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RESEARCH ARTICLE

FACTORS ASSOCIATED WITH THE FAILURE OF INDUCTION OF LABOUR -AN OBSERVATIONAL STUDY

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Abstract

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Introduction:-

Labour is the process that leads to birth of a child. It is characterized by forceful and painful uterine contractions that effect cervical dilatation and cause fetus to descend through the birth canal. It begins with the onset of regular uterine contractions and ends with delivery of the newborn and expulsion of the Placenta.¹ There are times, where delivery outweigh the benefits of continuation of pregnancy and there comes the need for “**Induction of Labour**”.

Induction of labour means initiation of uterine contractions (after period of viability) by any method (medical, surgical or combined) for the purpose of Delivery.²

Induction of labour occurs in 25% of all term pregnancies around the world. In the United States, the latest numbers point towards an overall induction rate of 23% of all pregnancies.³

In developed countries, it is said that the proportion of infants delivered at term following induction of labour can be as high as one in four deliveries.⁴ WHO Global Survey on Maternal and Perinatal Health, in 24 countries included 373 health-care facilities where nearly 300 000 deliveries takes place, stated that 9.6% of the deliveries involved induction of labor. Overall the things found in the survey are, the facilities in African countries show lower rates of induction of labour (lowest: Niger, 1.4%) compared with Asian and Latin American countries (highest: Sri Lanka, 35.5%).⁵

National Institute of Child Health and Human Development (NICHD), Society of Maternal-Fetal Medicine (SMFM), United states and American College of Obstetricians and Gynecologists (ACOG) proposed that failed induction be defined as “the failure to generate regular contractions approximately every three minutes and cervical changes after at least 24 hours of oxytocin administration”.⁶ There is no single global figure that indicates the magnitude of failed induction of labour.⁷

One approach to diagnose a failed induction is, duration of the latent phase. One more definition is “Failed IOL should be defined as the inability to achieve the active phase of labour, considering that the definition of IOL is to enter the active phase of labour”.⁸

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The study is aimed to assess factors associated with failure of induction of labour attending labour room at a tertiary care hospital to develop steps that can manage success rate and meet the expectations and dreams of an every pregnant women.

Material & Methods:-

Study Design:

Observational study

Study Area:

Department of Obstetrics and Gynaecology at a tertiary care hospital.

Study Duration:

Patients will be enrolled for 12 months (1 JANUARY 2021- 31st DECEMBER 2021) and Data collection and analysis would be done for 6 months (1 JAN 2022-30 JUNE 2022)

Sample Size:

According to $n = \frac{4pq}{d^2}$ with 10% allowable error, minimum required sample size is 330. But in our study population we are including patients who ever is requiring IOL.

Subjects & Selection Method:

All the ANC mothers who ever is requiring Induction of labour .

Convenient sampling method is used.

Inclusion Criteria:

1. Nullipara at term
2. Post dated pregnancies
3. Term Pre Labour Rupture of Membranes
4. Hypertensive disorders of Pregnancy
5. Oligohydramnios, poly hydroamnios
6. Preterm labour
7. Intra Uterine growth restriction
8. Intra uterine death of the fetus
9. Gestational diabetic mothers
10. Preterm Pre labour rupture of membranes after 34 weeks
11. In women with an uncomplicated twin pregnancy at or near term
12. Fetus with major congenital anomaly

Exclusion criteria:

1. IOL not recommended for suspected Fetal Macrosomia
2. Previous LSCS
3. Contracted pelvis and cephalopelvic disproportion
4. Mal presentation (breech, transverse or oblique lie)
5. High risk pregnancies with fetal compromise
6. Mothers with heart diseases
7. Elderly primigravida with obstetric or medical complications
8. Umbilical cord presentation
9. Cervical carcinoma or pelvic tumors

Ethical Considerations:

The study is initiated after obtaining approval from the institutional ethics committee (IEC, tertiary care centre) as per ethical guidelines on biomedical research on science and methodology.

Procedure Methodology:-

Informed & written consent.

Adequate counseling about the risks & benefits.

Review of maternal history and profile.

Evaluation for indications to rule out contraindications.

