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Induction of labour in Unfavourable cervix at Government Maternity Hospital, Tirupathi

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Abstract: *Induction of labour is one of the most common obstetric interventions. The incidence of induction varies from setting to setting ranging from 5% to 22% of all labour room admissions and depends upon the institutional protocol[1].*

Aims: *1.To compare the risk of caesarean delivery after induction of labour in women with unfavourable cervix to that of women with favourable cervix.*
2.To compare the efficacy of induction methods used in women with unfavourable cervix.

Methodology: *This study was performed on 324 mothers,who fulfilled the inclusion criteria mentioned who were admitted to Government Maternity Hospital affiliated to the Department of Obstetrics and Gynaecology,Sri Venkateswara Medical College Tirupathi.The mothers with favourable cervix(Bishop score >=5) were included in Group 1,which consisted of 162 mothers.The mothers with unfavourable cervix (Bishop score <5) were included in Group 2 which were further classified in to 3 sub groups.Group 2A consisted 54 mothers in whom induction was done using Foley catheter.Group 2B consisted of 54 mothers in whom induction was Dinoprost Gel was used as a cervical ripening agent.Group 2C consisted of 54 mothers in whom Tab.Misoprostol was used.*

Results*: The cesarean delivery is 16% in favourable cervix and 29.6% in unfavourable cervix which is statistically significant. The estimated Relative risk for cesarean delivery in unfavourable cervix group is* ***1.96 times*** *compared to favourable cervix group which is* ***statistically significant.***

The change in Bishop Score (before and after induction) in Group 2A was 3.31 ± 0.567 ,in Group 2B was 3.08 ± 0.83,in Group 2C was 5.93 ± 1.071 and the change was statistically significant.The change in Bishop score was high in Group 2C and statistically significant.

The Induction to Active phase Interval in Group 2A is 7.09 ± 3.638hrs(Range 2.33 - 24.00hours) ,in Group 2B is 8.01 ± 1.412hrs (Range 5.00 - 10.83hours) ,in Group 2C is 8.55 ± 2.707hrs (Range 3.00 - 15.00hours) .Thus Group 2A had shorter Induction to Active phase interval than Group 2B and Group 2C and the difference was statistically significant.The Induction to Delivery Interval in Group 2A is 13.42 ± 3.659 hrs(Range-5.17 - 28.00 hours) ,in Group 2B is 15.42 ± 3.253 hrs (Range-7.00 - 20.50hours) ,in Group 2C is 15.94 ± 5.995 hrs (Range-4.00 – 29.00 hours) .Thus Group 2A had shorter Induction to Delivery interval than Group 2B and Group 2C and the difference was statistically significant. The neonatal complications were higher in Group 2(26%) compared to those in Group 1(16%),but the difference was not statistically significant. The neonatal complications were highest in Group 2C(44.4%) and least in Group 2A(24.1%).The maternal complications were higher among Group 2(10.5%) compared to those in Group 1(9.9%). Maternal complications were highest among Group 2B(13%) and lowest among Group 2A(7.4%).

Conclusion: *There is a significant increase in the risk of cesarean delivery in induction of labour with unfavourable cervix compared to those with favourable cervix. Induction with Foley catheter found to be effective method in unfavourable cervix in terms of lesser Induction to active phase interval,Induction to delivery interval,neonatal and maternal complications. ,Misoprostol found to be effective in terms of significant change in pre and post induction Bishop scores and lesser cesarean delivery rate.Further research is needed with larger sample size involving different institutions and research on the preventive aspects of cesarean section in unfavourable cervix .*

Keywords: *unfavourable cervix,Favourable cervix,caesarean section.*

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I. Introduction

Induction of labour is one of the most common obstetric interventions. The incidence of induction varies from setting to setting ranging from 5% to 22% of all labour room admissions and depends upon the institutional protocol[1]. In developed countries, the number of infants delivered at term following induction of labor can be as high as one in four deliveries[2]. The World Health Organization (WHO) Global Survey on Maternal and Perinatal Health, conducted in 24 countries which included nearly 3,00,000 observations, showed that 9.6% of them were delivered by labor induction[3]. Induction of labor has merit as a therapeutic option when the benefits of expeditious delivery outweigh the risks of continuing the pregnancy.The benefits of labor induction must be weighed against the potential maternal and fetal risks associated with this procedure[4].The infant should be delivered in good condition in an acceptable time frame and with a minimum of maternal discomfort and side effects. Alternatively labour induction may be complicated by uterine tachysystole, uterine hyperstimulation with fetal heart rate abnormalities or fetal distress, prolonged labour, prolonged membrane rupture**,** chorioamnionitis and cesarean delivery. Because of the presence of underlying maternal and fetal medical conditions leading to induction and because the uterus and uterine cervix are often not prepared for labour when induction becomes necessary it may be associated with prolonged labour and a significantly increased risk of cesarean delivery when compared to women entering labour spontaneously[5,6].

With primary cesarean delivery rate on the rise and a trend towards declining attempted vaginal birth after cesarean section avoidance of an unnecessary first cesarean delivery has important implications for both current and future pregnancies.

Successful labour is clearly related to the state of cervix. A 'ripe' soft yielding cervix requires a lower quantum of uterine work than an 'unripe', hard and rigid one would. An unripe cervix fails to dilate well in response to myometrial contraction[7]. Women with an unfavourable cervix have increased risk of induction failure and increased risk of cesarean delivery. Studies about induction of labour and caesarean delivery showed varied results most of them concluded and increased incidence of caesarean delivery after induction. The purpose of this study is to explore the risk of cesarean delivery after induction of labour in an unfavourable cervix and to compare the efficacy of induction methods used in unfavourable cervix.

II. Material And Methods

The present prospective comparative study was carried out in nulliparous and multiparous women at term with singleton pregnancy admitted to labour ward and to Antenatal ward,Government Maternity Hospital affiliated to the Department of Obstetrics and Gynaecology,Sri Venkateswara Medical College,Tirupathi for a period of one year from November 2017 to October 2018 after obtaining permission from the Institutional Ethical Committee.It is a tertiary teaching centre where each year around 13000 to 14000 deliveries take place.

Aims: 1.To compare the risk of caesarean delivery after induction of labour in women with unfavourable cervix to that of women with favourable cervix.

2.To compare the efficacy of induction methods used in women with unfavourable cervix.

