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Induction of Labour with intracervical Foley's catheter and intravaginal Misoprostol

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Abstract

Background: Induction of labour is a common procedure in obstractics so there is need to have safe procedure for mother and fetus with least complications. Intracervical insertion of Foley's catheter with intra vaginal misoprostol has been shown to be safe and effective method of cervical priming in the induction of labour. We evaluated indications, effectiveness and outcome of this method in induction of labour

Material and Methods: 100 women were enrolled for the study presented in the department of Obs and Gynecology, Govt. Medical College, Patiala requiring induction of labour. All had singleton pregnancy with cephalic presentation, intact membranes and gestations ≥ 37 weeks. History of caesarean section, uterine surgery and low lying placenta were excluded. Women who had Bishop score <2 , 16 F Foley's catheter was inserted into the cervical canal and 25 µgm of misoprostol was given intra vaginal and repeated 4 hourly maximum of 5 doses. Catheter was left undisturbed until spontaneous explusion or 4 hours after the last dose of misoprostrol. If labour was not induced by above procedure it was considered failed induction.

Results: Out of 100 women 98 had successful induction and 2 had failed induction. 84 had normal virginal delivery and 14 had cesarean section due to various reasons.

Keywords: Foley's Catheter, Misoprostol, Lower segment cesarean section, Induction of Labour

Introduction

Induction of labour is defined as initiation of labour by artificial means prior to spontaneous onset at viable gestational age with aim of achieving vaginal delivery in pregnant women.[1]In developed countries, rate of induction of labour has doubled and it accounts for 25% of all deliveries[2].The goal of induction of labour is to achieve vaginal delivery in a safe timely manner, to prevent unnecessary LSCS and for safe neonatal outcome.[3]Globally it is estimated that approx. 10% of all deliveries involves induction of labour ranging from 1.4% in Nigeria to 35.5% in Srilanka[4]. Induction of labour refers to the process whereby uterine contractions (>3 in 10 minutes each lasting for 30-45 seconds), cervical softening and effacement are initiated by medical or surgical means before the onset of spontaneous labour[5].

Common Indications for Induction of Labour are[4]: Postdated pregnancy, FGR, Pre eclampsia, PROM, Fetal death in utero, Chorioamnionitis, Maternal diabetes, Rh isoimmunisation, Congenital malformation.

Cervical ripening is a complex process that results in physical softening and distensibility of the cervix, ultimately leading to cervical effacement and dilatation[6.]Medical cervical ripening and labour induction should mimic the physiological process of spontaneous ripening and labour as closely as possible[7]. Success of induced labour depends upon the degree of ripening of cervix which can be assessed by Bishop scoring which includes[8]. Cervical dilatation, length of cervix, consistency of cervix, Position of cervix and station of presenting part. Better success for induction of labour occurs with higher scores (maximum Bishop score 13)

Methods of Induction of Labour: Mechanical, surgical, pharmacological and combined methods

1. Mechanical methods: These are among the oldest and most important approach used for induction of labour[1.]

It includes: Hygroscopic Laminaria Tent, Extra Amniotic Saline and Transcervical Foley's Catheter

Advantages of Mechanical methods are low cost low risk of tachysystole, fewer systemic side effects, convenient storage[9], comparable efficacy, no hyperstimulation and can be used in scarred uterus.

Disadvantages are increase risk of maternal and neonatal infection from introduction of a foreign body[10], disruption of a low-lying placenta, maternal discomfort upon manipulation of cervix, frequent need of augmentation of labor[5], Risk of rupture of membrane and cord prolapse.

a) **Hygroscopic Laminaria Tents**: It absorbs the endocervical and local tissue fluids causing the device to expand in the endocervix and provides controlled mechanical dilatation of cervix.[11]

b**) Extra-Amniotic Saline Infusion -** is a procedure in which sterile saline is infused continuously via a catheter placed in the extra-amniotic space.

c) **Transcervical Foley's Catheter**: The mechanical action of Foley's catheter strips the foetalmembrane from the lower uterine segment which cause release of lytic enzymes that act on phospholipid to form arachnoid acid which in turn is converted to prostaglandin A which improves the consistency and effacement of cervix.[5]

The ACOG (2009) guidelines recommend the Foley's catheter as a sensible and effective alternative to prostaglandins for cervical ripening/labour induction (grade A recommendation).[12]

According to WHO recommendations (2011) balloon catheters are recommended for labour induction.

2. Surgical methods: Stripping of the membranes and artificial rupture membrane (ARM).

3.Pharmacological Methods: Prostaglandins, Mifepristone, Oxytocin, Relaxin

i) PGE2 GEL: It is given as endocervical or endovaginal gel.

ii) PGE1 analogue: Misoprostol is used by sublingual, oral, buccal, vaginal and rectal route. Misoprostol is extensively absorbed and undergoes rapid desterification to free acid (misoprostol acid) which is responsible for its clinical activity. Peak plasma concentration occurs after 15-30 minutes. Misoprostol is water soluble. Oral tablets contain 25 microgram, 100 microgram or 200 microgram of misoprostol.