Reliable estimation of gestational age, presentation and fetal weight.

Maternal pulse, blood pressure, temperature, respiratory rate and findings on abdominal palpation must be recorded.

Evaluation of base line fetal heart rate pattern by auscultation & fetal monitoring.

Maternal pelvis assessment and clinical evaluation for possible cephalopelvic or fetopelvic disproportion.

Assessment of cervical status using Modified Bishop scoring system to predict the likelihood of success and select appropriate method of induction of labour.

Indication for induction and gestational age along with Modified Bishop Score should be documented at the time of the decision for induction of labour is made.

“SELECTION OF METHOD & PROTOCOL IS INDIVIDUALISED”

Decisions regarding the choice of induction method will depend upon the relative preference of affecting vaginal delivery in 24hrs, minimizing the incidence of uterine hyper stimulation with adverse FHR changes and avoid caesarean section.

Methods and Protocols:-

1. Intracervical Dinoprostone gel: The gel should be stored in a refrigerator at ‘2 to 8°C’.

The application (3 g gel/0.5 mg dinoprostone) can be repeated in 6 hours depending on bishop score but not exceeding 3 doses in 24 hours. It is placed inside the cervix, but not above the internal os.

Ambulation of the patient is allowed after 30 minutes of insertion.

Temperature, pulse, respiratory rate, blood pressure, fetal heart rate, uterine activity and vaginal bleeding are examined immediately after insertion then hourly for 4 - 6 hours.

If necessary, oxytocin for augmentation of labour is started only 6 hours after the last dose.

2. MISOPROSTOL (PGE1) used as transvaginally or orally for IOL (ACOG2003). A dose of 25mcg vaginally every 4 hours. Total of 6-8 doses can be repeated based on bishop’s score.

3. Oxytocin titration in PROM mothers and in patients with favorable bishop score

4. Misoprostol protocol followed by augmentation with oxytocin after 6hrs from the last dose taking bishops as reference for monitoring the progression.

5. Amniotomy (Artificial rupture of membranes) followed by +/- oxytocin.

Bishops score and Partograph are used as supportive tools in finding the progression of induction of labour, failure of induction of labour, induction delivery interval and outcome of the labour.

Statistical Analysis:

The collected data entered into Microsoft excel 2019 and analysis was done through open Epi version 3.01.

Descriptive statistics like frequency tables graphs and descriptive summaries were used to describe the study variables. An odds ratio for a 95% confidence interval was employed for the strength and directions of association between independent variables and the outcome variables. P value of <0.01 was used to describe statistical significance.

Results:-

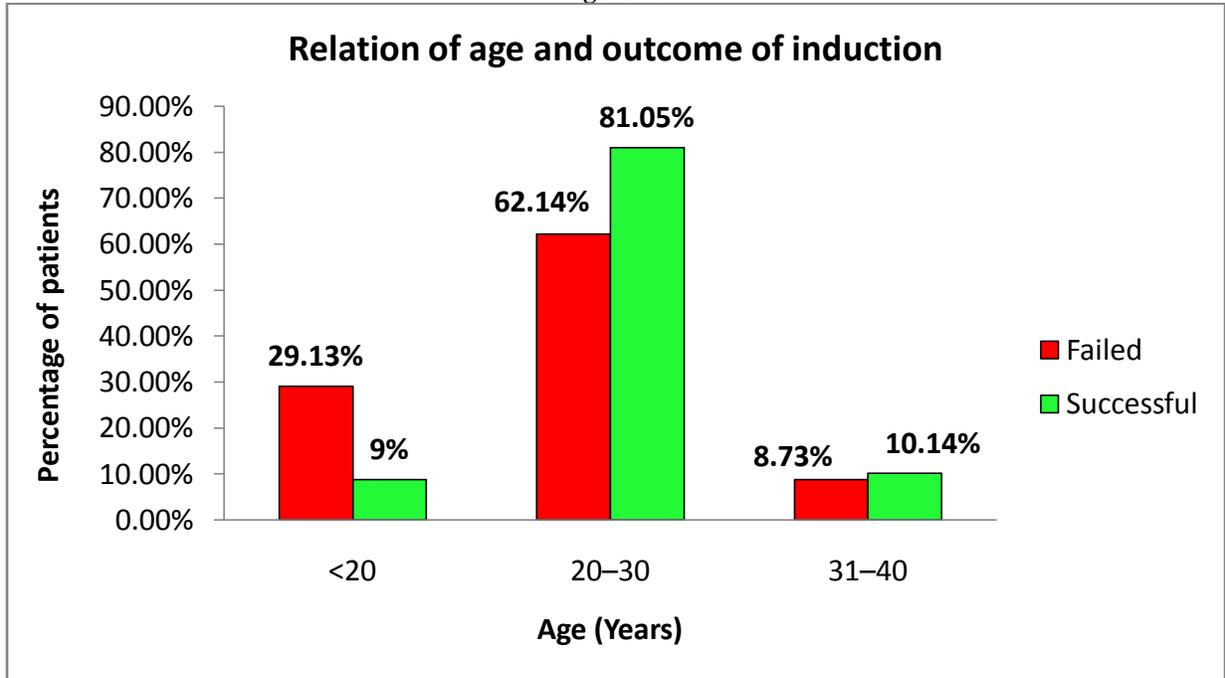
We considered 330 patients in our cross sectional study. Out of which 103 subjects constituted for failed induction of labour.