Objectives:

1. To record and compare the number of caesarean deliveries after induction of labour in women with unfavourable cervix to that of women with favourable cervix.
2. To determine the a)Induction-active phase interval

a. Induction-delivery interval
b. maternal outcome in terms of PPH,perineal tears,sepsis
c. Fetal outcome in terms of low APGAR,SNCU admissions,NICU admissions among the three induction methods used in those with unfavourable cervix.

Study Design: Prospective Comparative study

Study Location: This was a tertiary care teaching hospital based study done in the Department of Obstetrics and Gynaecology at Government Maternity Hospital, Tirupati,Andhra Pradesh,India

Study Duration: November 2017 to October 2018.

Sample size: 324 patients.

Sample size calculation: The sample size calculated assuming the target population to be 12000 and hypothesized % frequency of outcome factor in the population being 70%+/-5 at a confidence level of 95%was 315.We planned to include 324 patients (Group I- Control, Group II- Cases of 162 patients for each group) after excluding 6 subjects who left against the medical advice,5subjects who were excluded because of confounding factors like nonspecific interventions,change in presentations of fetuses.

Inclusion criteria:

a) Nulliparous and multiparous women
b) Singleton pregnancy.
c) Gestational age between 37 and 42wks.
d) Live fetus.
e) Vetex presentation
g) Having indication for induction of labour
h) Adequate pelvis
i) Reassuring FHR.

Exclusion criteria:

a)Those women not giving consent for the study.
b)Contraindications for induction of labour:

1) Cephalo pelvic disproportion
2) Fetal malpresentation – Breech presentation, transverse lie,oblique lie.
3) Placenta previa or vasa previa
4) Cord presentation
5) Previous h/o uterine scar

c)Heart disease to the patient
d)Active genital herpes infection
e)Intrauterine fetal demise
f)Fetal anomalies
g)Medical contraindication/known hypersensitivity to oxytocin or prostaglandins.

III. Methodology

Subjects in the alloted ward of the investigator and those admitted during round the clock duties of the investigator fulfilling the inclusion criteria were enrolled after taking informed consent and were followed through out their delivery and in their post natal period till discharge from hospital by the investigator.The subjects were alloted by statified selective sampling method to Group1 (those mothers with a favourable cervix i.e.,Bishop score ≥5) and to Group 2 (those mothers with an unfavourable cervix i.e.,Bishop score <5).Once a subject with favourable cervix was alloted to Group 1,the next subject with an unfavourable cervix was alloted to Group 2.The subjects in Group 2 were consecutively alloted to sub groups 2A,2B and 2C depending on the type of cervical priming induction method used-2A-induced with Foley Cathetor,2B-induced with Dinoprost Gel and 2C-induced with Tab.Misoprostol 25µg.The relevant information of the subjects-detailed history,general examination,obstetric examination,investigations,progression of labour and their follow up are noted down . Management of labour was at the discretion of the labour ward team on duty.Clinical findings of the senior most Medical Officer or Senior resident was recorded for the study.

In Group 1 subjects with a favourable cervix,labour was allowed to progress either spontaneously or augmented with Artificial Rupture of Membranes and use of Oxytocin and a combination of both.

In Group 2A subjects no-16 Foley cathetor was inserted under strict aseptic precautions by direct visualisation with the assistance of a speculum and the balloon was inflated with60ml of distilled water and retracted into the cervical os to facilitate the balloon resting on the internal cervical os and the cathetor was taped to the patient's inner thigh.They are closely monitored for maternal vital signs,progress of labour and fetal heart rate by intermittent auscultation.spontaneous expulsion of ballon was awaited or any balloon in vagina removed during pervaginal examination after 12 hrs of insertion.

In Group 2B labour was induced by application of Dinoprost Gel 0.5mg(PGE2) in to the posterior fornix under strict aseptic precautions and direct visualisation using a speculum.women is allowed to be in supine position for 30 min. They are closely monitored for maternal vital signs,progress of labour and fetal heart rate by intermittent auscultation.In cases of inadequate uterine action,the dose is repeated every 6th hrly for a maximum of 3doses in 24Hrs.

In Group 2C labour was induced by Tab.Misoprostol (PGE1)25µg kept per vaginally and the dose repeated every 4-6th Hrly for a maximum of 6 doses.In subjects with Premature Rupture Of Membranes,tablet is given orally.

In all the three methods,when cervix is ripened without adequate uterine action,augmentation of labour is done with Oxytocin(in not less than 4hrs of induction).Oxytocin drip is prepared by adding 2.5U Oxytocin to 500ml of Ringer Lactate solution,labelled and started at a rate of 10 drops per minute and increased every 30 min by 10 drops till 60 drops/min until adequate uterine contrations are achieved.If still there is no adequate

uterine action,second drip is prepared by adding 5U Oxytocin to 500ml of Ringer Lactate solution,labelled and started at a rate of 30 drops per minute and increased every 30 min by 5 drops till 60 drops/min.

In any of the groups at any stage in case of fetal distress or uterine abnormality or any side effects noted,induction is stoped and decision for cesarean delivery considered at the discretion of the consultant obstetrician.

For the study purpose,uterine action was considered satisfactory if 2-3 contractions occur in 10 min period and each contraction lasts for >30 seconds and unsatisfactory if the above said criteria was not satisfied.

Tachysystole was defined as >5 contractions per 10 minute period averaged over 30 min window.This is further sub divided in to two categories, one with and one without fetal heart rate changes.

Non Reassuring Fetal Heart Rate was confirmed using CTG when the non reactive pattern occurs.

Failed Progression of labour is defined as lack of progressive cervical dilatation or lack of fetal descent and abnormal labour pattern as follows-

- Prolonged latent phase->20hrs in nulliparous women and >14hrs in multiparous women
- Protracted active phase dilatation- <1.2 cm/hr in primigravidae and <1.5 cm/hr in multigravidae
- Protracted descent in active phase- <1cm/hr in primigravidae and <2 cm/hr in multigravidae
- Secondary arrest of dilatation for >2hrs
- Secondary arrest of descent in second stage of labour for >1hr.

Ethical considerations: Ethical committee permission was obtained on from the Institutional Ethical Committee,Sri Venkateswara Medical College,Tirupathi.

Statistical analysis: Data was entered in MS Excel 2007 Microsoft corporation Publication.Results were analysed using SPSS software.ANOVA,paired t test,chi square test were used.For continuous data averages were calculated,for categorical data frequencies were calculated.percentages were corrected to decimals for convenience.

