequencies of pregnancy exceeding beyond 41weeks. **[RR=0.59, 95% CI 0.46-0.74] and after 42 weeks [RR=0.28, 95%CI 0.15-0.5].**

Method: digital separation of foetal membrane circumferentially along the lower uterine segment and cervix during vaginal examination. It is possible in partially dilated cervix.

This technique is associated with discomfort, can cause irregular uterine contractions, small amount of bleeding or accidental rupture of membranes can occur. [5,6]

2. Mechanical method of IOL:

Hygroscopic cervical dilator:

- Natural (sea weed stem): Laminaria tent
- Synthetic: Dilapan

Transcervical balloon catheter:

- Single bulb catheter [cervical bulb] - Foley's
- Double bulb catheter [uterine and vaginal bulb]- Cook's Catheter

Advantages:

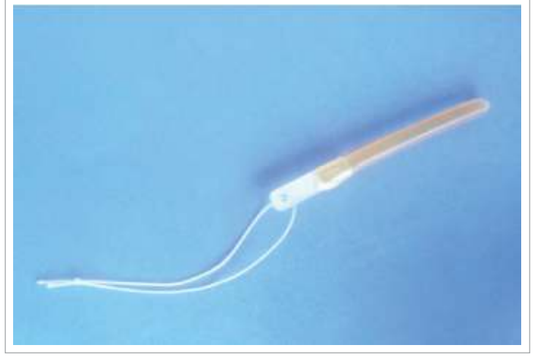
- Minimal risk of uterine tachysystole
- Minimal impact on the foetal heart rate pattern
- The safest mode of IOL in women with previous uterine surgery, severe oligohydroamnios, IUGR with abnormal Doppler and grand multipara.
- Good patient acceptability
- Cost effective and reversible method with no systemic side effects.

Mechanism of action and technique of introducing mechanical dilator

1. **Hygroscopic osmotic cervical dilators** are rigid rods inserted into cervix.

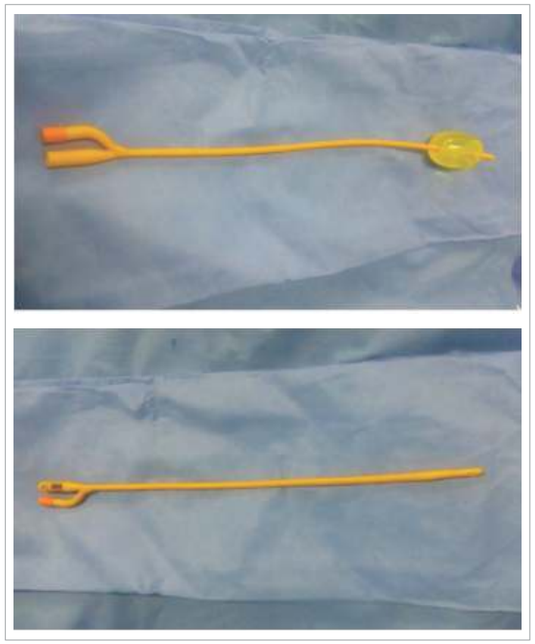
   They absorb endocervical and local tissue fluid which causes the device to swell up in the endocervix and provide mechanical pressure and further PG release.[7]

Figure 1: Dilapan hygroscopic dilator



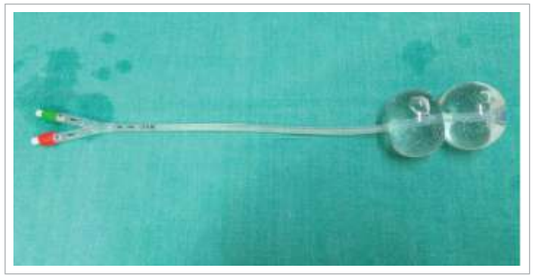
2. **Balloon device** Single bulb: Foley's bulb inflated with 30 to 60 ml sterile water or normal saline [NS] and catheter placed in such a way that inflated bulb rests against the internal cervical OS.

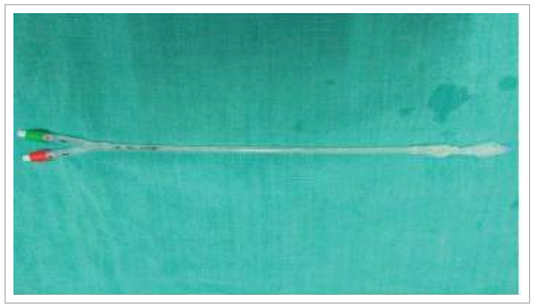
Figure 2: Foley's single balloon catheter

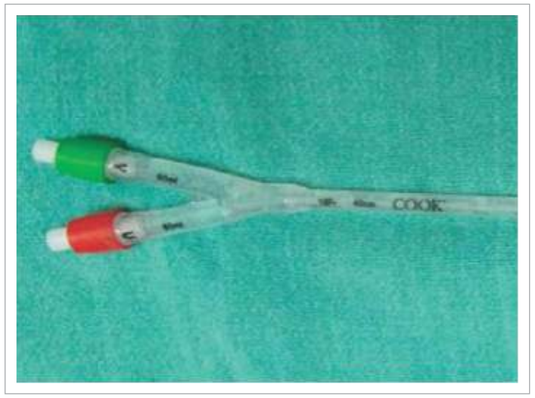


Double balloon inflation: This procedure involves an 18 Fr, 40cm long silicone catheter with a silicon tip and 2 silicone balloons (uterine and vaginal). Each balloon is inflated upto 80ml (maximum) of isotonic solution through separate inflation lumen. Uterine balloon after inflation rests against internal os and vaginal balloon rests outside external OS.

Figure 3: Cook's double balloon catheter







3. Extra amniotic saline infusion (EASI):

It is a method of IOL at term but more often used in second trimester termination of pregnancy. In this method, the catheter is placed by direct visualization during per speculum examination. Catheter bulb is inflated with 40ml of sterile water or normal saline. With the help of infusion pump, saline is infused at rate of 40ml/hour. Removal of catheter to be done after 6 hours or during ARM.[8,9]

Assessment

1. Balloon catheter to be removed after 12 hours and 6 hours in EASI followed by ARM.
2. If ARM is not possible. IOL can be replanned with PGs or a combination method.
3. When there is difficulty in passing urine or moderate to severe pain or discomfort balloon volume to be partially deflated.

Contraindication: PROM

4. Oxytocin:

It is a synthetic analogue of the endogenous oxytocin and most potent uterotonic agent. It remains the gold standard and most widely used agent for augmentation of labour. In general it is less successful when used for induction. Most trial shows that oxytocin is appropriate when BS is 6 or more or once spontaneous labour sets in.

Hence a cervical ripening agent should be used prior to administration of oxytocin in women with low BS. All augmented labour need continuous CTG monitoring as oxytocin can cause hypertonic contraction and foetal heat rate abnormality.

Mechanism: oxytocin stimulates the rhythmic contraction of uterine smooth muscle

By activating G protein coupled receptor that trigger increase intracellular calcium level in uterine myofibrils. Simultaneously increase local PG production which further stimulate uterine contraction.

Potential side effects

- Nausea, vomiting
- Foetal heart rate pattern changes
- Tachysystole, Hypertonus
- Rare complication: Fluid over load

Prerequisites before administration of oxytocin

- Reassuring CTG.
- Perform ARM if membranes are intact.
- Increment in oxytocin by low concentration or high concentration method as per institutional protocol.
- Maternal and foetal monitoring prior to increasing oxytocin infusion.
- Ensure adequate relaxation between contractions.

Protocols for oxytocin administration:

1. Use volumetric infusion pump or programed delivery pumps for correct infusion concentration. If manually titrating, ensure accurate drip rate of infusion
2. Record dose in miliunit per minute (mU/min) or drop rate according to labour room protocol
3. Increase dose at 30 min interval
4. Aim for contractions 3–4 in 10 minutes and relaxation of 40–60 seconds initially
5. Dose titration to be done against contraction and relaxation
6. Once active labour establish maintain dose and increase as and when required.
7. Discontinue oxytocin if tachysystole, hypertonic contraction or nonreassuring CTG
8. Consider starting oxytocin at half the dose after reassuring CTG and then gradually increase.

Two regimens are described for oxytocin infusion: Low dose and high dose regimen

Table 4: Low dose and high dose regimens of oxytocin administration

REGIMEN	STARTING DOSE (mU/min)	INCREASE BY (mU/min)	DOSAGE INTERVAL (min)
Low	0.5–1	1	30–40
High	6	6*	15–40

*In case of tachysystole, after resolution, increment by 3mU/min.

