Maternal and Fetal Outcomes of Various Methods of Induction of Labor in a Tertiary Care Centre

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Abstract: <u>Background</u>: Induction of labor refers to iatrogenic stimulation of uterine contractions before the onset of spontaneous labor as a therapeutic option when benefits of expeditious delivery outweigh the risks of continuing the pregnancy.¹ According to the National Center for Health Statistics, the overall rate of labor induction was 31.4% in 2020 compared to 27.1% in 2018 and 9.6% in 1990.2The rates of induction of labor (IOL) are rising worldwide with arate of 20–30% in developed countries at present .² However, this procedure is not free of risks, which include an increase in operative vaginal or caesarean delivery and excessive uterine activity with risk of fetal heart rate abnormalities³. <u>Material and Methods</u>: An observational Study was conducted at the department of Obstetrics and Gynaecology, Government Medical College, Nagpur with a sample size of 140 patients including all the preterm and term patients admitted in obgy department and were indicated for induction of labor with a study duration of 30 months. Data was entered in MS Excel worksheet, coded and analysed with the statistical software, STATA, version 10.1, 2011 by StataCorp, Texas (USA). <u>Results</u>: There are multiple methods of induction of labor, including mechanical and pharmacological ones and also various standard guidelines on induction of labor. Both of the pharmacological agents, oxytocin and Misoprostol are effective in induction of labor, reducing Caesarean sections and achieving vaginal births, however the risk of hypertonic contractions and hyperstimulations leading to fetal distress was much higher among those involving use of misoprostol particularly among those induced with higher doses of Misoprostol making oxytocin a safer option.

Keywords: IOL: Induction of labor, American college of Obstetrician and Gynecologists, Maternal and fetal outcome

1. Introduction

Induction of labor refers to iatrogenic stimulation of uterine contractions before the onset of spontaneous labor as a therapeutic option when benefits of expeditious delivery outweigh the risks of continuing the pregnancy,¹

The rate of labor induction is steadily increasing and, in industrialized countries, approximately one out of four pregnant women has their labor induced. Induction of labor should be considered when the benefits of prompt vaginal delivery outweigh the maternal and/or fetal risks of waiting for the spontaneous onset of labor⁻³

However, this procedure is not free of risks, which include an increase in operative vaginal or caesarean delivery and excessive uterine activity with risk of fetal heart rate abnormalities.³

Induction of labor (IOL) is certainly one of the most frequently performed obstetric procedures in the world: recent data indicate a percentage of induction of up to 35.5% in Sri Lanka 24.5% in the United States, and from 6.8 to 33% in Europe ^{.2}

The American College of Obstetricians and Gynecologists (ACOG) has an extensive list of recommendations on delivery timing, some of them being, Oligohydramnios (with the timing at 36 0/7 to 37 6/7 weeks),Fetal intrauterine growth restriction (with no abnormal Doppler at 38 0/7 to 39 6/7 weeks , with absent end-diastolic flow at 34 0/7 weeks of gestation and with reversed end-diastolic flow at 32 0/7 weeks or at the time of diagnosis if diagnosed later. Preeclampsia without severe features at 37 0/7 weeks of gestation or at the time of diagnosis if diagnosed later and preeclampsia with severe features with the timing at 34 0/7

weeks of gestation or at the time of diagnosis if diagnosed later.⁴

Few of the contraindications being vasa previa or placenta previa, transverse fetal presentation, history of a prior classical cesarean section, active herpes infection, a previous myomectomy breaching the endometrial cavity or a previous classical Caesarean section.⁴

Two primary methods of induction of labor are mechanical and pharmacological.

Mechanical cervical ripening of the cervix can be done using a Foley catheter or double-balloon device (i.e., Cook catheter) placed through the endocervical canal.[2] Osmotic dilators, Laminaria, and synthetic dilators are also used for cervical ripening and placed in the cervical OS while pharmacological forms of IOL include synthetic prostaglandins and synthetic oxytocin.