IV. Results

This study was performed on 324 mothers,who fulfilled the inclusion criteria mentioned (after excluding 6 subjects who left against the medical advice,5subjects who were excluded because of confounding factors like nonspecific interventions,change in presentations of fetuses)who were admitted to Government Maternity Hospital affiliated to the Department of Obstetrics and Gynaecology,Sri Venkateswara Medical College Tirupathi.The mothers with favourable cervix(Bishop score >=5) were included in Group 1,which consisted of 162 mothers.The mothers with unfavourable cervix (Bishop score <5) were included in Group 2 which were further classified in to 3 sub groups.Group 2A consisted 54 mothers in whom induction was done using Foley catheter.Group 2B consisted of 54 mothers in whom induction was Dinoprost Gel was used as a cervical ripening agent.Group 2C consisted of 54 mothers in whom Tab.Misoprostol was used.

Table No. 1 : Distribution of subjects in to groups

Group	No. of Mothers	Percentage
Group 1	162	50.0
Group 2A	54	16.7
Group 2B	54	16.7
Group 2C	54	16.7
Total	324	100.0

Graph No.1: Distribution of primi and multigravidae among the groups

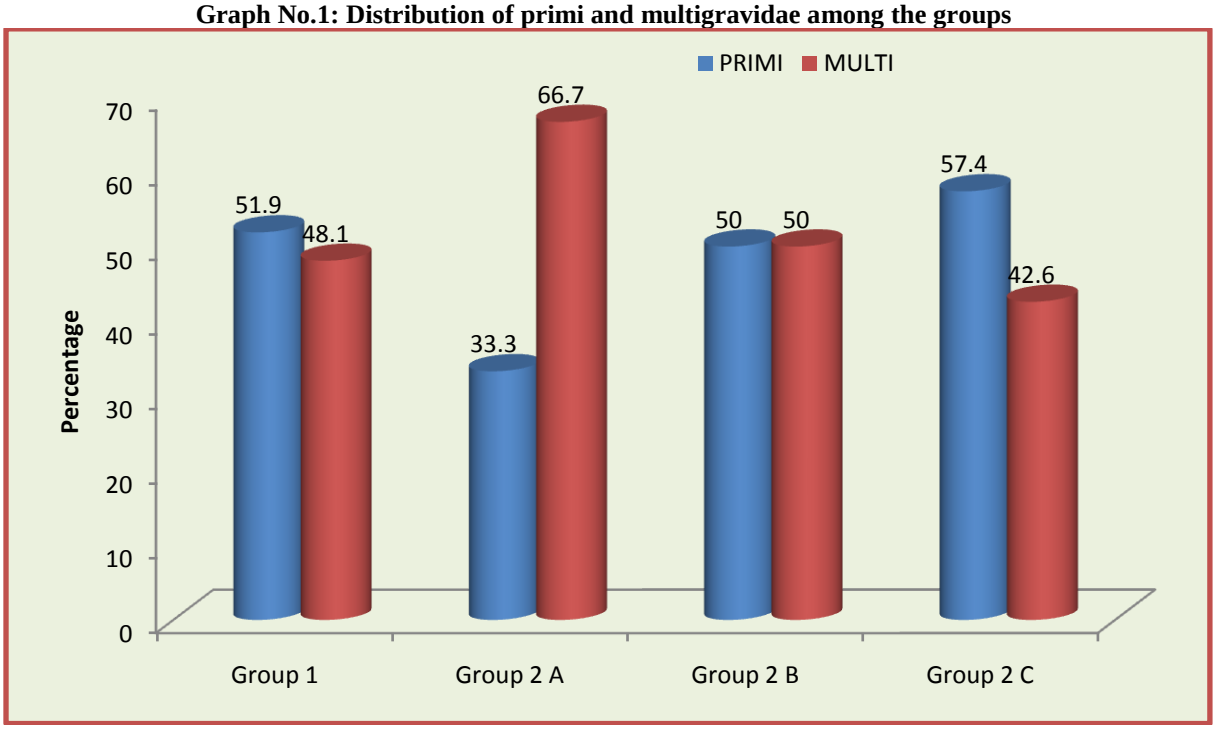


Table No. 2 : Demographic Characteristics among different groups

Demographic Parameters	Group 1 Mean ± SD	Group 2A Mean± SD	Group 2B Mean± SD	Group 2C Mean ± SD	p-value
Age(yrs)	21.73± 2.821	25.22 ± 3.413	25.33 ± 4.287	**25.65 ± 4.426**	f=29.843 *p<0.001
Gestational Age (wks)	39.38± 3.059	39.87 ± 1.332	**39.91 ± 1.719**	39.44 ± 1.208	f=1.019 p>0.001
Bishop Score at Induction	**7.02± 1.396**	2.89 ± 0.904	2.96 ± .699	**2.72± 0.763**	f=362.747 *p<0.001

*significant at 0.01 level;

Data presented as mean(±standard deviation) student t test used.Statistically significant differences existed between the groups in age and Bishop score at induction.

Table No.3: Characteristics of delivery in Group I

Bishop Score at Admission	No. of Mothers n (%)	Admission to Delivery Interval (Hrs –min)	p-value
≤ 6	52 (32.10)	5.31 ± 1.98	t =5.294 (*p<0.001)
≥ 7	110 (67.90)	**3.99** ± 1.17	

*significant at 0.01 level;

The table shows that the mothers with Bishop score ≥ 7 delivered within 4 hrs of admission.

Table No.4: Method of augmentation of labor and mode of delivery in Group 1

Method of augmentation in Group 1	Mode Of Delivery					
	NVD		Instrumental		LSCS	
	n	%	n	%	n	%
Spontaneous	74	**59.7**	4	33.3	9	**34.6**
Oxytocin	23	18.5	1	8.3	8	30.8
ARM	0	.0	0	.0	2	7.7
ARM + Oxytocin	27	21.8	7	**58.3**	7	26.9
Total	124	100.0	12	100.0	26	100.0

The table shows that more number of LSCS (34.6%) and Normal Vaginal Delivery(59.7%)occurred in spontaneous progression of labor and more number of instrumental delivery occurred in ARM+Oxytocin augmentation of labour in Group 1.