Age Distribution:

Table 1:- Relation of age and outcome of induction: (N = frequency).

Age (years)	Outcome of induction		OR (95% CI)
	Failed N(%)	Successful N(%)	
<20	30 (29.13)	20 (8.81)	2.22 (1.02-5.12) *
20–30	64 (62.14)	184 (81.05)	0.31 (0.18-0.51)
31–40	09 (8.73)	23 (10.14)	1
Total	103 (100)	227 (100)	* P<0.01 (Significant)

Figure 1:-



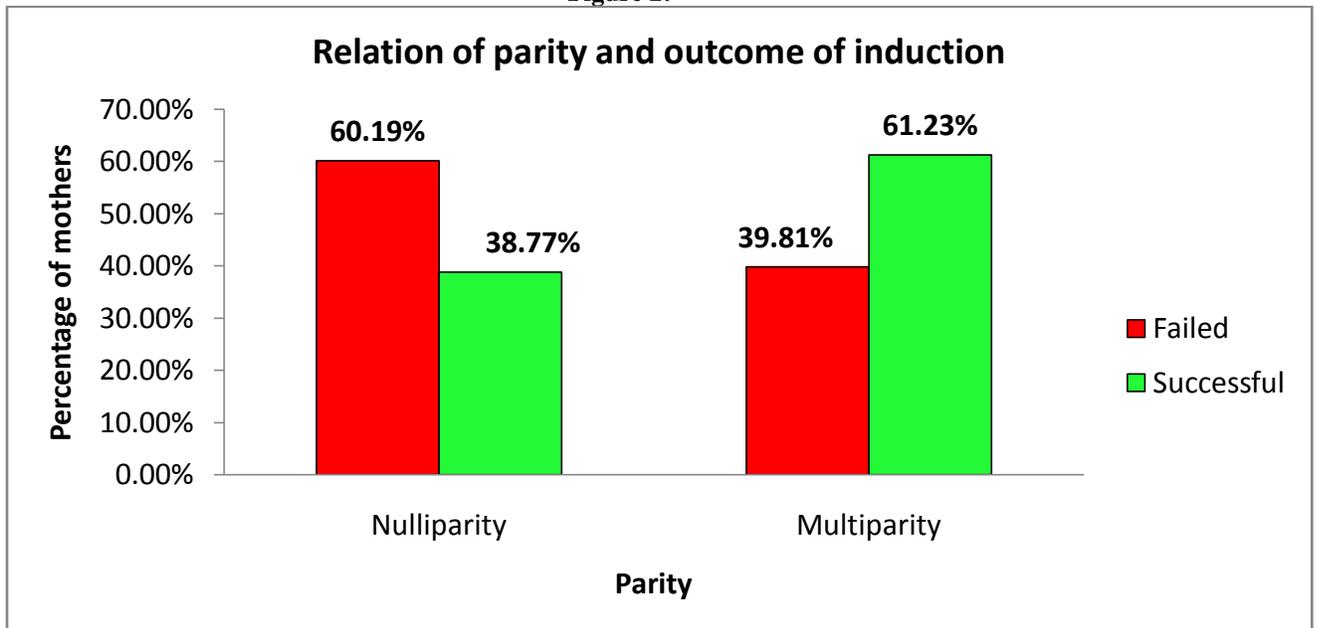
Most of the age group induced were belonging to the age group 20-30 yrs. However it is statistically insignificant .It is evident that age group less than 20yrs is significantly related to the failure of induction of labour.