High dose low volume oxytocin infusion used with infusion pump for patients requiring fluid restriction such as cardiac disease and severe preeclampsia. Low dose oxytocin infusion rate is regulated by manually calculated drip rate adjustment or through infusion pump.[10,11]

Figure 4: Oxytocin infusion pump

5. Surgical method of IOL :

Deliberate rupture of amniotic sac is referred as amniotomy or artificial rupture of membranes [ARM].This is done by rupturing amniotic sac digitally or artificially with forceps or hook. Amniotomy followed by induction with oxytocin significantly reduces induction delivery period.

Relative contraindication: Unstable lie, polyhydramnios, mal-presentation, mobile head and cord presentation

Device used for amniotomy: Amni hook, Kocher's forceps, amnicut

Post procedure monitoring

- FHR recording or monitoring
- Advise immediate or early oxytocin commencement

Figure 5: Amnihook

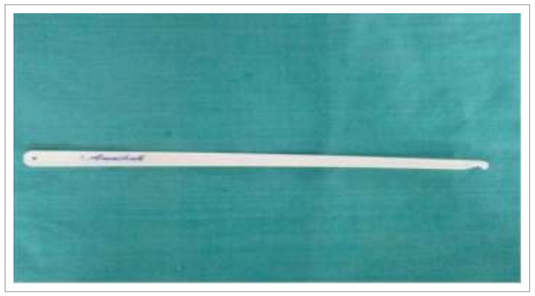
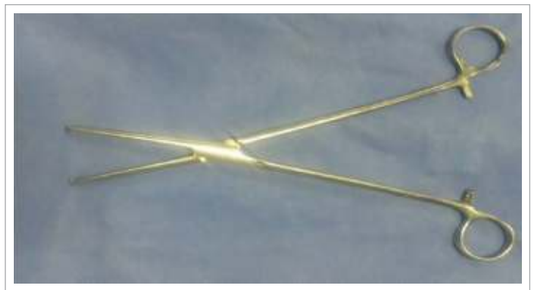


Figure 6: Kocher's forcep



Prostaglandins

a) Prostaglandin E2:

Pharmacological agent: Dinoprostone

- Vaginal gel: Dinoprostone Gel/Prepidil
- Timed release formulation/Cervidil

Procedure: Deposit gel in high vagina, posterior fornix or intracervical

Repeat dose after 6 hours to a maximum of 3 doses within 24 hours

If BS is less than 6, then re -induction can be considered.

Advantages: Shortening of induction to delivery interval and reduction in oxytocin use.

Prostaglandins can be used with caution in PROM (prelabour rupture of membrane)

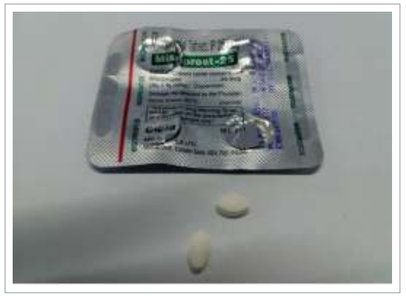
Side effects: Fever, chills, vomiting, diarrhoea and hyperstimulation.

Storage of PGE2 should be done in a refrigerator at 20 degree Celsius.

PGE2 is FDA approved for cervical ripening in patient at term.[12]

Figure 7: Prostaglandin E2

Figure 8: Prostaglandin E1



Prostaglandin E1

Misoprostol is available and primarily marketed for peptic ulcer treatment. The uterotonic and cervical softening effects on the female genital tract were considered as side effect rather than therapeutic effect, when PGE1 was first introduced for peptic ulcer therapy.

Although not FDA approved, it is used in obstetrics for cervical ripening, priming and for labour induction. Higher doses are used in termination of pregnancy.[13-15]

Advantages:

- Stable at room temperature, easy storage
- Comparatively inexpensive, easy administration

Dosages: 25 and 50 microgram (ACOG recommends 25 microgram and 50 micrograms only for selected cases)

Frequency of administration should not be more than 3–6 hours

Caution: Oxytocin should not be administered less than 4 hours after last dose of misoprostol

Side effects: Diarrhea is the most common adverse effect followed by nausea, vomiting, headache and febrile illness. Incidence of tachysystole, meconium stained liquor and scar rupture in previous uterine surgery is more with PGE1.

Routes: Oral, vaginal, sublingual, buccal

Administration: High in posterior fornix

Contraindications: Previous uterine surgery

* Further reading and Research: MVI (misoprostol vaginal insert) controlled release retrievable polymer chip for gradual release over 24 hours.

Table 5: Comparison of dose and route of PGE1 and PGE2

Drug	Route	Frequency	Maximum Dose
PGE2 - Dinoprostone	Vaginal gel–0.5mg	6th hourly	3 doses
	Timed release insert–10mg, 0.3mg/hour	24 hours	-
PGE1 - Misoprostol	Vaginal 25mcg	3–6th hourly	3 doses
	Oral 50mcg	3–6th hourly	3 doses

Table 6: Summary of all methods

Method	GA and MBS	Indication	Specific points	Concerns
Sweeping &stretching	39 to 41 weeks	-	OPD procedure, Cervix atleast partially dilated	Discomfort, Bleeding
ARM	MBS >6	-	foetal monitoring	Polyhydramnios, Unstable lie, mobile head
Mechanical method	Bishop score <6	TOLAC* IUGR Failed PG Induction	No systemic side effects Good acceptability	-
Pgs	MBS <6	Cervical ripening agent	Systemic side effects	Tachysystole, meconium stained liquor
Oxytocin	MBS <6	Post ARM For augmentation of labour	Foetal monitoring	-

* TOLAC: Trial of labour after caesarean

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5. Maternal and Foetal Surveillance in pregnancies beyond EDD

Dr Madhavi M Gupta,
Professor
Department of Obstetrics & Gynecology,
Maulana Azad Medical College, New Delhi.

Definitions

The duration of pregnancy ranges from 40 0/7 weeks - 41 3/7 weeks (280 to 290 days from the first day of the last menstrual period for a regular 28-day cycle).[1] A pregnancy by convention is considered to be prolonged after 41 0/7 weeks. (Professional consensus).[1]

The *International Classification of Diseases* defines term pregnancy as delivery between 37 weeks 0 days and 41 weeks 6 days.[2,3]

The recommendations of a multi organization workshop in December 2012 have designated births occurring between 37 weeks 0 days and 38 weeks 6 days as early term and those at 39 weeks 0 days through 40 weeks 6 days as full term. They also recommended referring to deliveries at 41 weeks 0 days through 41 weeks 6 days as late term.[4] Post-term pregnancy refers to a pregnancy that has reached or extended beyond 42 0/7 weeks of gestation from the last menstrual period (LMP)

Frequency of prolonged and postterm pregnancies

The frequency of post-term pregnancies is very heterogeneous: in Europe and the United States, it ranges from 0.5% to 10% according to country. In 2011, the overall incidence of post-term pregnancy in the United States was 5.5%.[5] In France, prolonged pregnancies (41+0 weeks) involve 15–20% of pregnant women, and post-term pregnancies (42+0 weeks) approximately 1%.

A secondary analysis of two WHO databases: the WHO Global Survey (WHOGS) on Maternal and Perinatal Health [6] conducted in Africa, Asia and Latin America and the WHO Multi-country Survey (WHOMCS) on Maternal and Newborn Health conducted in Africa, Asia, Latin America and the Middle East [7] was done. The prevalence of prolonged pregnancy at facility setting in WHOGS, WHOMCS and combined databases were 7.9%, 7.5% and 7.7% respectively. [8]

These variations simultaneously reflect the diversity of the populations studied and the variations in obstetric practices between countries: early pregnancy dating by ultrasound and increasingly frequent recourse to induction of labour have jointly contributed to a progressive diminution in the incidence of prolonged and postterm pregnancies in most countries.[9]

Risk Factors

The commonest cause of prolonged pregnancy is inaccurate dating. Gestational age is generally overestimated when using the standard clinical criteria consequently increasing the incidence of postterm pregnancy. When it is truly a postterm pregnancy, the cause is usually unknown.

The common risk factors are - nulliparity, a male foetus, previous postterm pregnancy, genetic predisposition, maternal obesity and foetal disorders like anencephaly and placental sulfatase deficiency

Complications

Maternal Complications

There is a significant increase in the risks to the mother. In prolonged pregnancies, the cesarean section rate–especially the emergency cesarean rate-is increased by approximately 1.5. There is an increased risk of labour dystocia (9–12% versus 2–7% at term), severe perineal lacerations (3rd & 4th degree tears), related to macrosomia (3.3% versus 2.6% at term), postpartum haemorrhage, infection and operative vaginal delivery. Maternal anxiety can increase when the pregnancy crosses the EDD.

A large retrospective study has shown that there is a statistically significant increase in the rate of maternal complications after 40 weeks of gestation and even beyond 39 weeks for some morbidities.[10]

Foetal and Neonatal Risks

Several studies have demonstrated that pregnancy after 41 0/7 weeks is associated with increased risk of perinatal morbidity and mortality.