Table No.5: Indications for Induction in group 2

Indication for Induction	GROUP		
	Group 2A n (%)	Group 2B n (%)	Group 2C n (%)
APE (Ante Partum Eclampsia)	2 (3.7)	2 (3.7)	1 (1.9)
MPE (Mild Pre Eclampsia)	14 (25.9)	8 (14.8)	2 (3.7)
GDM (Gestational Diabetes Mellitus)	1 (1.9)	2 (3.7)	0 (.0)
GHTN(Gestational Hypertension)	6 (11.1)	6 (11.1)	3 (5.6)
Imminent Eclampsia	1 (1.9)	2 (3.7)	1 (1.9)
IUGR(Intra Uterine Growth Retardation)	2 (3.7)	1 (1.9)	0 (.0)
Past dates	19 **(35.2)**	17 **(31.5)**	10 (18.5)
Oligohydramnios	2 (3.7)	4 (7.4)	1 (1.9)
PROM (Premature Rupture Of Membranes)	0 (.0)	0 (.0)	28 **(51.9)**
Rh Negative	3 (5.6)	4 (7.4)	0 (.0)
Severe PE(severe Pre Eclampsia)	4 (7.4)	8 (14.8)	8 (14.8)
Total	54 (100.0)	54 (100.0)	54 (100.0)

The table shows that Past Dates is the most common indication for induction in Group 2A (35.2%) and Group 2C(31.5%) and PROM(Premature Rupture Of Membranes) is the most common indication for induction in Group 2C(51.9%).

Table No.6: Change in Bishop score before and after induction

Bishop Score	GROUP			P-value
	Group 2A	Group 2B	Group 2C	
Pre-induction	2.89± 0.904	2.96± .699	2.72± .763	f-value = 706.84 (*p<0.001)
Post-induction	6.20± 1.471	6.04± 1.529	8.65± 1.834	f-value = 1063.569 (*p<0.001)
Mean difference	3.31 ± 0.567	**3.08 ± 0.83**	**5.93 ± 1.071**	f-value = 188.22 (*p<0.001)

*Significant at 0.01 level.

The change in Bishop Score (before and after induction) in Group 2A was 3.31 ± 0.567 ,in Group 2B was 3.08 ± 0.83,in Group 2C was 5.93 ± 1.071 and the change was statistically significant.The change in Bishop score was high in Group 2C and statistically significant.

Table No.7: Induction to Active phase Interval

	Group 2A (n=53)	Group 2B (n=51)	Group 2C (n=50)
Range	2.33 - 24.00	5.00 - 10.83	3.00 - 15.00
Mean ± SD	**7.09 □ 3.638**	8.01 □ 1.412	**8.55 □ 2.707**
p-value	F-value = 3.691; p=0.027; P< 0.05 significant at 0.05 level.		

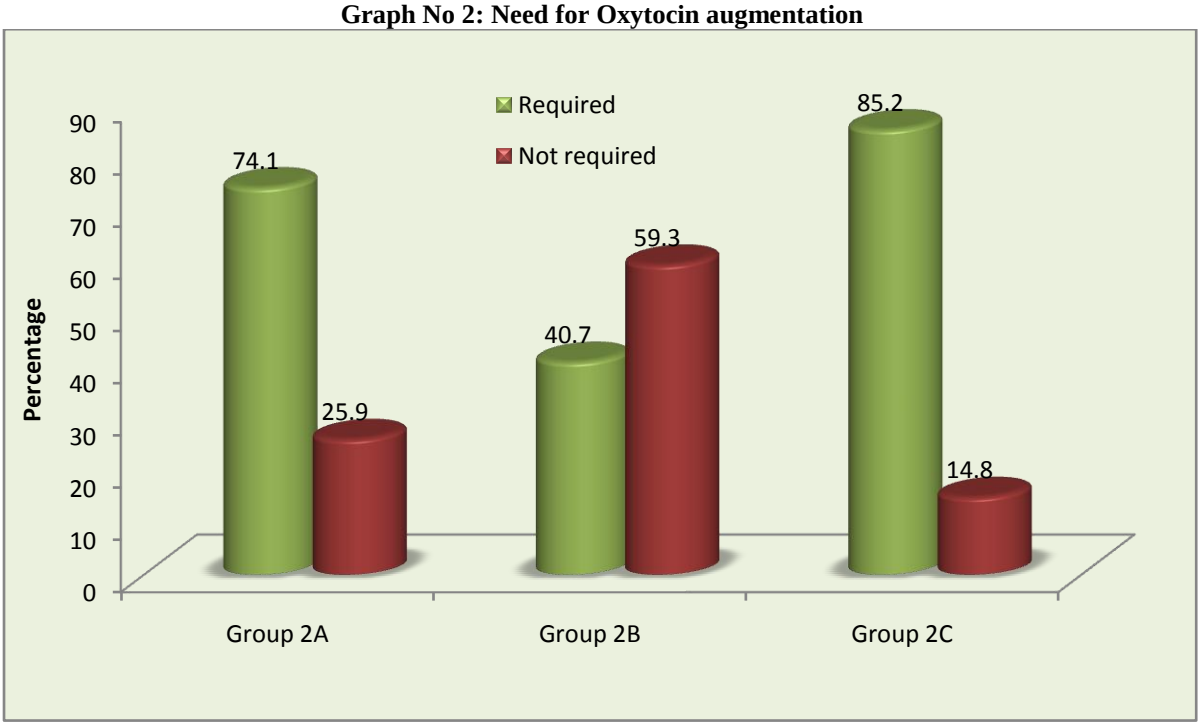
The Induction to Active phase Interval in Group 2A is 7.09 ± 3.638hrs(Range 2.33 - 24.00hours) ,in Group 2B is 8.01 ± 1.412hrs (Range 5.00 - 10.83hours) ,in Group 2C is 8.55 ± 2.707hrs (Range 3.00 - 15.00hours) .Thus Group 2A had shorter Induction to Active phase interval than Group 2B and Group 2C and the difference was statistically significant.

Table No.8: Induction to Delivery Interval

	Group 2A (n=53)	Group 2B (n=51)	Group 2C (n=50)
Range	5.17 - 28.00	7.00 - 20.50	4.00 – 29.00
Mean ± SD	**13.42 □ 3.659**	15.42 □ 3.253	**15.94 □ 5.995**
p-value	F-value = 4.766; p=0.010; P< 0.05; significant at 0.05 level		

The Induction to Delivery Interval in Group 2A is 13.42 ± 3.659 hrs(Range-5.17 - 28.00 hours) ,in Group 2B is 15.42 ± 3.253 hrs (Range-7.00 - 20.50hours) ,in Group 2C is 15.94 ± 5.995 hrs (Range-4.00 – 29.00 hours) .Thus Group 2A had shorter Induction to Delivery interval than Group 2B and Group 2C and the difference was statistically significant.