Misoprostol is cheap, widely available, stable at room temperature and ease of administration.

Misoprostol is not used in term pregnancies with a prior cesarean birth or major uterine surgeries because of increased risk of uterine rupture.[13]

Side Effects of Misoprostol includes hypertonicity of uterus, nausea and vomiting, diarrhea, pyrexia and shivering

b) Mifepristone: It is an antiprogesterone agent.

c) Oxytocin: Although oxytocin is a safe and effective initiator of uterine contraction, its success depends upon preinduction cervical score.

d) Relaxin:

4. Combined methods:

a) ARM of membrane with oxytocin augmentation
b) Balloon catheter with prostaglandin E2
c) Balloon catheter with prostaglandin E1
d) Combination of a balloon catheter with oxytocin
e) Balloon Catheter combined with Extra-Amniotic Saline Infusion

The most effective method of cervical ripening in unripe cervix is combination of mechanical methods with prostaglandins. As mechanical devices result in cervical dilatation and PG agents soften and efface the cervix. The combination of the two methods may result in a greater degree of cervix ripening and successful labour induction.

Thus this study was conducted where Foley's catheter was combined with intravaginal misoprostol for induction of labour.

Aims and Objectives

1. To study the effects of intravaginal misoprostol with Foley's catheter
2. To study the adverse effects of above procedure.

Materials and Methods

The present study was conducted in Department of Obstetrics and Gynaecology, Government Medical College, Rajindra Hospital Patiala. 100 women with indication for induction of labourwere enrolled in the study after fulfilling the inclusion and exclusion criteria.

Inclusion criteria

Gestation age ≥37 weeks, Bishop ≤ 4, Singleton pregnancy, Cephalic presentation, Intact membranes, Parity less than 4.

Exclusión criteria

Previous uterine surgery, Placenta Previa, Allergy to prostaglandins, CPD.

Method

100 women were enrolled and detailed history was recorded. Period of gestation was ascertained by LMP and/or earliest ultrasound. A thorough general physical, systemic and obstetrical examination was done. Vaginal examination was done to assign Bishopscore and pelvic assessment.

Under aseptic precaution 16 F Foley's catheter was introduced beyond the internal os and its balloon was inflated with 30-60 ml sterile water. Traction was applied by taping the distal end of the catheter with medial aspect of the thigh.

Simultaneously 25µgm of tablet misoprostol was kept intravaginally into the posterior fornix and the same was repeated every 4 hourly to a maximum of 5 doses (125 microgram) or till adequate uterine contractions were achieved. Catheter was checked for its position and traction at 4-6 hours interval. Intracervical catheter was removed after 24 hrs if it wasn't expelled.

If abnormal pattern of uterine contractions and fetal heart was noted further induction with misoprostol was stopped. If she didn't go into labour by the above method, the method is declared failed.

Partogramwas maintained. Any deviation from normal was recorded. Induction delivery interval was calculated. Mode of delivery and maternal and foetal outcome were recorded.

Observations

Maximum number of subjects were in the age group of 21-25 years. The mean age was 24.32±3.35years.There were 72% primigravidae and 28% multigravida. Majority of the patients were from lower socioeconomic group. The mean gestational age was 39.069 ±1.596

Table 1: Bishop score at start of induction

Bishop Score	Primi	Multi	Total
2	18	8	26
3	31	10	41
4	23	10	33
Total	72	28	100

26% of the cases were with Bishop score 2 at the start of induction of labour.

Preeclampsia was the most common indication for induction of labouri.e. 37%.The second most common indication was postdated pregnancy accounting for 25% of casesfollowed by antepartum hemorrhage and Antepartum Eclampsia (9%)

Table 2: Result of induction of labour

Result	No	%age
Successful induction	98	98.0
Failed induction	2	2.0
Total	100	100.0

Out of 100 women, 98 were induced successfully and had adequate uterine contractions. Two patients didn't go into labour even after 125µgm of misoprostol and the intracervical catheter was removed after 4 hours of observation of last dose of misoprostol. They were induced by alternate method of induction, one of them delivered vaginally and one underwent LSCS due to fetal distress. They were considered as cases of failed induction.

Among 98women who had successful induction 85.71% women had vaginal delivery while 14.29% underwent LSCS due to fetal distress, non progress of labour(NPOL)

38.57% of primigravidae and 42.86% of multigravidae expelled the catheter in 6 hours.25.71% of the primigravidae and 17.86% of the multigravidae took 12-24 hours to expel the catheter. 2.86% of primigravidae and 10.71% of multigravidae landed up in LSCS before expulsion of the catheter due to various indications though they went into labour.