The perinatal mortality rate, defined as stillbirths plus early neonatal deaths, at 42 weeks of gestation, is twice as high as that at term (4–7 versus 2–3 per 1000 deliveries, respectively). It increases 4-fold at 43 weeks and 5–7-fold at 44 weeks. Utero-placental insufficiency, intrauterine infection and meconium aspiration are believed to be the underlying causes of the increased perinatal mortality rates in these cases.[11]

Pregnancies progressing beyond 41 0/7 weeks also have increased foetal morbidity in the form of macrosomia (two fold increased risk) leading to birth trauma, passage of meconium, meconium aspiration syndrome and postsmaturity.

Oligohydramnios is found more commonly in postterm pregnancies after 42 0/7 weeks than earlier. In these cases there is more likelihood of umbilical cord compression, foetal heart rate abnormalities, meconium-stained fluid, umbilical cord artery blood pH of less than 7, and lower apgar scores.[12]

As pregnancy progresses beyond the estimated date of delivery there is an increased risk of stillbirth and neonatal mortality at each gestational week. In a large retrospective study of over 170,000 births the rates of stillbirth were found to be significantly higher in postterm pregnancies when compared with term pregnancies with a nadir at 41 weeks.[13]

Management

Pregnancy dating

Accurate estimation of gestational age (GA) is crucial to the diagnosis and management of late term and postterm pregnancies.[14]

It decreases the incidence of late term and postterm pregnancies (from 9.5%–1.5%).[15]

Ultrasound early in pregnancy for foetal biometry is the most precise and reproducible method for assessing GA.[16]

In the first trimester pregnancies are dated according to the crownrump length (CRL). In the second trimester the biparietal diameter (BPD) may be used alone or in combination with femur length (FL). The accuracy of CRL for dating is superior to that of 2nd or 3rd trimester biometry.

When there is still uncertainity about the GA after 22 weeks repeating foetal biometry 2–3 weeks later helps in reassessing the growth process and at times to estimate the GA.

When to begin monitoring and how often?

From 37 0/6 to 43 0/6 there is a regular increase in the risk of perinatal mortality (Eight-fold higher rate of still birth) but there is no threshold at which a clear increase is visible. If monitoring is initiated at 40 0/6 weeks nearly half of the pregnancies would require close monitoring. As the rate of maternal and foetal-neonatal complications significantly increases after 41 0/7 weeks it is reasonable to begin monitoring then. It would cover 20% of women and reduce perinatal morbidity. Most retrospective studies on antepartum surveillance commenced monitoring between 41 weeks and 42 weeks of gestation.[17]

A retrospective study of nearly 1000 women suggests that antenatal testing may be equally beneficial when initiated after the EDD at 40 weeks as similar rates of abnormal test results were found in the post EDD and the ⩾ 41 weeks groups.[18]

The frequency recommended is 2–3 times per week.

Antepartum foetal surveillance

Evidence of benefits from antenatal surveillance is lacking and no single antenatal test is superior to another. Normal antenatal monitoring results usually are reassuring

No specific foetal surveillance test can predict acute events like cord accidents or placental abruption in a postterm pregnancy.

The most commonly used tests are

- Cardiotocography (CTG)
- Non-stress test (NST)
- Foetal biophysical profile (BPP)
- Modified biophysical profile (NST and amniotic fluid assessment)
- Amniotic fluid (AF) volume assessment (amniotic fluid index (AFI) or deepest pocket),

In pregnancies beyond EDD there is a significant risk of oligohydramnios and of increased morbidity and mortality after 41 + 0 weeks

Evidence supports that ultrasonographic assessment of amniotic fluid volume starting at 41 0/7 weeks and thereafter twice a week to detect *Oligohydramnios* is essential. Oligohydramnios is commonly defined as a single deepest vertical pocket of amniotic fluid of 2 cm or less (not containing umbilical cord or foetal extremities) or an amniotic fluid index of 5 cm or less. Measurement of the largest fluid pocket is recommended, because measurement of the amniotic fluid index (that is, the sum of the four quadrants) is accompanied by more diagnoses of oligohydramnios, inductions of labour, and cesarean sections for foetal distress without any improvement in neonatal prognosis.[19] In cases of oligohydramnios, defined as less than 2 cm in the largest pocket at ⩾ 41 weeks delivery is usually indicated.

Maternal Surveillance

The main maternal complications that need to be excluded are carbohydrate intolerance and gestational hypertension.

A recent retrospective cross-sectional study has concluded that for low risk women expectantly managed at term, there is a risk of developing hypertensive complications for each additional week of pregnancy, with associated increases in maternal and neonatal morbidities. The risk of developing any hypertension in expectantly managed women was 4.1% after 37 weeks, 3.5% after 38 weeks, 3.2% after 39 weeks and 2.6% after 40 weeks.[20]

Ketonuria should be assessed as it may alter the results of foetal well-being tests.[21] As the risk of stillbirth is increased in nulliparous and not in multipara hence parity should also be considered.[22]

Maternal stature should be evaluated when macrosomia is suspected to minimize the risk of birth trauma to both the mother and the newborn.[14]

When to induce labour?

In the absence of specific disorder based on current evidence, labour induction can be considered between 41 0/7 to 42 0/7 weeks of gestation. Induction of labour after 42 0/7 weeks and by 42 6/7 weeks of gestation is not recommended in view of the increased perinatal morbidity and mortality.[23] The mode of induction will be determined by the mother's cervical condition, uterine scar, parity, body mass index and age. Consideration should also be given to the woman's preference and the organization of care.[1]

How should delivery be induced?

Different methods of induction are available

- Stripping of membranes
- Oxytocin
- E2 prostaglandins (dinoprostone)
- E1 prostaglandins (misoprostol) - Not approved officially for prolonged pregnancies. Contraindicated in the presence of a uterine scar.
- Mechanical methods-Intracervical Foley catheter

Case of uterine scar

No increase in the risk of uterine rupture associated with vaginal birth after caesarean (VBAC) attempted at or beyond EDD. The failure rate of VBAC increased with advancing gestational age, from 22.2% before 40 weeks of gestation to 35.4% after 41 weeks of gestation.[24]

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6. Evidence based interventions/labour room practices for labour and delivery management

Dr. Smiti Nanda,
Senior Professor and Head, Post Graduate Institute of Medical Sciences, Rohtak, Haryana, India.
Dr. Anjali Gupta,
Professor, Post Graduate Institute of Medical Sciences, Rohtak, Haryana, India.

What is evidence based interventions?

Evidence based interventions (EBI) are treatments that have been proven effective (to some degree) through outcome evaluations. EBI uses a continuum of integrated policies, strategies, activities and services whose effectiveness has been proven or informed by research and evaluation.

The impact of evidence based interventions

The basic principle of EBI is that we should treat when there is evidence of benefit and not treat if evidence shows no benefit.

Enema prior to labour

Tradition/routine practice: Giving enema prior to labour has been routine practice in delivery wards of many countries and settings. It was thought an enema prior to labour / or in early labour would:

- Reduce the soiling of the perineum and the consequent embarrassment for women.
- Reduce the length of labour
- Reduce the chance of infection for both the mother and the baby.
- Other hypothetical advantages include stimulation of uterine contractions and facilitation of descent of the foetal head because of an empty bowel.

Disadvantages suggested are:

- It is a very unpleasant procedure
- Enemas could produce a watery faecal soiling whilst giving birth, they could potentially increase the risk of infections.
- Add to the workload of delivery wards.
- Increase the cost of delivery.

Considering the uncertainties regarding use of this practice, it was important to assess the effect of enemas used during labour on mother and the neonate.

Evidence

Cochrane review 2013[1] aimed to evaluate whether giving enemas during the first stage of labour has any effect on infection rates (in mothers and newborns), the duration of labour, perineal wound dehiscence in the mother, perineal pain and fecal soiling. The review included four trials (1917 women) that had compared outcomes of administering enema versus no enema.

Enema versus no enema: maternal outcomes

No significant difference was found in infection rates for puerperal women (two RCTs; 594 women; risk ratio (RR) 0.66, 95% confidence (CI) 0.42 to 1.04)

- Two trials (1179 women) reported on the total duration of labour; no statistically significant difference was observed in the duration of labour (MD 28.04 min, 95% CI –131.01 to 187.10) but there was a high level of heterogeneity between the findings of the two trials.
- There was also no observed difference between groups regarding the duration of the second stage of labour (MD 5.2 min, 95% CI –2.56 to 12.96).
- No significant differences were observed in the rates of second or third degree perineal trauma (RR 0.68, 95% CI 0.39 to 1.21). Intrapartum infection was marginally increased among women who received routine enema (RR 4.62, 95% CI 1.03 to 20.68) but women requiring systemic antibiotics following the birth were similar between the two comparison groups (RR 1.16, 95% CI 0.73 to 1.84; one trial, 428 women).