Graph No 2: Need for Oxytocin augmentation



The graph shows that the need for augmentation of labor with oxytocin drip was maximum for Group 2C.

Table No.9: Outcome of labour among favourable and unfavourable cervix groups

Mode of delivery	Group 1						Group 2					
	Primi		Multi		Total		Primi		Multi		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
NVD	67	41.4	57	35.2	124	76.5	38	23.5	55	34.0	93	57.4
Instrumental	8	4.9	4	2.5	12	7.4	10	6.2	11	6.8	21	13.0
LSCS	9	5.6	17	10.5	26	16.0	28	17.3	20	12.3	48	29.6
Total	84	51.9	78	48.1	162	100.0	76	46.9	86	53.1	162	100.0
Chi-square	$\chi2$= 4.385; (p=0.112); df= 2 P>0.05 Not significant						$\chi2$= 3.886; (p=0.143); df= 2 P>0.05; Not significant					

Mode of delivery	Group 1 n(%)	Group 2 n(%)	significance
LSCS	26**(16%)**	48**(29.6%)**	**p<0.01 *significant at 0.01 level.**

Thus the cesarean delivery is 16% in favourable cervix and 29.6% in unfavourable cervix which is statistically significant.

But the differences among primigravidae and multigravidae in the mode of delivery is not statistically significant.

Table No.10: Relative risk of cesarean delivery among favourable and unfavourable cervix groups

Mode of delivery	Group 1	Group 2	Estimated relative risk (95% CI)
LSCS	26	48	1.96 (1.29 – 2.98)
Vaginal delivery	124	93	

Relative risk	1.9640
95% CI	1.2927 to 2.9839
z statistic	3.163
Significance level	P = 0.0016
NNT (Harm)	5.985
95% CI	14.527 (Harm) to 3.769 (Harm)

*(p<0.001)

The estimated Relative risk for cesarean delivery in unfavourable cervix group is **1.96 times** compared to favourable cervix group which is **statistically significant.**

Table No .11: Indication for LSCS among different groups

Indication	Group I		Group 2	
	n	%	n	%
Cord prolapse	2	7.69%	0	0.0
FTP (Failure to progress)	10	38.46%	16	33.33%
Fetal distress (NRFAR+NRFHR+NSL)	12	46.15%	24	50%
Secondary Arrest of present	1	3.84%	1	2.08%
IUGR	0	0%	2	4.16%
Deflexed head	1	3.84	2	4.16%
Others	0	0	3	6.25%
Total	26	100	48	100%

Fetal distress is the most common indication for LSCS in both the groups.

Table No .12: Outcome of labor among unfavourable cervix groups

MOD	GROUP								
	Group 2A			Group 2B			Group 2C		
	Primi	Multi	Total	Primi	Multi	Total	Primi	Multi	Total
	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
NVD	9 (16.7)	22 (40.7)	31 (57.4)	10 (18.5)	17 (31.5)	27 (50.0)	19 (35.2)	16 (29.6)	35 (64.8)
Instrumental	2 (3.7)	5 (9.3)	7 (13.0)	4 (7.4)	5 (9.3)	9 (16.7)	4 (7.4)	1 (1.9)	5 (9.3)
LSCS	7 (13.0)	9 (16.7)	16 (29.6)	13 (24.1)	5 (9.3)	18 (33.3)	8 (14.8)	6 (11.1)	14 (25.9)
Total	18 (33.3)	36 (66.7)	54 (100)	27 (50.0)	27 (50.0)	54 (100)	31 (57.4)	23 (42.6)	54 (100.0)
Chi-square	$\chi 2$= 1.111; (p=0.574); df= 2 P>0.05; Not significant			$\chi 2$= 5.481; (p=0.06); df= 2 P>0.05; Not significant			$\chi 2$= 1.184; (p=0.553); df= 2 P>0.05; Not significant		

Thus the cesarean delivery is highest in Group 2B(33.3%) and lowest in Group 2C(25.9%),but the difference is statistically not significant. The differences among primigravidae and multigravidae in the mode of delivery is also not statistically significant.

Graph No 3: percentages of LSCS among different groups

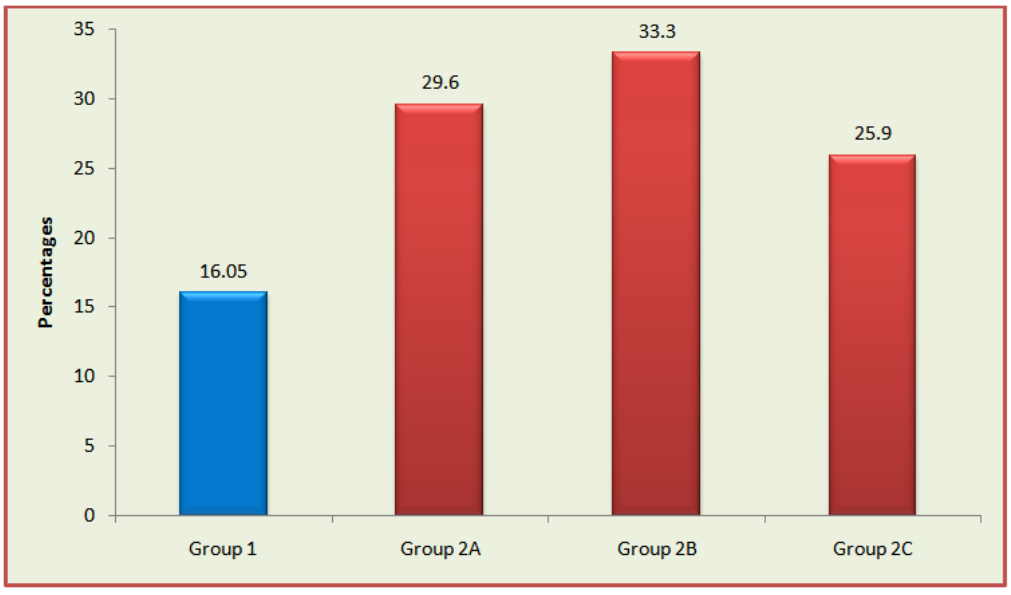


Table No .13: Neonatal variables

Variables	Group 1	Group 2A	Group 2 B	Group2 C
Mean birth Weight (kg)	2.75 ± 0.286	2.84 ± 0.593	2.90 ± 0.453	**3.13 ± 0.339**
APGAR	n (%)	n (%)	n (%)	n (%)
8-10	144 (88.9)	41 (75.9)	41 (75.9)	49 **(90.7)**
6-8	17 (10.5)	12 **(22.2)**	11 (20.4)	5 (9.3)
4 – 6	0 (0.0)	1 (1.9)	2 (3.7)	0 (0.0)
2 - 0	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)