Prostaglandins are used for cervical ripening. Misoprostol, prostaglandin E1 (PGE1), and dinoprostone, prostaglandin E2 (PGE2), are used in various doses and routes of administration.³

Oxytocin is administered intravenously in varying dosing regimens (Low dose and high dose regime) to induce labor by stimulating uterine contractions.⁵

There are different guidelines for induction of labor that suggests use of various mechanical and pharmacological methods. Various studies have been conducted worldwide comparing different pharmacological and mechanical methods with varying results. The FOGSI protocol is widely adopted in India due to its evidence-based approach and structured guidelines, ensuring standardized care and typically involves the use of pharmacological agents like

oxytocin and prostaglandins(PgE2 gel form in case of unfavourable cervix)⁵

Ideally, all pregnant women would enter labor spontaneously at the safest time to yield the best health outcomes for both themselves and their newborns. Unfortunately, this does not always happen and leaves obstetric providers weighing the maternal and fetal risks of continued expectant management versus labor induction.⁶

Several elements have been reported to affect the success rate of an induction, including the Bishop score, maternal parity, body mass index (BMI), age, medical comorbidities, fetal gestational age, and estimated weight, as well as the hospital site and provider practice.⁷

2. Materials and Methods

The present study was conducted for a duration of 30 months in the department of Obstetrics and Gynaecology, Government Medical College, Nagpur among 140 Preterm and term patients admitted in the department and are indicated for induction of labor.

Inclusion Criteria

- Singleton pregnancy
- Willing for delivery at the institute
- Willing to participate in the study
- Women with a gestational age more than 28weeks
- Women requiring induction of labor as per any indication mentioned by The American College of Obstetricians and Gynecologists (ACOG)

Exclusion Criteria

- Patients with multiple pregnancies.
- Patients with congenital anomaly of fetus.
- Patient unreliable to follow up.
- Patients not willing to deliver at this institute
- Patients with unreliable LMP and not confirmed by early USG .
- Previous cesarean sections.

After approval from institutional ethical and informed consent from participants indicated for labor, the subjects were taken for study.

The data included gestation age, presenting complaints, USG, outcome, complications, duration of labor, blood transfusions and other interventions if needed were collected then a detailed proforma and data was analyzed.

All patients were followed up from there admission until discharge from the hospital

A thorough physical examination was carried out which including pulse rate, blood pressure in semi recumbent position, pallor, icterus, pedal edema, heart sounds, lung sounds.

Detailed obstetric examination, including per abdominal (height of uterus, presentation, amount of liquor and fetal heart sounds and uterine activity was noted) and pervaginum examination was performed according to which bishop's score was calculated.

Basic investigations like CBC, sickling, liver function tests, kidney function tests. blood grouping and Rh typing, oral glucose tolerance tests and thyroid profile were performed.

Study population was randomised into various induction methods after taking there written consent and patients were followed through there delivery and upto safe discharge from the hospital.

Details of delivery were recorded in the form of preterm or term delivery, Mode of delivery- LSCS and Normal vaginal delivery. Details of Maternal outcome in the form of blood and blood products transfusions, any complications during delivery, postpartum period, ICU admissions and maternal deaths were recorded.

Details of fetal outcome was recorded in the form of live births, term and preterm births, IUD, still birth, NICU admission, complications and neonatal deaths.

Data was collected using case record sheet and was documented, analyzed and interpreted with the statistical software, STATA, version 10.1, 2011 by StataCorp, Texas (USA) as per the laid down protocol. Data obtained from the study was subjected to appropriate statistical analysis so as to facilitate interpretation.

Table 2								
Method of induction	No. of patients	%						
As per the ACOG protocol	77	55						
Not per the protocol	63	45						

3. Results

In the present study out of the 140 cases ,61.4% were the booked patients, while 38.5% being emergency admissions including referrals and unregistered patients.

46.43% were primigravida and 53.57% were multigravida.

27.8% were in the age group of 18 years to 24years, 40.7% were in the age group 25 years to 29years. 22.14% were in the age group 30 to 34 years. 9.3% were in the age group more than 35 years. Hence maximum number was found in the age group 25 to 29year.

In our study, around 55% our patients were induced as per the protocol given by ACOG I.e use of oxytocin low dose or high dose and foley's or use of prostaglandins E2 among unfavourable cervix.Rest were induced with the other methods as mentioned above.

In the present study, out of the 140 cases ,57.8% delivered vaginally and rest 42.2% underwent LSCS due to various indications among which maximum i.e.39% were due to fetal distress and 2% due to non progress of labor.