Parity Status:

Table 2:- Relation of parity and outcome of induction:

Parity	Outcome of induction		OR (95% CI)
	Failed N (%)	Successful N (%)	
Nulli parity	62 (60.19)	88 (38.77)	2.14 (1.48-3.10) *
Multi parity	41 (39.81)	139 (61.23)	
Total	103 (100)	227 (100)	* P<0.01 (Significant)

Figure 2:-



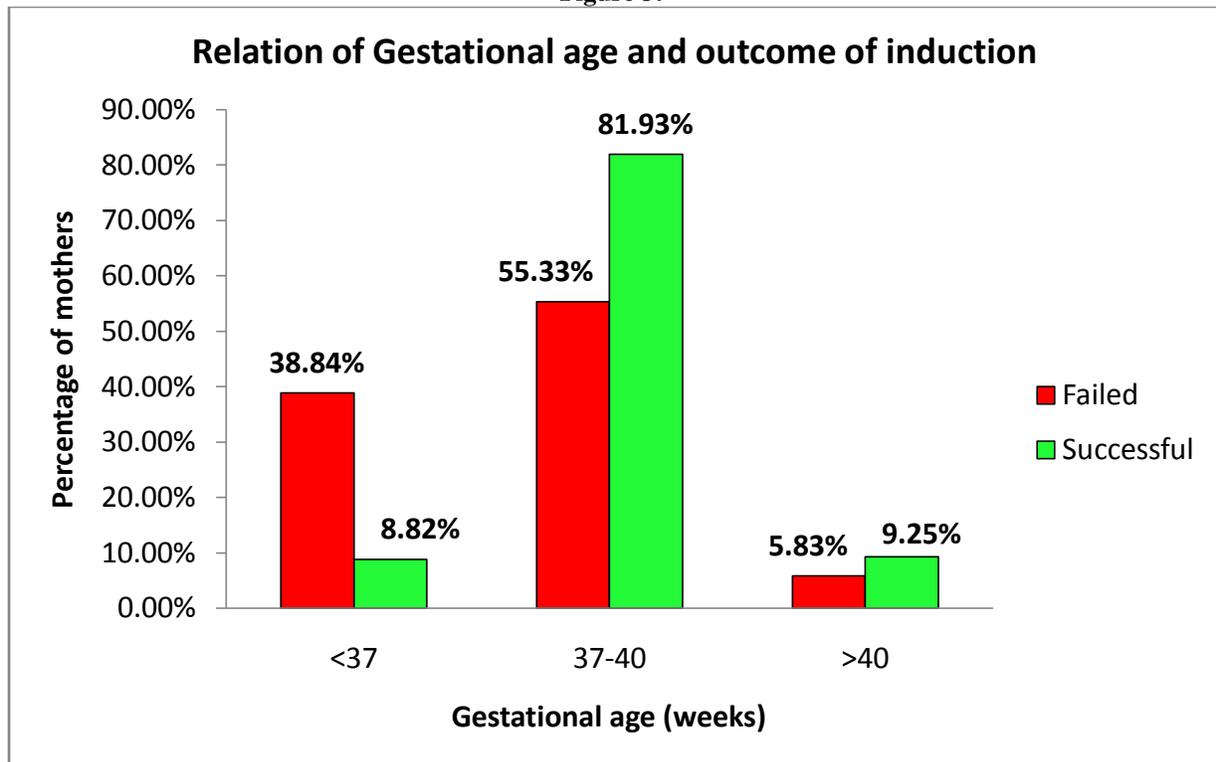
The odds ratio of nulliparous is 2.14 times greater than multiparous group with significant P value. Thus nulliparity is significantly associated with failure of IOL.