Table No.14: Neonatal complications among favourable and unfavourable cervix

Neonatal complications	GROUP				p-value
	Group 1		Group 2		
	n	%	n	%	
NICU	4	2.5	2	1.2	t = 1.5619
SNCU	14	8.6	28	17.3	p=0.008
MAS	3	1.9	5	3.1	P>0.05
IUGR	3	1.9	5	3.1	Non significant
Still Birth	1	0.6	1	0.6	
Others	1	0.6	1	0.6	
Total	26	**16.0**	42	**26.0**	

The neonatal complications were higher in Group 2(26%) compared to those in Group 1(16%),but the difference was not statistically significant.

Table No.15: Neonatal complications among unfavourable cervix groups:

Neonatal complications	GROUP						F-value
	Group 2A		Group 2B		Group 2C		
	n	%	n	%	n	%	
NICU	2	3.7	0	.0	0	0.0	F-value =0.037
SNCU	9	16.7	8	14.8	11	20.4	P =0.963
MAS	1	1.9	3	5.6	12	**22.2**	(P>0.05)
IUGR	1	1.9	4	7.4	0	.0	Not significant
Still Birth	0	0.0	0	0.0	1	1.9	
Others	0	0.0	1	1.9	0	0.0	
Total	13	24.1	16	29.6	24	**44.4**	

The neonatal complications were highest in Group 2C(44.4%) and least in Group 2A(24.1%) ,but the difference was not statistically significant.

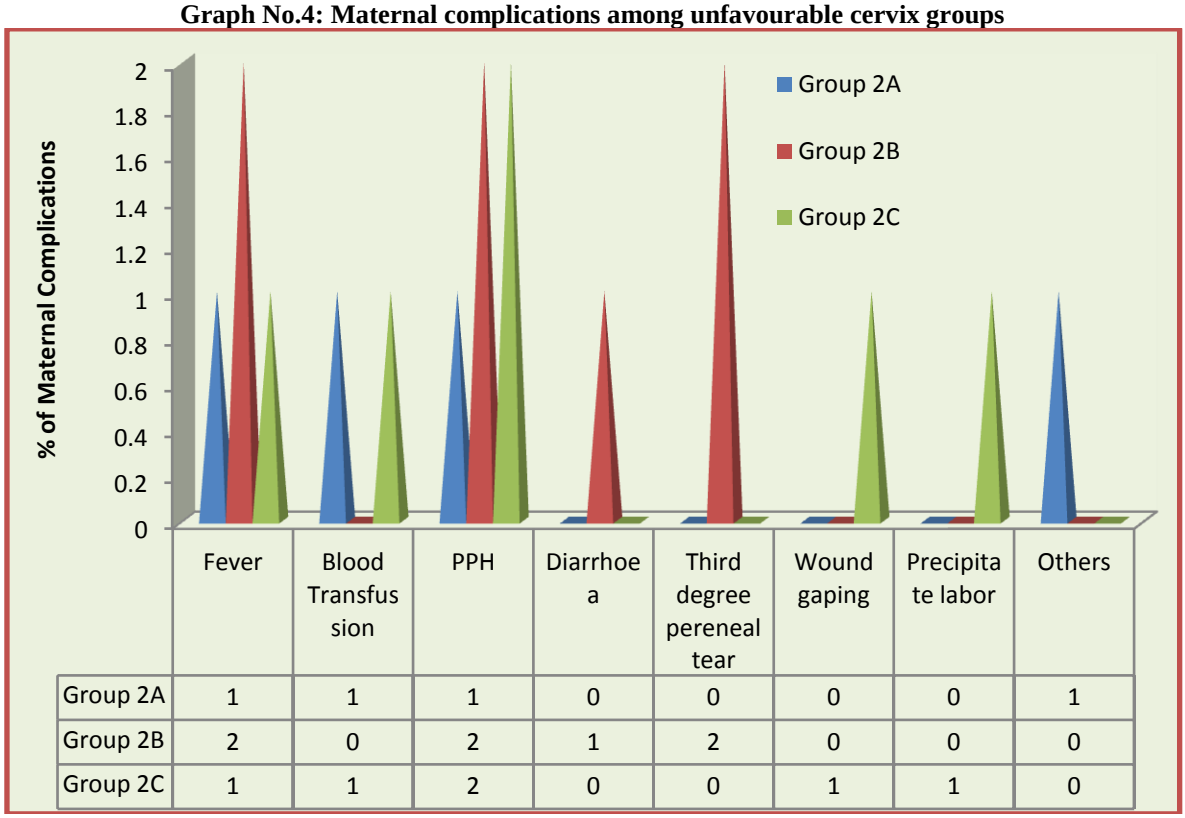
Table No.16:maternal complications among favourable and unfavourable cervix

	Group 1		Group 2	
Maternal complication	n	%	n	%
Fever	6	3.7	4	25.0
Blood Transfussion	2	1.2	2	25.0
PPH	2	1.2	5	25.0
Diarrhoea	2	12.5	1	.0
Third degree pereneal tear	2	12.5	2	.0
Wound gaping	2	12.5	1	.0
Precipitate labor	0	.0	1	.0
Others	0	.0	1	25.0
Total	16	**9.9**	17	**10.5**

P>0.05 Not significant

The maternal complications were higher among Group 2(10.5%) compared to those in Group 1(9.9%),but the difference was not statistically significant.

Graph No.4: Maternal complications among unfavourable cervix groups



	Fever	Blood Transfusion	PPH	Diarrhoea	Third degree pereneal tear	Wound gaping	Precipitate labor	Others
Group 2A	1	1	1	0	0	0	0	1
Group 2B	2	0	2	1	2	0	0	0
Group 2C	1	1	2	0	0	1	1	0

Maternal complications were highest among Group 2B(13%) and lowest among Group 2A(7.4%),but the difference was not statistically significant.