- One trial (1027 women) reported women's level of satisfaction with childbirth (measured on a Likert scale but reported as a continuous outcome): the mean scores were identical in the two groups (MD 0.00, 95% CI–0.10 to 0.10).
- There was less faecal soiling (one RCT; 152 women; RR 0.36, 95% CI 0.17 to 0.75), higher satisfaction levels of labour attendants, accoucheurs and perineorrhaphy operators (one RCT; 1027 women; mean difference (MD) 0.17, 95% 0.08 to 0.26; MD 0.26, 95% 015 to 0.37; MD 0.11, 95% 0.02 to 0.20)

Enema versus no enema: infant outcomes

There was no significant difference in the rate of infants with low Apgar scores at five minutes (RR 1.31, 95% CI 0.57 to 3.06), in neonatal umbilical infection rates (two RCTs; 592 women; RR 3.16, 95% CI 0.50 to 19.82). Rates of neonatal infection (variously defined) were similar between the groups (RR 0.61, 95% CI 0.24 to 1.52)

Recommendation

WHO (2014)[2] does not recommend administration of enema for reducing the use of labour augmentation.

- Routine use of enema has neither been shown to reduce the duration of labour nor confer any other clinical benefits. It is considered invasive and associated with discomfort for women.
- The Guideline Development Group put its emphasis on the feasibility of implementing this recommendation, the reduction in health resource use and acceptability by caregivers and women and therefore made a strong recommendation against this intervention.

Conclusion: No experimental evidence supports the routine use of enema and the procedure usually generates maternal discomfort, increases the workload of health workers attending to the woman during labour, and increases the cost of care. Enemas does not improve puerperal or neonatal infection rates, episiotomy dehiscence rates or maternal satisfaction. Therefore, their use is unlikely to benefit women or newborn children, and there is no reliable scientific basis to recommend their routine use.

Hair cutting versus perineal shaving

Tradition: Shaving is a routine procedure in many settings.

- Preparation for childbirth includes practice of pubic hair removal
- Believed to reduce the risk of infection if the perineal tears or an episiotomy is performed.
- Makes suturing easier and safer.

Disadvantage:

- Using a razor to shave the perineum can create cutaneous micro lacerations that may lead to colonization with micro-organisms.
- Women often consider the procedure to be embarrassing and painful, and they may also suffer discomfort and itching when the pubic hair regrows.
- Potential for increased risk to the health care provider or to the woman of HIV and hepatitis infections through cuts or abrasions induced by shaving.

Evidence: Cochrane review 2014[3] assessed the effects of routine perineal shaving before birth on maternal and neonatal outcomes, according to the best available evidence. Three controlled trials that involved a total of 1039 women were included. Each used an antiseptic skin preparation and compared perineal shaving with cutting vulval hairs.

The primary outcome for all three trials was maternal febrile morbidity; no differences were found (risk ratio (RR) 1.14, 95% confidence interval (CI) 0.73 to 1.76). No differences were found in terms of perineal wound infection (RR 1.47, 95% CI 0.80 to 2.70) and perineal wound dehiscence (RR 0.33, 95% CI 0.01 to 8.00) in the most recent trial involving 500 women, which was the only trial to assess these outcomes. In the smallest trial, fewer women who had not been shaved had Gram-negative bacterial colonization compared with women who had been shaved (RR 0.83, 95% CI 0.70 to 0.98). There were no instances of neonatal infection in either group in the one trial that reported this outcome. There were no differences in maternal satisfaction between groups in the larger trial reporting this outcome (mean difference (MD) 0.00, 95%

CI -0.13 to 0.13). No trial reported on perineal trauma. One trial reported on side-effects of perineal shaving and these included irritation, redness, burning and itching.

Conclusion: There is insufficient evidence to suggest that perineal shaving confers any benefit to women on admission in labour. Furthermore, the potential for side-effects suggests that shaving should not be part of routine clinical practice.

Episiotomy

Tradition: Episiotomy during vaginal delivery was first recommended in 1920 as a way to protect the pelvic floor from lacerations and protect the foetal head from trauma. It was rapidly adopted as a standard practice and has been widely used since then. However, over the last several decades, there has been a growing body of evidence that episiotomy does not provide these purported benefits and may contribute to more several perineal lacerations and future pelvic floor dysfunction.

Evidence: The question of whether to apply a policy of routine episiotomy is important for clinical practice and for the health and well-being of women and babies. Cochrane review[4] included 11 randomized controlled trials that compared episiotomy as needed (selective episiotomy) with routine episiotomy in terms of benefits and harms for mother and baby in women at low risk of instrumental delivery. For women where an unassisted vaginal birth was anticipated, a policy of selective episiotomy may result in 30% fewer women experiencing severe perineal/vaginal trauma (RR 0.70, 95% CI 0.52 to 0.94; 5375 women; eight RCTs; low-certainty evidence). Both selective and routine episiotomy have little or no effect on infants with Apgar score less than seven at five minutes (four trials, no events; 3908 women, moderate-certainty evidence); and there may be little or no difference in perineal infection (RR 0.90, 95% CI 0.45 to 1.82, three trials, 1467 participants, low-certainty evidence). There is probably little or no difference for long-term (six months or more) dyspareunia (RR1.14, 95% CI 0.84 to 1.53, three trials, 1107 participants, moderate-certainty evidence); and there may be little or no difference for long-term (six months or more) urinary incontinence (average RR 0.98, 95% CI 0.67 to 1.44, three trials, 1107 participants, low-certainty evidence).

NICE's guideline[5] on intrapartum care recommends that an episiotomy should only be done:

if there is a clinical need, such as when instruments are used during birth or where there is suspected foetal compromise.

Routine episiotomy is not recommended in the following circumstances:

- During spontaneous vaginal birth
- After third-degree trauma from previous childbirth (injury to perineum involving the anal sphincter complex)
- After fourth-degree trauma from previous childbirth (injury to perineum involving the anal sphincter complex and anal epithelium).

Conclusion: Routine episiotomy reduces perineal/vaginal trauma is not justified by current evidence.

Both NICE's guideline and the Royal College of Obstetricians and Gynaecologists (RCOG)[6] guideline recommend that if episiotomy is indicated, a mediolateral episiotomy should be done. It can protect against obstetric anal sphincter injuries (OASIs). This should originate at the vaginal fourchette and usually be directed towards the right side.

The RCOG guideline[6] specifically recommends that the angle of the episiotomy cut should be at 60 degrees to the midline. If the cutting angle is less than 45 degrees to the perineal midline, there is a higher risk of OASIs. Cutting angles greater than 60 degrees to the perineal midline have been shown to be ineffective, because they do not relieve the pressure on the perineum. Due to distension of the perineum during childbirth, the angle of the episiotomy at the time it is cut is different to the angle as viewed after birth. Therefore, in order to ensure that a truly mediolateral post-delivery angle of 45 degrees is achieved, it is necessary to cut a 60-degree episiotomy.

Perineal Support

Tradition: Clinicians have used 'hands on' approaches at the time of birth, including applying downward pressure with one hand to aid in flexion of the baby's head, and/or guarding or supporting the perineum with the other. Head flexion was justified on the belief that the smallest diameter of the foetal head will emerge. This belief has prompted debate, with some arguing that it cannot achieve this aim

and only serves to place more pressure on the perineum. In contrast, there has been a shift to a 'hands poised' approach where the accoucheur is ready to put light pressure on the baby's head in case of rapid expulsion, but not touch the head or perineum otherwise. A recent Cochrane review[7] concluded that there was no difference between 'hands on' and 'hands poised or off' but that substantial heterogeneity existed and effects could be in either direction.

Evidence: McCandlish et al (1998) trial, which recruited 5,316 women, compared two methods of management; 'hands on', in which the midwife placed pressure on the baby's head to support ('guard') the perineum, with lateral flexion to facilitate delivery of the shoulders, and 'hands poised', in which the midwife kept her hands poised, not touching the perineum or foetal head and allowing spontaneous delivery of the shoulders. Women in the 'hands poised' group were more likely to report 'mild' perineal pain at 10 days' post birth. The only other statistically significant differences were in two secondary outcomes: episiotomy rates were lower in the 'hands poised' group, and manual removal of the placenta was more common. Mayerhofer et al (2002) trial of 1,076 women also compared 'hands on' and 'hands poised'. Findings confirmed those of McCandlish et al. (1998) of no statistically significant differences in overall perineal injury, but an increased rate of episiotomy and third degree tear in the 'hands on' group. NICE (2007) guidance is that either of these techniques could be used to facilitate spontaneous vaginal birth.