Gestational Age:

Table 3:- Relation of Gestational age and outcome of induction.

Gestational age (weeks)	Outcome of induction		OR (95% CI)
	Failed (%)	Successful (%)	
<37	40 (38.84)	20 (8.82)	3.33 (1.38-9.07)
37-40	57 (55.33)	186 (81.93)	0.35 (0.20-0.57)
>40	06 (5.83)	21 (9.25)	1
Total	103 (100)	227 (100)	* P<0.01 (Significant)

Figure 3:-



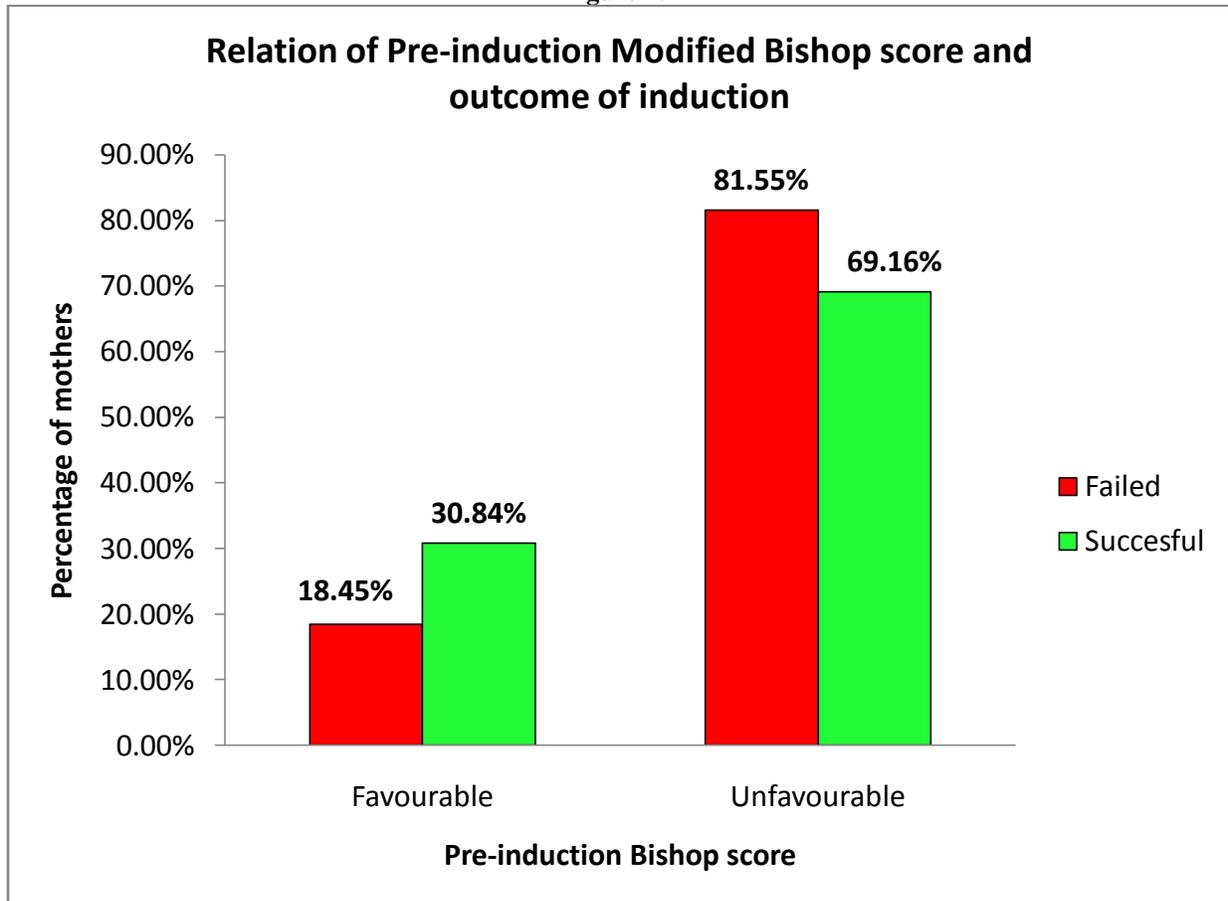
In this category, odds ratio of gestational group <37weeks is 3.33 times higher than other group. Hence gestational age <37weeks is significantly associated with failed IOL.