V. Discussion

The findings of the present study which was undertaken to study the risk of cesarean delivery after induction of labour among unfavourable cervix compared to those with favourable cervix and efficacy of induction methods used in unfavourable cervix,suggests that there is a significant increase in the risk of cesarean delivery among women who underwent induction in an unfavourable cervix.This association between induction and increased risk for cesarean delivery has been documented in many studies.Most of the studies have found that there is two fold increased risk of cesarean delivery with induction of labour compared to spontaneous labour.

The mean age in favourable cervix group was 21.7yrs and that in unfavourable cervix is 25.4yrs.Age has an influence on labour.pregnancy below 20 yrs pose more complications as mother is also in developing phase.In contrast,increasing age increases the resistance of cervix for dilatation and so ripening of cervix will be delayed in women aged more than 35 yrs.most of the women in our study were of reproductive age group(92.3%).In **Sotiradis A et al**[8] the women between 39+0 and 39+6 gestational weeks were taken as the authors stated that the rate of maternal and perinatal complications increases after 39 wks .**Vrouentaets FP et al**[9] found maternal age is of 30 yrs and older as one of the factors which significantly poses an increased risk for cesarean delivery.**Hye Ran Lee et al**[10]also found advanced maternal age as an increased risk factor for cesarean delivery.

In this study The most common indication for induction among all three unfavourable cervix groups was past dates(28.4%).The most common indication for induction among Foley's group (35.2%) and Dinoprost Gel group(31.5%) was past dates.Premature Rupture Of Membranes (51.9%)was the most common indication in Misoprostol Group.In the study by **Parul S Jani et al**[11] 46.6% reported PROM and 24% reported post datism as an indication for induction.

Bishop score at the time of induction is a very important factor in determining the successful outcome of labour.Increase in Bishop score increases the success of outcome of induction of labour.In the Favourable cervix the mean Bishop score was found to be 7.02.67.9% among favourable cervix group were found to have a Bishop score≥7 and delivered within 4hrs of admission.The mean Bishop score among unfavourable cervix was 2.87.In a study by **Parul S Jani et al**[11] the mean Bishop score was found to be 3.2 in study and control groups.
Studies comparing the cesarean delivery rate among spontaneous labour group and induced labour groups:

studies	Cesarean delivery in	Cesarean delivery in induction group

	Spontaneous group	
David P Johnson et al,1997-1999[12]	11.5% 18.1% in those with Bishop score≥5	23.7% 31.5% in those with Bishop score<5
Yeast,Jones and Poskin,1999[13]	7.9%	18.5%
Syeb et al,1999[14]	7.8%	• Elective induction-17.5% • Medical induction-17.7%
Cammu et al,2002[15]	6.5%	9.9%
Vrouenraets FP et al,2005[9]	12%	• Elective induction-23.8% • Medical induction-23.4%
Vahratian et al,2005[16]	13.9%	• Elective induction with cervical ripening-41.3% • Elective induction without cervical ripening-16.8%
Hye Ran Lee et al,2008-09[10]	5.3%	17.3%
Walker et al,2016[17]	33%in expectant group	32% in induction group
Sotiradis A et al,2018[8]		Decreased risk of cesarean delivery in elective induction of labour in uncomplicated singleton pregnancies from 39 wks gestation(RR 0.86;95%CI,0.78-0.94;I^2=0.1%)
Present study,2017-18	16% with Bishop Score≥5	29.6% with Bishop Score<5

Comparative Data of patient characteristics in the spontaneous and induction groups in different studies:

Study	Maternal age(yrs)		Gestational age (wks)		Bishop score		Birth weight(kg)	
	Spontaneous	induced	Spontaneous	induced	Spontaneous	induced	Spontaneous	induced
David P Johnson et al,1997-1999[12]	26.4±5.9	26.8±5.7	39.5±1.1	39.8±1.3	8.19±2.40	5.30±2.3	3.4±0.4	3.5±0.5
Syeb et al,1999[14]	28.6	29.7	39.2	39.8	-	-	3.4	3.4
Cammu et al,2002[15]	27.2±4	27.0±4.1	39.8±0.9	39.8±0.9	-	-	3.4±0.2	3.4±0.2
Vrpuenraets FP et al,2005[9]	29.4±5.2	29.1±4.7	39.9±1.2	40.3±1.6	7.9±2.6	3. 3±2.5	3.3±0.4	3.3±0.5
Vahratian et al,2005[16]	25.3±5.9	26.7±6.4	39.0 ±0.9	39.7±0.6	-	-	3.3±0.4	3.5±0.4
Present study,2017-18	21.73±2.821	25.4±9.1	39.38±3.059	39.74± 1.6	7.02±1.4	2.87±0.4	2.75±0.3	2.96±0.4

Comparative data on indications for induction:

Study	Past dates n %	GHTN n %	Pre eclampsia n %	GDM n %	IUGR n %	Rh-ve n %	Elective n %
Syeb et al,1999[14]	121(41.2)	5(1.7)	10.9(32)	4(1.4)	10(3.4)		88(61.5)
Vrpuenraets FP et al,2005[9]	144(23.07)	74(11.8)	61(9.7)	3(0.4)	19(3.0)	1(0.1)	189(30.2)
Present study,2017-18	46(28.4%)	16(9.26%)	44(27.2%)	3(1.9%)	3(1.9%)	7(4.3%)	-

Studies comparing efficacy of induction methods(Foley's induction,Dinoprost Gel,Misoprostol)

Studies	Effective method	In terms of	Other conclusions
W Chen et al[18]	Vaginal misoprostol	Achieving vaginal delivery <24hrs	But associated with higher rates of uterine hyperstimulation with FHR changes
Pradeepa T et al,2017[19]	Dinoprost Gel+Misoprostol Group	Induction to Delivery interval was less (9.35hrs).	Foley's catheter is an effective method for patients with poor Bishop score, especially in those with oligohydramnios
Parul S Jani et al,2002[11]	Vaginal misoprostol	Lesser need for oxytocin augmentation(12%)and shorter Induction-Delivery interval(57.3% within 6hrs)	
Present study, 2017-18	Foley catheter	• Lesser Induction to active phase interval(7.09hrs) • Lesser Induction to	Significant change in pre and post induction Bishop score was observed with Misoprostol

		delivery interval(13.42hrs) • Fewer neonatal(13%) and maternal (7.4%)complications	(5.93±1.071hrs) and it had lesser cesarean section rate (25.9%).