However, more recently there have been interventional studies[8,9] using programmes which have successfully reduced OASIS rates, all of which have described manual perineal protection/ 'hands on' techniques. These include: 1. Left hand slowing down the delivery of the head. 2. Right hand protecting the perineum. 3. Mother NOT pushing when head is crowning (communicate). 4. Think about episiotomy (risk groups and correct angle). The best method of perineal support/protection is unclear, with the Ritgenmanoeuvre (delivering the foetal head, using one hand to pull the foetal chin from between the maternal anus and the coccyx and the other on the foetal occiput to control speed of delivery) no better than 'standard care' (not specifically defined but it included perineal protection/ 'hands on')

According to Cochrane review 2017[10] using 'hands off' the perineum resulted in fewer women having an episiotomy (low-quality evidence), but made no difference to numbers of women with no tears (moderate-quality evidence), first-degree tears (low-quality evidence), second-degree tears (low-quality evidence), or third-or fourth-degree tears (very low-quality evidence). None of the studies provided data on the number of tears requiring suturing.

It is noted that it is very hard to ensure that practitioners fully comply with 'hands off' as they are able to use their clinical judgement and intervene when they feel it necessary. Additionally the terms 'hands on', 'hands off' and 'perineal support' all mean very different things in all the included studies. Similarly, that 'hands on' techniques are poorly described. It is clear that all studies aimed at a slow and controlled delivery of the head.

Either the 'hands on' (guarding the perineum and flexing the baby's head) or the 'hands poised' (with shands off the perineum and baby's head but in readiness) technique can be used to facilitate spontaneous birth (RCOG 2014).[5]

Conclusion: The preferred technique for a low-risk birth appears to have changed from 'hands on' to 'hands poised or off', but 'hands on' can be adopted in situations of high risk for OASI. Further research is needed to establish whether there is an association with the rising OASI rate and the change in preferred perineal management technique for a low-risk birth.

Water Birth

Water birth is the process of giving birth in a tub or pool of warm water.

Belief: It is believed that water birth reduces stress during labour and birth which also reduces foetal and maternal complications. The theory behind this is that the baby has been in the amniotic sac for nine months and emerging in water environment is gentler and less stressful for both mother and baby.

Evidence: Cochrane systemic review 2009[11] included 12 trials (3,243 women): 8 related to just the first stage of labour: one to early versus late immersion in the first stage of labour; two to the first and second stages; and another to the second stage only. We identified no trials evaluating different baths/pools, or the management of third stage of labour. Results for the first stage of labour showed there was a significant reduction in the epidural/spinal/paracervical analgesia/anaesthesia rate amongst women allocated to water immersion compared to controls (478/1,254 versus 529/1,245; risk ratio (RR) 0.90; 95% confidence interval (CI) 0.82 to 0.99, six trials). There was also a reduction in duration of the first stage of labour (mean difference -32.4 minutes; 95% CI -58.7 to -6.13). There was no difference in assisted vaginal deliveries (RR 0.86; 95% CI 0.71 to 1.05, seven trials), caesarean sections (RR 1.21; 95% CI 0.87 to 1.68, 8 trials), use of oxytocin infusion (RR 0.64; 95% CI 0.32 to 1.28, 5 trials), perineal trauma or maternal infection. There were no differences for Apgar score less than 7 at 5 minutes (RR 1.58; 95% CI 0.63 to 3.93, 5 trials), neonatal unit admissions (RR 1.06; 95% CI 0.71 to 1.57, three trials), or neonatal infection rates (RR 2.00; 95% CI 0.50 to 7.94, five trials). Of the 3 trials that compared water immersion during the second stage with no immersion, one trial showed a significantly higher level of satisfaction with the birth experience (RR 0.24; 95% CI 0.07 to 0.80).They found no increase in maternal infections (RR, 0.99; 95% CI, 0.50–1.96; five trials) with immersion during the first stage of labour. There was no statistically significant difference in the frequency of postpartum hemorrhage among women undergoing immersion during the second stage of labour (RR, 0.14; 95% CI, 0.10–2.71; one trial). The available evidence does not suggest an increased risk of adverse maternal outcomes with water immersion during labour and delivery.

Concerns have been expressed that immersion in water during delivery may predispose the infant to potentially serious neonatal complications, such as infection, water aspiration (fresh-water drowning), and umbilical cord avulsion. Individual case reports and case series have reported several serious adverse outcomes among neonates intentionally delivered in water. No increased frequency of adverse neonatal outcomes after second-stage immersion or delivery while submerged was found by the 2009 Cochrane synthesis of randomized trial. The Cochrane review noted limited data regarding morbidity & mortality, concluding that "there is insufficient evidence about the use of water immersion during second stage of labour & therefore clear implications cannot be stated".

Recommendations of ACOG[12] :

Immersion in water during the first stage of labour may be associated with shorter labour and decreased use of spinal and epidural analgesia and may be offered to healthy women with uncomplicated pregnancies between 37 0/7 weeks and 41 6/7 weeks of gestation.

- There are insufficient data on which to draw conclusions regarding the relative benefits and risks of immersion in water during the second stage of labour and delivery. Therefore, until such data are available, it is the recommendation of the American College of Obstetricians and Gynecologists that birth occur on land, not in water.
- A woman who requests to give birth while submerged in water should be informed that the maternal and perinatal benefits and risks of this choice have not been studied sufficiently to either support or discourage her request.
- Facilities that plan to offer immersion during labour and delivery need to establish rigorous protocols for candidate selection; maintenance and cleaning of tubs and pools; infection control procedures, including standard precautions and personal protective equipment for health care personnel; monitoring of women and fetuses at appropriate intervals while immersed; and moving women from tubs if urgent maternal or foetal concerns or complications develop.

Conclusion: The use of water during labour and birth continues to be an area with limited high quality evidence and many researchers have called for further studies. Furthermore, the College recognizes that despite the opinions expressed in this document, a woman may request immersion during the second stage of labour, including giving birth while submerged. If the physician believes, based on evidence, that second-stage immersion and giving birth while submerged would be detrimental to the overall health and welfare of the woman or the fetus, he or she should not perform such a delivery.

Position at delivery

Tradition: In today's standards labouring women are confined to supine-lithotomy position, for the convenience of the health personnel. When women are lying or semi-lying in bed, it is easier to access the woman's abdomen to monitor the foetal heart rate.

Disadvantage: Lithotomy position is not based on evidence and it comes with multitude of poor factors. This position is illogical making the birth needlessly complicated, turning natural process into medical event. It is not ideal for the birthing mother to push the baby uphill against the gravity.

It is suggested that women in upright positions give birth more easily because the pelvis is able to expand as the baby moves down; gravity may also be helpful and the baby may benefit because the weight of the uterus will not be pressing down on the mother's major blood vessels which supply oxygen and nutrition to the baby.

Evidence: Cochrane review 2017[13] assessed the possible benefits and risks to the mother and baby, by giving birth in upright positions compared with supine positions. Review included data from 30 randomized controlled trials involving 9015 pregnant women who gave birth without epidural anaesthesia. When women gave birth in an upright position, as compared with lying on their backs, the length of time they were pushing (second stage of labour) was reduced by around six minutes (19 trials, 5811 women; very low-quality evidence). Fewer women had an assisted delivery, for example with forceps (21 trials, 6481 women; moderate-quality evidence). The number of women having a caesarean section did not differ (16 trials, 5439 women; low-quality evidence). Fewer women had an episiotomy although there was a tendency for more women to have perineal tears (low-quality evidence). There was no difference in number of women with serious perineal tears (6 trials, 1840 women; very low-quality evidence) between those giving birth upright or supine. Women were more likely to have a blood loss of 500 mL or more (15 trials, 5615 women; moderate-quality evidence) in the upright position but this may be associated with more accurate ways of measuring the blood loss. Fewer babies had problems with fast or irregular heartbeats that indicate distress (2 trials, 617 women) when women gave birth in an upright position although the number of admissions to the neonatal unit was no different (4 trials, 2565 infants; low-quality evidence).

RCOG[14] recommends for breech delivery 'Either a semi-recumbent or an all-fours position may be adopted for delivery and should depend on maternal preference and the experience of the attendant.'

According to Nice Guidelines[5]: Discourage the woman from lying supine or semi-supine in the second stage of labour and encourage her to adopt any other position that she finds most comfortable.

Conclusion: More research into the benefits and risks of different birthing positions would help us to say with greater certainty which birth position is best for most women and their babies. Overall, women should be encouraged to give birth in whatever position they find comfortable.

Companionship at birth

Tradition: Companion at birth is defined as the continuous presence of a support person during labour and birth. Historically, women have generally been attended and supported by other women during labour. However, in hospitals worldwide, continuous support during labour has often become the exception rather than the routine.