Distribution Of Bishop Scoring For Cervical Status

Table 4:- Relation of Pre-induction Modified Bishop score and outcome of induction:

Pre-induction Bishop score	Outcome of induction		OR (95% CI)
	Failed (%)	Successful (%)	
Favourable	19 (18.45)	70 (30.84)	8.26 (5.23-13.66)*
Unfavourable	84 (81.55)	157 (69.16)	
Total	103 (100)	227 (100)	*P<0.01

Figure 4:-



We assessed Odds ratio of subjects with unfavourable score is 8.26 times greater than the subjects with favourable bishops score. Hence unfavourable bishop score with significant P value is highly associated risk factor for FAILED IOL.

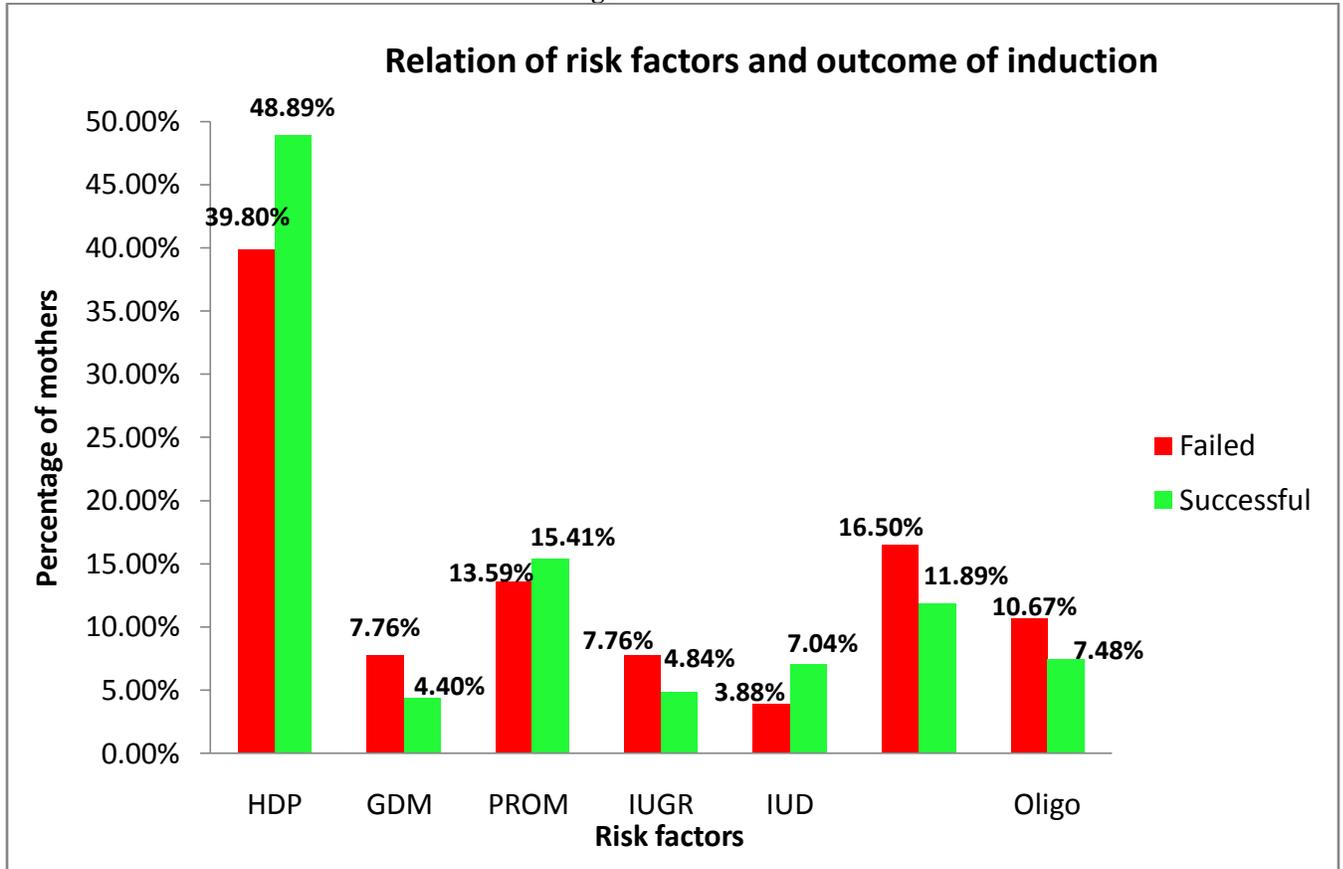
Indications of Induction of Labour:

Table 5:- Relation of risk factors and outcome of induction:

Risk factors	Outcome of induction		OR (95% CI)
	Failed (%)	Successful (%)	
HDP	41 (39.80)	111 (48.89)	1.79 (1.31-2.44)*
GDM	8 (7.76)	10 (4.40)	0.1 (0.05-0.2)
PROM	14 (13.59)	35 (15.41)	0.39 (0.26-0.57)
IUGR	8 (7.76)	11 (4.84)	0.11 (0.05-0.20)
IUD	04 (3.88)	16 (7.04)	0.16 (0.09-0.26)
Post dates	17 (16.50)	27 (11.89)	0.31 (0.20-0.47)
Oligo	11 (10.67)	17 (7.48)	0.18 (0.10-0.30)

* P<0.01 (Significant)

Figure 5:-



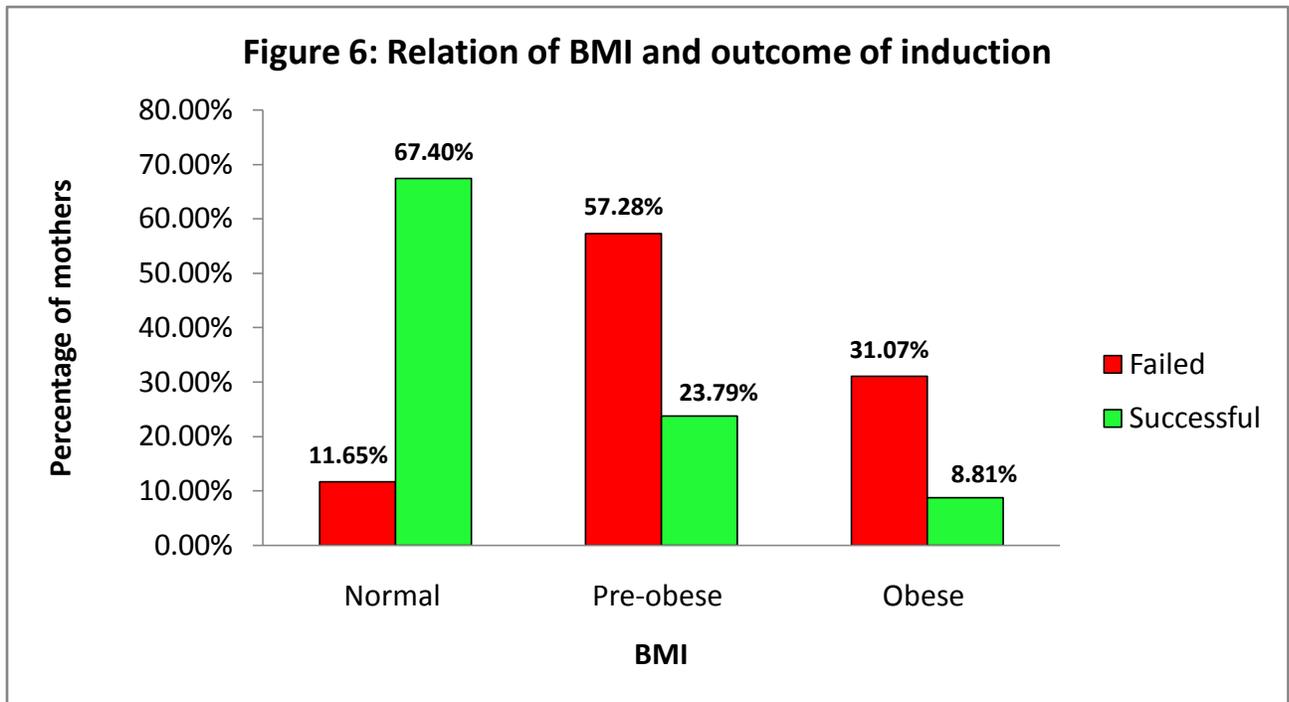
We assessed HDP odds ratio found to be 1.79 times higher than any other indication with significant P value <0.01. Hence HDP is significantly associated with FAILED IOL