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Distribution of subjects according to Six Labor Induction Methods							
Method	Procedure	No.	%				
Group A	Pitocin titration and ARM	19	13.57				
Group B	Foley's followed by pitocin and ARM	42	30.00				
Group C	Foley's followed by 1st miso and pitocin and ARM	19	13.57				
Group D	Foley's followed by 1st miso only	27	19.29				
Group E	Foley's induction followed by 2 dose of miso and pitocin	14	10.00				
Group F	Foley's induction followed by 3 dose of miso	3	2.14				
Group G	Cerviprime gel followed by pitocin	16	11.43				
Total		140	100				

Comparison of Maternal Outcomes by Six Induction Methods

Maternal Outcome	2	Group A	Group B	Group C	Group D	Group E	Group F	Group G
LSCS IVO FD	No.	4	4	4	10	4	1	2
	%	21.05%	9.52%	21.05%	37.04%	28.57%	33.33%	12.50%
LSCS IVO MSL	No.	1	5	5	3	6	1	2
	%	5.26%	11.90%	26.32%	22.22%	42.86%	33.33%	12.50%
LSCS IVO MSL-FD	No.	0	0	0	0	1	0	0
	%	0.00%	0.00%	0.00%	0.00%	7.14%	0.00%	0.00%
LSCS IVO non Progress	No.	1	0	1	0	1	0	0
	%	5.26%	0.00%	5.26%	0.00%	7.14%	0.00%	0.00%
NVD	No.	13	33	9	11	1	1	12
	%	68.42%	78.57%	47.37%	40.74%	7.14%	33.33%	75.00%
NVD with MSL	No.	0	0	0	0	1	0	0
	%	0.00%	0.00%	0.00%	0.00%	7.14%	0.00%	0.00%
Total	No.	19	42	19	27	14	3	16
	0/	100 000/	100 000/	100 000/	100 000/	100 000/	100 000/	100 000/

Pearson Chi²(30) = 51.8711, P value = 0.008 (Significant)

In our study it was found that the correlation of with maternal outcome with various methods of induction was statistically significant (P=0.008, Significant).

Maximum study population was in the age group 21-24 years. In our study it was found that the correlation of age with mode of delivery was statistically significant (P= 0.0258, Significant).

Also, parity had a significant correlation with the rate of vaginal delivery, previous vaginal births favours the chances of vaginal delivery.

In our study, use of oxytocin in induction of labor and its correlation with vaginal births showed a statistical significance with the P value = 0.0001.

In our study, the correlation between age groups, parity and Bishop's score among various methods was found to be not significant.

The interval between time of induction and delivery among various methods was not significant. Hence, use of Misoprostol or oxytocin both decreases the interval, however the variation between them was found to be insignificant.

In our study it was found that fetal complications had a significant correlation with the various methods of induction of labor. (Pearson chi2(12) = 22.7386, P value = 0.030 (Significant)).It was found that higher dose of Misoprostol had a higher incidence of neonatal deaths.

4. Discussion

This is an observational study conducted in the department of obstetrics & Gynecology from January 2023-August 2024 at a tertiary care center with the study population of 140 patients admitted in department of OBGY, booked or unbooked through OPD's or emergency in third trimester and requiring induction of labor for various indications.

Patients were induced by various methods involving mechanical or pharmacological methods or their combinations and then divided into various groups according to the method of induction used. 28)

The ARRIVE Trial ⁸(2018) which is a large multicenter trial that examined the outcomes of elective induction of labor at thirty-nine weeks compared to expectant management (waiting for labor to start naturally), found that inducing labor at thirty-nine weeks reduced the risk of cesarean delivery compared to waiting, without increasing adverse outcomes for mothers or babies.

This study was conducted in 140 patients with maximum patients in the age group 21-24 years.

In our study it was found that the correlation of age with mode of delivery was statistically significant (P=0.0258, Significant).

Koo et al. $(2012)^9$ in a cohort study found that advanced maternal age (typically defined as 35 years and older) is associated with a higher risk of cesarean delivery.

The researchers suggested that this increased risk could be due to a variety of factors, including higher rates of medical complications such as preeclampsia, gestational diabetes, and fetal malpresentation in older mothers.

Bayrampour, et al $(2010)^{10}$ in a study concluded that women of advanced maternal age are more likely to undergo cesarean section compared to younger women.

The review cited reasons such as increased rates of labor dystocia (difficult labor) and elective cesareans due to concerns about potential complications in older mothers

In our study, around 55% our patients were induced as per the protocol given by ACOG i.e. use of oxytocin (low dose or high dose along with foley's or prostaglandins E2 gel among unfavourable cervix.) Rest were induced with the other methods as mentioned above.

Various fetal and maternal outcomes i.e. mode of the delivery, duration of induction, fetal complications, neonatal deaths and maternal outcomes were compared.