Supportive care during labour may enhance physiological labour processes, as well as women's feelings of control and confidence in their own strength and ability to give birth. This may reduce the need for obstetric intervention and also improve women's experiences. Some women like to have their husband or partner; others prefer a close family relative, friend, or a traditional birth attendant (TBA). Experiences from different settings have shown that the best person to have as a childbirth companion is often an older woman from the community, someone who has had children herself. However, encouraging the husband/partner to be more involved with the birth, where it is acceptable, may also be beneficial for the whole family.

Evidence: The intervention has been recommended by the World Health Organization (WHO)[15] to improve labour outcomes and women's satisfaction with care. It has also been identified as a key element in the WHO vision of quality of care for pregnant women and newborns. In an innovative move aimed at reduction in Maternal Mortality Ratio and Infant Mortality Rate, the Ministry of Health and Family Welfarehas taken a significant decision to allow birth companions during delivery in public health facilities. The companions are women who have experienced the process of labour and provide continuous one - to - one support to other women experiencing labour and child birth. Birth companions provide emotional support (continuous reassurance), information about labour progress and advice regarding coping techniques, comfort measures (comforting touch, massages, promoting adequate fluid intake and output).

Cochrane 2017[16] reviewed 26 studies that provided data from 17 countries, involving more than 15,000 women in a wide range of settings and circumstances. The continuous support was provided either by hospital staff (such as nurses or midwives), or women who were not hospital employees and had no personal relationship to the labouring woman. In other cases, the support came from companions of the woman's choice. Women allocated to continuous support were more likely to have a spontaneous vaginal birth (average RR 1.08, 95% confidence interval (CI) 1.04 to 1.12; 21 trials, 14,369 women; low-quality evidence) and less likely to report negative ratings of or feelings about their childbirth experience (average RR 0.69, 95% CI 0.59 to 0.79; 11 trials, 11,133 women; low-quality evidence) and to use any intrapartum analgesia (average RR 0.90, 95% CI 0.84 to 0.96; 15 trials, 12,433 women). In addition, their labours were shorter (MD -0.69 hours, 95% CI -1.04 to -0.34; 13 trials, 5429 women; low-quality evidence), they were less likely to have a caesarean birth (average RR 0.75, 95% CI 0.64 to 0.88; 24 trials, 15,347 women; low-quality evidence) or instrumental vaginal birth (RR 0.90, 95% CI 0.85 to 0.96; 19 trials, 14,118 women), regional analgesia (average RR 0.93, 95% CI 0.88 to 0.99; 9 trials, 11,444 women), or a baby with a low five-minute Apgar score (RR0.62, 95% CI 0.46 to 0.85; 14 trials, 12,615 women). Postpartum depression could be lower in women who were supported in labour, but insufficient evidence. They did not find any difference in the numbers of babies admitted to special care. No adverse effects of support were identified.

Conclusion: A trained birth companion contributes to reduced tension and shortened labour, increases mother's feelings of control, decreases interventions and caesareans. It also enhances the partner's participation, improves outcome for the newborn, facilitates parent/infant bonding, and decreases postpartum depression while increasing positive feelings about the birth experience. Women should be encouraged to have a companion of her choice present during labour and birth. However, local conditions should also be taken into consideration.

Continuous intrapartum electronic foetal monitoring

Continuous electronic foetal monitoring was developed in the 1960s to assist in the diagnosis of foetal hypoxia during labour. The evidence for the benefits of continuous CTG monitoring, as compared to intermittent auscultation, in both low and high-risk labours is scientifically inconclusive. When compared to intermittent auscultation, continuous CTG has been shown to decrease the occurrence of neonatal seizures, but no effect has been demonstrated on the incidence of overall perinatal mortality or cerebral palsy. The use of continuous intrapartum CTG in low-risk women is more controversial. Several factors, including gestational age and medication administered to the mother, can affect FHR features. As a general rule, if the fetus continues to maintain a stable baseline and a reassuring variability, the risk of hypoxia to the central organs is very unlikely. Continuous CTG should be recommended when either risk factors for foetal compromise have been detected antenatally, are detected at the onset of labour or develop during labour.

When foetal hypoxia/acidosis is anticipated or suspected (suspicious and pathological tracings), and action is required to avoid adverse neonatal outcome, this does not necessarily mean an immediate cesarean section or instrumental vaginal delivery. The underlying cause for the appearance of the pattern can frequently be identified and the situation reversed, with subsequent recovery of adequate foetal oxygenation and the return to a normal tracing. Excessive uterine activity is the most frequent cause of foetal hypoxia/acidosis and it can be detected by documenting tachysystole in the CTG tracing and/or palpating the uterine fundus. It can usually be reversed by reducing or stopping oxytocin infusion, removing administered prostaglandins if possible, and/or starting acute tocolysis with beta-adrenegic agonists (salbutamol, terbutaline, ritodrine) atosiban, or nitroglycerine. During the second stage of labour, maternal pushing efforts can also

contribute to foetal hypoxia/acidosis and the mother can be asked to stop pushing until the situation is reversed. Aorto-caval compression can occur in the supine position and lead to reduced placental perfusion. Excessive uterine activity may also be associated with the supine position possibly due to the stimulation of the sacral plexus by the uterine weight. In these cases, turning the mother to her side is frequently followed by normalization of the CTG pattern. Transient cord compression is another common cause of CTG changes (variable decelerations), and these can sometimes be reverted by changing the maternal position or by performing amnioinfusion. Sudden maternal hypotension can also occur during labour, usually after epidural or spinal analgesia, and it is usually reversible by rapid fluid administration and/or an intravenous ephedrine bolus. Good clinical judgement is required to diagnose the underlying cause for a suspicious or pathological CTG, to judge the reversibility of the conditions with which it is associated, and to determine the timing of delivery, with the objective of avoiding prolonged foetal hypoxia/acidosis, as well as unnecessary obstetric intervention.[17]

Limitations of CTG: CTG analysis is subject to considerable intra- and interobserver disagreement, even when experienced clinicians use widely accepted guidelines. The main aspects that are prone to observer disagreement are the identification and classification of decelerations, the evaluation of variability, and the classification of tracings as suspicious and pathological. Unnecessary obstetric intervention confers additional risks for the mother and newborn and may result from poor CTG interpretation, limited knowledge of the pathophysiology of foetal oxygenation, and inadequate clinical management.

Where continuous electronic foetal monitoring is required, and if the electronic foetal monitoring to date is considered to be normal, monitoring may be interrupted for short periods of up to 15 minutes to allow personal care (e.g. shower, toilet). Such interruptions should be infrequent and not occur immediately after any intervention that might be expected to alter the foetal heart rate (e.g. amniotomy, epidural insertion or top-up etc.). Consideration should be given to instituting electronic foetal monitoring prior to insertion of a regional anaesthetic or paracervical block to establish baseline foetal heart rate characteristics.

The normal CTG is associated with a low probability of foetal compromise and has the following features: Baseline rate 110–160 bpm. Baseline variability of 6–25 bpm. Accelerations of 15 bpm for 15 seconds. No decelerations. All other CTGs are by this definition abnormal and require further evaluation taking into account the full clinical picture.

The following features are unlikely to be associated with foetal compromise when occurring in isolation: Baseline rate 100–109 bpm. Absence of accelerations. Early decelerations. Variable decelerations without complicating features.

The following features may be associated with significant foetal compromise and require further action: Baseline foetal tachycardia >160 bpm. Reduced or reducing baseline variability (3–5 bpm). Rising baseline foetal heart rate. Complicated variable decelerations. Late decelerations. Prolonged decelerations.

The following features are likely to be associated with significant foetal compromise and require immediate management, which may include urgent delivery: Prolonged bradycardia (5 minutes). Absent baseline variability (persists). Escalation of care if necessary to a more experienced practitioner.[18]

Conclusion: Continuous CTG monitoring should be considered in all situations where there is a high risk of foetal hypoxia/acidosis, whether due to maternal health conditions (such as vaginal haemorrhage and maternal pyrexia), abnormal foetal growth during pregnancy, epidural analgesia, meconium stained liquor, or the possibility of excessive uterine activity, as occurs with induced or augmented labour. Continuous CTG is also recommended when abnormalities are detected during intermittent foetal auscultation. CTG analysis needs to be integrated with other clinical information for a comprehensive interpretation and adequate management.

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7. 'Curbing the cut': How to check the spiraling caesarean section rates in India?

Dr. Japleen Kaur: Reproductive Endocrinology and Infertility,
Department of Obstetrics & Gynaecology, Post Graduate Institute of Medical Education & Research (PGIMER), Chandigarh, India.
Dr. Rashmi Bagga: Professor
Department of Obstetrics & Gynaecology, Post Graduate Institute of Medical Education & Research (PGIMER), Chandigarh, India.