Table 3: Distribution of subjects according to induction delivery interval

Time in hours	No.	%age
6-12 hours	42	50.00
>12-24hours	35	41.67
>24hours	7	8.33
Total	84	100.00

Nearly 50%of subjects delivered in less than 12 hours. majority of the cases,91.67% delivered within 24 hours and only 8.33% of the women needed > 24 hours to deliver. The mean induction delivery interval came out to be 14.58±6.67 hours.

Majority of the cases (45%) delivered with 50µg (2doses) and 30% of the cases delivered with 75µg (3 doses) of misoprostol. The mean dose of misoprostol required for vaginal delivery was 73.73±26.44 µg.

14 patients had caesarean section and the indications were meconium stained liquor, non progression of labour and fetal distress.The Apgar of the newborn delivered by virginal delivery at 1minute was 6.976±3.699 and by LSCS was7.857±2.348.

Asphyxia was seen in 9.18%of the neonates. Neonatal jaundice occurred in 4.08% of the newborn. Around 2% of the newborn had hypoglycemia.

Hypertonicity was observed in 6.12% of the cases. The other less common complications were postpartum haemorrhage, shivering, nausea and vomiting.

Discussion

Induction of labour is a commonly practiced intervention in obstetrics. Induction of labour with unfavourable cervix results in prolonged labour and increased rate of cesarean section, more so in primigravidae. With time various methods of induction of labour came into practice. Each method has certain advantages and disadvantages. So no single method of labour induction can be called superior to the other. We conducted this study in our department and found that use of a combination of the Foley's catheter and vaginal misoprostol for induction of labor shortened induction-to-delivery time by an average of 5 hours.

In our study the mean age came out to be 24.32±3.354years.And is particularly comparable with the study of Carbone JF[4] and Charaya E[2] regarding mean age and differs slightly from other authors[14,15,18]

In the present study, the mean gestational age is 39.069 ±1.596 weeks. It is found to be concordant with the other studies[1,3,14,15,18]

Table 4: Bishop score at the start of induction

Author name and year of Study	Bishop Score
Charaya E (2016)[1]	2.50±1.35
Present study (2016)	3.0700±.76877

In our study bishop score was 3.0700±.76877 which was comparable to the study conducted by Charaya E (2016).[1]

In the present study the main indications for induction of labour were preeclampsia in 37% and postdated pregnancy in 25% which were also the main factors for induction in other studies[3,14]

while Kehl S[18] also had post dated pregnancy as main indication for induction of labour but the incidence of preeclampsia in his study was just 1.99%.In our study APE (9%) and APH (11%) were other main indications for induction of labour.

Gestational diabetes mellitus (GDM)was the other common indication for induction of labour in study by Carbone JF[4] and Kehl S[18] while in the study conducted by Baron B[41] the other common indication was Fetal growth restriction (FGR) whereas in our study GDM and FGR were the indications in 2% and 3% respectively.

Table 5: Induction delivery interval of subjects in various studies

Author name and year of study	
Chung et al(2003)[15]	16.6 ± 8.2 hrs
Ande A(2012)[16]	514 ± 175 mins
Carbone F (2013)[3]	15.3 66.5 hrs
Kehl S(2015)[18]	32.43 hrs
Lanka S (2014)[17]	26.52 hrs
Charaya E (2016)[1]	11.76±5.89 hrs
Present Study (2016)	14.58±6.67 hrs

In the present study, the mean induction delivery interval came out to be 14.58±6.67 hours.

The present study is consistent with studies done by Carbone JF[4], Ande A[16]and Charaya E[2]study.

Table 6: Vaginal delivery rate within 24 hours

Author name and year of study	%age
Baron B (2003)[14]	45.00%
Carbone F (2013)[3]	89.10%
Charaya E (2016)[1]	92.00%
Present Study (2016)	91.67%

In our study 91.67% cases were delivered within 24 hours. Our results are concordant with the studies done by CharayaE[2] and Carbone JF.[3]

Chung et al,[15] Baron B,[14] Carbone JF[4] studies have shown higher LSCS rate while Kehl S[18] and Ande A[16]studies have shown lesser LSCS rate.

In our study, 85.71% cases had successful vaginal delivery. LSCS required in 14.29% of cases after successful induction. These results are comparable to Charaya E2 study.

In our study the mean dose of mesoprostol required was 76.78 µg whereas the mean dose required for induction of labour in the study conducted by Kehl S (2015)[18] was 100 µg.

The incidence of uterine hypertonicity in our study was 6.12% and 5.05% which was comparable to the study conducted by Baron B[14], but much lesser than the incidence found in the study by Chung et al (2003).[15]

Conclusion

It is concluded from the present study that intracervical catheter and misoprostol combination is better for induction of labour with unfavourable Bishop score. The Induction delivery interval and mean amount of misoprostol are reduced. Rate of cesarean section, maternal and fetal complications were less. Hence combination of Foley's catheter and vaginal misoprostol is a good option for patients with unfavourable Bishop score undergoing induction of labour.

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