In our study, use of oxytocin in induction of labor and its correlation with vaginal births showed a statistical significance with the P value = 0.0001 and Pearson chi2(6) = 25.9312.

Alfirevic Z,et al(2013)¹¹ in a systemic review also found that oxytocin is effective in increasing the likelihood of vaginal delivery within twenty-four hours and may reduce the need for cesarean sections in certain contexts, particularly when combined with cervical ripening agents.

32) Meta-analysis by **Wei et al.** (2009) ¹²also found that early administration of oxytocin (before the cervix is fully effaced or dilated) significantly reduced the duration of labor without increasing adverse outcomes and can be beneficial in managing labor.

Study by Adeniji et al. (2011)¹³ also found that while both drugs were effective, oxytocin was associated with a lower incidence of uterine hyperstimulation and abnormal fetal heart rate patterns. Additionally, oxytocin had a more predictable effect on labor progression, which may make it a safer option in certain populations.

The present study showed that the average time interval to the onset of labor and also to the occurrence of vaginal delivery was significantly shorter in the patients induced for labor, however the difference between the time interval among patients induced by various method was not much significant (ANOVA, P = 0.0662, Not significant)

In our study it was found that the correlation of maternal outcomes among various methods of induction was statistically significant. (P=0.008, Significant).

Among total patients induced with oxytocin (low dose or high dose, along with or without use of mechanical method or prostaglandin E2) 6 patients developed hypertonic contractions landing into emergency cesarean sections in view of meconium stained liquor with fetal distress. While among those induced by Misoprostol (single dose or multiple, with or without use of mechanical methods),13 patients developed the same leading to emergency LSCS.

Wing et al. (1995)¹⁴ also found that misoprostol is effective in initiating labor but carries a significant risk of hypertonic uterine contractions (also known as uterine tachysystole), particularly with higher doses. The researchers noted that the incidence of uterine hyperstimulation—defined as excessive uterine contractions that could lead to fetal distress—was higher in women receiving misoprostol compared to other induction agents.

Sanchez-Ramos et al. $(1997)^{15}$ in a randomized trial also found a higher incidence of uterine hyperstimulation (hypertonic contractions) compared to oxytocin. Uterine hyperstimulation was defined as more than five contractions in ten minutes or contractions lasting more than two minutes, which could increase the risk of fetal distress.

In our study it was found that fetal complications had a significant correlation with the various methods of induction of labor. (Pearson chi2(12) = 22.7386, P value = 0.030 (Significant))

It was found that higher dose of Misoprostol had a higher incidence of neonatal deaths due to various causes such as respiratory distress, hypoxic ischema in neonates.

Hofmeyr et al. (2010)¹⁶ in a Cochrane Review found that while both oxytocin and Misoprostol were effective in inducing labor, the use of vaginal prostaglandins was associated with a higher risk of uterine hyperstimulation with fetal heart rate changes, which could lead to fetal distress. Oxytocin, on the other hand, had a lower risk of causing hyperstimulation but was sometimes less effective in achieving vaginal delivery within 24 hours.

ACOG Practice Bulletin No. 107 (2009) reviewed the risks and benefits of various induction agents, including oxytocin, misoprostol, and mechanical methods like Foley catheters and noted that while misoprostol is effective, it is associated with a higher risk of uterine tachysystole (excessive contractions), which can lead to fetal distress. The bulletin recommended careful monitoring and dose adjustments to minimize these risks.

5. Conclusion

The rate of induction of labor is increasing and in industrialized countries, approximately one out of four pregnant women has their labor induced. Induction of labor should be considered when the benefits of prompt vaginal delivery outweigh the maternal and/or fetal risks of waiting for the spontaneous onset of labor.¹⁷

However, this procedure is not free of risks, which include an increase in operative vaginal or caesarean delivery and excessive uterine activity with risk of fetal heart rate abnormalities.

There are multiple methods of induction of labor, including mechanical and pharmacological ones and also various standard guidelines on induction of labor.

Apart from monitoring of the patients induced for labor, one need to be very cautious regarding the correct dosage, titration and the route of pharmacological method.

Both of the pharmacological agents, oxytocin and Misoprostol are effective in induction of labor, reducing Caesarean sections and achieving vaginal births, however the risk of hypertonic contractions and hyper- stimulations leading to fetal distress was much higher among those involving use of misoprostol, particularly among those induced with higher doses of Misoprostol making oxytocin a safer option.

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