Introduction

Cesarean section (CS) rates have been increasing at an alarming rate over the past few decades.[1] Determinants of this change are controversial and are under careful scrutiny. On one hand CS rates have been used as a surrogate marker for indicating access to adequate obstetric services, whereas on the other hand an increased risk of maternal mortality and adverse pregnancy outcomes has been associated with higher CS rates.[2,3]

Cesarean rates in India and worldwide

The worldwide overall CS rate in a World Health Organization (WHO) conducted Global Survey (WHOGS) in Asia in 2007–2008 and in a Multi-Country Survey (WHOMCS) in 2010-2011, has shown a significant rise from 26.4% to 31.2% (p= 0.003), with the exception of Japan.[1,3,4] In these two surveys, data from India included 24,695 and 30,608 deliveries, at 20 health facilities (2 month data for institutes with more than 6000 deliveries per year and 3 month data for those with below 6000 deliveries per year). The respective CS rates were 17.7 % and 19.3%. High CS rates have been commonly observed in the following states in India: Kerala (31.8%), Andhra Pradesh (29.3%) and Tamil Nadu (23.2%), with large variations (up to 20%) between urban and rural areas as well as government and private sector.[5]

Need for reducing CS rates

The optimal CS rate remains controversial in both developing and developed countries even though the WHO (1985) stated that a CS rate above 10–15% is unlikely to improve pregnancy outcomes.[6] The concern over rising CS rates stems from the fact that it is a major surgical procedure with increased short and long-term risks, both for the mother and the newborn.[7] These include increase in the duration of hospital stay, hemorrhage and blood transfusion, thromboembolism, infection as well as anesthetic complications. In subsequent pregnancies, the risk of bladder injury and morbidly adherent placenta increase, thus leading to long-term morbidity and mortality. In addition, CS adds to the expense compared to vaginal delivery.

Understanding the determinants of CS

Determinants of the priori risk of CS include nulliparity, previous CS, multiple pregnancy, induction of labour, malpresentation, and prematurity.[8] Researchers attempting to elucidate the potential causes of the current increasing trend in abdominal delivery, have incriminated factors like cesarean delivery on maternal request, medicolegal concerns, obesity and increasing maternal age.[8,9,10] Thus, many a times there may not be an absolute indication and expectant mothers and the attending doctors are faced with multiple factors both for and against performing the procedure. The common medical indications for CS reported in international literature are non-progress of labour, previous uterine surgery (previous CS / hysterotomy / myomectomy), non-reassuring foetal status and foetal malpresentation in that order whereas studies form India have shown that previous CS, cervical dystocia and foetal distress as more common causes.[11,12]

Proposed strategies aimed at reduction of CS rates

i) **CS audit and feedback:** Labour ward audit cycle should be undertaken with the aim of classifying and assessing labour ward events and outcomes in order to suggest suitable modifications in management. It is based on the principle of Hawthorne effect, which states that if one's actions are knowingly observed, behaviour is likely to change. In a study published from Post Graduate Institute of Medical Education & Research (PGIMER), Chandigarh, a reduction in CS rate was noted in the year after application of caesarean audit compared from the preceding year.[13] A consensus on lack of necessity of CS was achieved in 6.7% cases. Some examples were CS for deep transverse arrest in which a vaginal instrumental delivery could have been attempted and cases of failed induction of labour where cervical ripening was found to be inadequate. Similar results about the usefulness of an audit and detailed analysis of indications of CS, have been published from Sri Lanka.[14] Application of standard systems of audit and classification can help in streamlining the audit and also help in internal and external comparison. The Robson's ten group classification system has been most commonly used for this purpose and also helps in identifying the target groups for interventions to reduce CS rates.[15] It classifies expectant mothers into mutually exclusive groups based on 5 distinct characteristics available on admission, namely single/multiple, nulliparity /multiparity/multiparity with CS scar, cephalic/breech presentation, spontaneous/induced labour onset and term (>37 weeks) gestation. The detailed classification is presented in Table 1.

Table 1: Robson Ten Group Classification System (15)

No. Groups	
1	Nulliparous, single cephalic, >37 weeks in spontaneous labour
2	Nulliparous, single cephalic, >37 weeks, induced or CS before labour
3	Multiparous (excluding previous CS), single cephalic, >37 weeks in spontaneous labour
4	Multiparous (excluding previous CS), single cephalic, >37 weeks, induced or CS before labour
5	Previous CS, single cephalic, >37 weeks
6	All nulliparous breeches
7	All multiparous breeches (including previous CS)
8	All multiple pregnancies (including previous CS)
9	All abnormal lies (including previous CS)
10	All single cephalic, <36 weeks (including previous CS)

ii) **Team approach:** Expertise required in taking the decision to perform a CS may be more than performing the procedure itself. A team-work approach with a mandatory second opinion from a senior obstetrician for all elective or emergency cesareans has been suggested.[16] Written labour ward protocols can guide the doctors on duty for decision making in case of dilemmas. Discussion of difficult case scenarios at seminars and clinical meets are another way of providing useful guidance.

iii) **Comprehensive assessment regarding indication of induction of labour and adequate use of cervical ripening agents is to be encouraged:** The report of the college mother and newborn from Belgium in 2009, had made the following recommendations regarding induction of labour, to check the rising cesarean rates.[16]

a) Informed consent for induction of labour, that involves the mother to be aware of the benefits and possible risks of the procedure.

b) Avoiding inductions before 40 weeks.

c) Assessment of the Bishop's score, to allow inductions only with a minimum score of 6.

d) If the cervix is not ripened even with use of ripening agents, the indication of labour induction should be reviewed and if possible deferred with the same being conveyed to the woman. Increased and judicious use of pre-induction cervical ripening agents like prostaglandins / Foley's catheter for unfavorable Bishop's score has been reiterated by studies from the Asian subcontinent also.[13,14]

iv) Objective assessment of the foetal status in labour: Intrapartum cardiotocography (CTG) must be evaluated in context with the maternal and foetal condition and not in isolation. A senior obstetrician's opinion can be sought in cases of equivocal tracings and if possible foetal blood sampling can be used to complement the CTG findings.[17]

v) Redefining the active phase of labour: Harper et al have demonstrated changing patterns of normal and induced labour over time, suggesting longer times and slower progress compared from Friedman's curves.[18] Thus a change in threshold of active labour was suggested by Sponge et al in the workshop on preventing a first caesarean, conducted under the aegis of National Institute of Child Health and Human Development, the Society for Maternal-Foetal Medicine, and the American College of Obstetricians and Gynecologists.[19] It was recommended that arrest of labour in active phase should be defined after 6 cm instead of the currently used 4 cm, warranting a change in the existing partograph and consequently reducing the CS rate for non-progress of labour.

vi) Encouraging operative vaginal delivery: Operative vaginal delivery with use of forceps and ventouse can help avoid CS when there is a need for expediting delivery or poor bearing down efforts. It is currently underutilized, probably on account of diminishing training and experience. Therefore, it has been recommended time and again, to intensify the supervised training during residency and supplemental training workshops to hone the skills involved in operative vaginal delivery, as a means to reduce CS rates.[19] External cephalic version is progressively being considered 'a lost art'. Although cesarean for breech presentation does not contribute much to the overall cesarean rate on account of small relative size of the group, yet training in this maneuver or allowing assisted breech vaginal delivery in selected patients can prevent some primary cesarean sections.

vii) Employing a trial of labour after cesarean (TOLAC) checklist including careful assessment of adequacy of pelvis and foetal size, to encourage suitable candidates to avoid an elective repeat CS.[14]

viii) Caesarean delivery on maternal request (CDMR): Client choices and even doctor preferences may encourage CDMR. Women may not want to undergo labour pain or wish to plan and choose the exact time of childbirth based on astrological beliefs. In a study, a government medical college in Kolkata reported an overall CS of 40.1%, compared to a private hospital reporting a CS of 72% in 2012.[20] Therefore, counseling the patients about benefits of vaginal delivery, provision of adequate labour analgesia, institution based medico legal reforms might help in reducing elective CS for non-medical indications.[19]

Conclusion: Rising CS rates are definitely a cause for concern. Multifaceted strategies including regular audit and feedback, identification of areas for improvement, application of protocol-based and team approach in labour wards, reinforcement of benefits of vaginal delivery over unindicated cesarean delivery to both the expectant mother and healthcare provider, can help in reducing the cesarean rates without adversely affecting the maternal and neonatal outcome.

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8. Improving the perception of Indian women to induction of labour

Dr. Ajesh N. Desai
Professor and Head of Department, Obstetrics and Gynaecology Dept, GMERS Medical College.
Dr. Shachi A. Joshi
Assistant Professor, Obstetrics and Gynaecology Dept., GMERS Medical College.