- A Prospective comparative study Efficacy of misoprostol over Dinoprostone gel and Foley's catheter as a cervical ripening agent by Parul S Jani[11] during April to August 2002, at the Department of Obstetrics and Gynecology, Guru Gobind Singh Hospital, Jamnagar, and M.P. Shah Medical College, Jamnagar, Gujarat, India to evaluate the efficacy of misoprostol as a cervical ripening agent and its comparison with dinoprostone gel and Foley's catheter in terms of success rate,safety, side effects, patient's compliance, and cost factor. This prospective study was carried out in 175 cases with gestational age equal to or greater than 28 weeks, no uterine activity at the time of induction, cervical dilatation should be less than 3 cm and effacement should be less than 50%, positive nonstress test without having history of antepartum hemorrhage, cesarean section, and allergy to prostaglandins.Of the 175 cases, 75 were induced with 50 μg misoprostol, 50 cases with intracervical Foley's catheter No. 18, and 50 cases with 0.5 mg intracervical dinoprostone gel, selected by purposive sampling method. Outcome measures such as a change in Bishop's score, need of augmentation, and induction delivery interval and complications such as hyperstimulation, fever, and meconium passage were compared between the three groups. Thirty-five (46.6%) of the patients showed premature rupture of the membrane as an indication of labor. The mean Bishop's score for induction was 3.20 in misoprostol group. Only 12% of the patients required augmentation in the misoprostol group, while it was 48% in the dinoprostone group and 72% in Foley's catheter group. Sixty-three (84%) patients in misoprostol group and 94% of patients in dinoprostone group delivered by vaginal delivery; 57.3% patients delivered within 6 h in misoprostol group (misoprostol: 57.3%, dinoprostone: 28%, Foley's catheter: 8%; $p < 0.001$). The incidence of thin meconium occurred in 12% in the misoprostol group, 10% in the dinoprostone group, and 18% in Foley's catheter group. In misoprostol and Foley's catheter groups, three patients developed a fever after induction. No patient reported diarrhea and vomiting. The incidence of cervical tear and vaginal laceration was similar in all the groups. No case of hyperstimulation was observed in our study. Misoprostol is quite cheaper than dinoprostone gel and Foley's catheter.

Variable	Parul S Jani et al study[11]	Present study
Division of number of subjects among induction groups	Foleys-50 Gel-50 Misoprostol-75	Foleys-54 Gel-54 Misoprostol-54
Division of Primi and Multigravidae	Foleys-40%P,60%M Gel-48%P,52%M Misoprostol-49.4%P,50.6%M	Foleys-33.3%P,66.7%M Gel-50%P,50%M Misoprostol-57.4%P,42.6%M
Mean Bishop Score	Foleys-3.22 Gel-3.26 Misoprostol-3.20	Foleys-2.89 Gel-2.96 Misoprostol-2.72
Meconium incidence	Foleys-28.2% Gel-26% Misoprostol-28%	Foleys- 1.9% Gel-5.6% Misoprostol-22.2%
Maternal Complications	Foleys-10% Gel-6% Misoprostol-11.9%	Foleys-7.4% Gel-13% Misoprostol-11.1%

The strength of this study is that both primigravidae and multigravidae are included in the study an efficacy of all the three commonly used methods of induction in unfavourable cervix are studied.The limitations are that even mothers with complications such as GDM,preeclampsia are included in the study which may have their influence on the increased cesarean delivery rate.The various factors affecting cesarean delivery rate are not studied.wide spectrum of Gestational age has been taken,limited number of subjects from one hospital-the findings may not be generalized to other populations of pregnant women.

Further Studies detailing the influence of various factors on the increase risk of cesarean delivery are needed.The exact mechanism to account for this increase needs to be known.A randomized trial needed to know the causation.

VI. Summary

- Out of 324 subjects studied,162 subjects had favourable cervix with Bishop score≥5 and 162 subjects had unfavourable cervix with Bishop score <5 among whom 54 were induced with Foley catheter,54 with Dinoprost Gel,54 with Tab.Misoprostol 25μg.The risk of cesarean delivery among the unfavourable cervix group compared to favourable cervix and the efficacy of induction methods used in unfavourable cervix were studied.
- The cesarean section rate was 16% among favourable cervix group and 29.6% in unfavourable cervix group which was significantly higher.

- The relative risk for cesarean delivery in unfavourable cervix is 1.96 times more compared to favourable cervix which is significant.
- The most common indication for LSCS is Fetal distress among both the groups(46.15% in favourable cervix and 50% in unfavourable cervix).
- Those mothers with Bishop score ≥7 delivered within 4hrs of admission.
- Induction with Foley catheter had significantly lesser Induction to Active Phase Interval(7.09±3.638 hrs) and lnduction to delivery interval(13.42±3.659hrs)compared to other two groups.It had fewer neonatal and maternal complications but the difference was not significant.
- Significant change in pre and post induction Bishop score was observed with Misoprostol (5.93±1.071hrs) and it had lesser cesarean section rate (25.9%).But it had highest incidence of neonatal complications (44.4%) most of it accounting to Meconium incidence (22.2%)
- The most common indication for induction among all three unfavourable cervix groups is past dates(28.4%).
- The most common indication for induction among Foley's group (35.2%) and Dinoprost Gel group(31.5%) was past dates.Premature Rupture Of Membranes (51.9%)was the most common indication in Misoprostol Group.
- The need for oxytocin augmentation was highest for Misoprostol group(85.2%).
- There was one still birth among favourable cervix group and one in unfavourable cervix group.
- Neonatal and maternal complications were more in unfavourable cervix groups compared to favourable cervix groups and among the sub groups of unfavourable cervix,they were highest in cerviprime Gel group and least in Foley catheter group.

VII. Conclusion

The present study suggests that there is a significant increase in the risk of cesarean delivery in induction of labour with unfavourable cervix compared to those with favourable cervix.The mothers presenting with unfavourable cervix to be considered as high risk as they have relatively more number of cesarean sections and the decision to undertake induction in them needs to be clear and clinically justified.more vigilance during the management of labour and development and practice of effective institutional induction protocols help in reducing primary cesarean section rate.Induction with Foley catheter found to be effective method in unfavourable cervix in terms of lesser Induction to active phase interval,Induction to delivery interval,neonatal and maternal complications.The low cost,stability in room temperature makes it an ideal method for cervical ripening in developing countries.In those presenting with very low Bishop score and in those with premature rupture of membranes,Misoprostol found to be effective in terms of significant change in pre and post induction Bishop scores and lesser cesarean delivery rate.Further research is needed with larger sample size involving different institutions and research on the preventive aspects of cesarean section in unfavourable cervix .

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