Introduction

Induction of labour (IOL) is defined as the interventional provocation of uterine contractions prior to the onset of spontaneous labour with the purpose of achieving vaginal delivery in a safe and timely manner. For decades, IOL has been a challenge to obstetricians, other maternity care givers, and most importantly mother and baby. It can often be a protracted process which makes providing patient-cantered quality-care a great difficulty. This difficulty is expected to increase as the number of women undergoing IOL continue to increase. While in the developed countries the policies and or guidelines are well defined, the developing countries lack the system protocol based management. Three per cent of caesarean sections (CS) in a large Australian population-based study are being performed for failed IOL. This rate is higher in other industrialized countries, with reports from Norway citing an induction failure rate of 4% and about 10% in the USA.[1] The data and studies addressing this issue in developing countries like India are few. Though the policy for induction varies in different countries the method of induction are uniformly followed worldwide.

There is no convincing evidence that the increase in inductions has been associated with improvements in maternal, foetal or neonatal outcomes, and women who are induced tend to be less satisfied with their experience of childbirth.[2] In this context, and with increasing pressure on healthcare resources, it is particularly important to address questions about how to provide safe induction of labour, in settings and ways that are acceptable to women, and in the most cost-effective way possible.[2]

The goal of induction is to achieve a successful vaginal delivery that is as natural as possible.

Induction of labour occurs in two stages: a pre-induction phase involving Cervical ripening followed by induction of uterine contractions. The ideal method to induce labour should be safe, painless, inexpensive, comfortable and effective. The most appropriate method for induction should be tailored to the individual patient's characteristics and needs and based on the clinician's experience. Induction of labour in special cases such as presence of a uterine scar, multiple pregnancy, grand multiparty, refractory inductions or the use of home/office inductions are still areas for debate. Although there is no clear definition, a patient may be considered refractory when no change in cervical score is observed 24 hours after starting induction and labour fails to progress to the active phase. Nulliparity, lower gestational age, low Bishop score and long cervical length are all predictors of unsuccessful induction and therefore can help identify induction-refractory patients.[3]

Review of literature

In a study[4] carried out in a developing country, 81 participants (9.5%) had IOL in a previous pregnancy confirming that the procedure is not uncommon. The rate of IOL varies widely in different countries and units, and between individual obstetricians within the same unit, and the reasons for this variability are not clear. However, such variation may be due to differences in the incidence of the indications for induction, lack of agreement on characterization of definition of various indications (e.g. of post-maturity or hypertension), differences in availability of resources, as well as to unexplained differences in opinion and practice. Nevertheless, there is no agreement or evidence to suggest an ideal rate.

The number of women whose labours are induced has risen dramatically over the past two decades. Rates in the USA and the UK currently exceed 20% of all births.[5] Even further, in some units in the USA, up to 50% of all births follow IOL.[6] However, researchers reporting from African countries have noted rates of <10%; albeit showing the same worldwide trend of progressive increase.[6]

In the study,[7] 442 participants (51.8%) were aware of cervical ripening (CR) and IOL. However, the overall knowledge was sub-optimal; especially regarding membrane sweeping and use of vaginal misoprostol. Perception was also sub-optimal as 84 out of 442 respondents (19.0%) were not aware of the indications of CR and IOL and only 219 (49.5%) believed that IOL prevents CS.

Antenatal healthcare givers constitute a major source of awareness of and knowledge about CR and IOL for pregnant women. Shortage of their services, combined with low level of women's education, is to be blamed for the relatively low level of awareness exhibited in this study. Poor knowledge of specific procedures and methods, and incorrect perceptions may also be related to difficulties of participants' recall, inadequate content of health education sessions or clinic consultation and lack of previous exposure.[8] The later may also explain why, in this study, knowledge was higher in women with a previous history of CR and IOL.

In the study,[7] 189 participants out of 442 (42.8%) considered that labour following IOL was more painful. This perception may be due to one or more of several reasons. It shows only limited choices of pain relief in labour are available in developing countries. Induced labour significantly differs from the physiological spontaneous onset labour, with a longer and often painful latent phase. Prostaglandins may be associated with significant discomfort. Simple analgesia may suffice, but some women will require stronger opiate or epidural analgesia.[9]

Women who are induced tend to be less satisfied with their experience of childbirth.[6] In this context, and with increasing pressure on healthcare resources, it is particularly important to address questions about how to provide safe IOL in settings and ways that are acceptable to women, and in the most possible cost-effective way.[10] Counselling about the cascade of events following IOL and its complications has been perceived as inadequate by parturient. Further, women who had IOL were not satisfied with the information they were given and desired more participation in decision-making.[9,11]

The finding which was reported by the majority of respondents [311 out of 442 (70.4%)] in this study of willingness to accept IOL in the index pregnancy or recommend it to somebody else despite concerns about pain and harm to baby and mother, is perplexing. Especially in developing countries, there is the possibility that willingness to re-experience a procedure is influenced by the recommendations of medical staff members whose knowledge and guidance may completely overwhelm maternal wishes.[12] Maternal autonomy has been noted to be influenced by fear of physician's negative attitude and reaction to refusal, the probability of occurrence of adverse consequences and/or abandonment of care should doctors' advice and recommendations be not followed.[13]

The problems of the developing countries

1. Illiteracy is a major deterrent among pregnant women. It leads to lack of awareness and hence lack of acceptance of IOL methods.
2. The lack of women empowerment renders the pregnant women incapable of taking decisions. Whether she should undergo IOL is decided by her partner and in laws.
3. Most of the maternity care services are provider centric in developing countries like India. What the service provider wants is what the patient is compelled to comply. The attitude in maternity care is information compliance rather than informed consent
4. Social and cultural taboos influence the decision making rather than evidence based data.
5. In many situations, the decision for induction though can be planned are taken in emergency leaving little time for the women to make informed decision.

6. Lack of quality antenatal care also influences the perception and knowledge of IOL

7. There is strong tendency to go for natural births among low socioeconomic population due to belief and customs.

8. Strong private sector presence in our country where health care remains unregulated remains enigma in our set up. This also contributes lack of evidence in evaluating perception of IOL among women taking care in such set up.

Recommendation for improving perception and experience for women undergoing IOL

1. It is recommended to conduct pre induction classes to provide information regarding IOL in cases induction are planned in complicated pregnancy so that women will take informed decision. This will improve perception and experience of women going for IOL.

2. Information technologies like providing brochures in vernacular language, discussion among women who have undergone induction and sharing their experience online, 24/7 help line to answer queries can be considered.

3. Theory of probability of success and failure should be discussed with all women where induction is planned. This should be evidence based and based on documented experience of the service provider. Hence it is necessary to carry out audits in our setup and establish policies accordingly.

4. Women should be given sufficient opportunities to discuss options and make balance decision

5. The transitional period between antenatal admission and actual IOL should be reduced as this increases stress on the pregnant women which may be associated with abnormal outcome. Negative outcome in terms of prolonged and painful labour ending in caesarean section adversely affect the perception and experience in this women.

6. Inductions should not be performed solely because of patient or care provider preference.

7. Institutions should have quality assurance programs and induction policies, including safety tools such as checklists, to ensure that inductions are performed only for acceptable indications.

8. Attendant should be allowed to remain present with pregnant women undergoing IOL as it improves experiences of women in labour and has positive.

9. Outpatient induction should be considered in low risk women as It reduces in patient hospitalisation, reduced workload for labour and delivery units, reduced healthcare costs and higher patient satisfaction. A standard protocol should be followed before the patient leaves the clinic and continuous telephone contact should be available in case of patient queries. Although several studies in the literature have assessed the safety of outpatient induction with various different agents, widespread use of outpatient labour induction cannot be advocated as further studies are required to confirm safety.[14]

Scope for research

1. Effect of evidence based protocol management with provision of brochures on various techniques of IOL in vernacular language on perception of labour.

2. Effect of presence of birth attendant during IOL on perception of pregnant women

3. Effect of Women empowerment and education and analysis of questionnaire based reviews of the experience of labour.

4. Perception of pregnant women undergoing IOL in different situation mentioned below can be undertaken

   a) Uncomplicated but indicated induction

   b) Complicated pregnancy

   c) Post term pregnancy

5. Effect of outpatient induction in low risk cases on experience and perception on pregnant women undergoing IOL.

Conclusion: Several factors influence the perception of women undergoing induction of labour. In developing countries like ours, the lack of awareness, increasing rate of caesarean section and the cost involved in the process of induction are the deterrent factors. The recommendations of better patient counselling and protocol based management should go a long way in improving the attitude of Indian women towards induction. Labour that is artificially induced does result in lower satisfaction rates as compared to that following spontaneous onset. The longer time delay between the start of the induction and the delivery plays a significant part in this, with the mode of administration of the inducing agent, more vaginal examinations and the increase in caesarean deliveries being perceived as secondary issues. There is a need to improve the information provided to women undergoing labour induction, to counter unrealistic expectations and thereby improve satisfaction. Recommendation mentioned above will go in long way to improve perception and have positive outlook towards induction of labour.

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