Distribution Of BMI:

In our study we assessed BMI in failed IOL. We observed subjects belonging to pre obese category (57.28%) are more than obese category (31.07%) are more than normal BMI subjects.

Table 6:- Relation of BMI and outcome of induction.

BMI	Outcome of induction		OR (95% CI)
	Failed (%)	Successful (%)	
Normal	12 (11.65)	153 (67.40)	1
Pre-obese	59 (57.28)	54 (23.79)	4.50 (2.40-8.41)
Obese	32 (31.07)	20 (8.81)	1.67 (0.82-3.52)
Total	103 (100)	227 (100)	* P<0.01 (Significant)

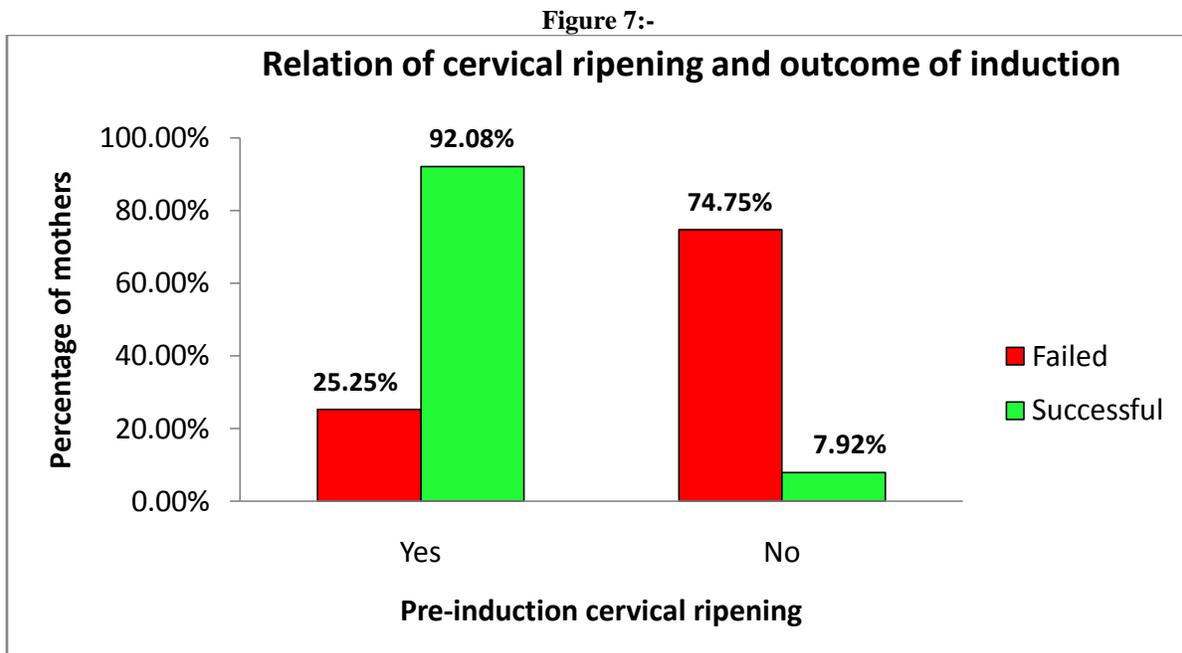


We found odds ratio of pre obese and obese is higher than normal BMI with P value <0.01 contributing for the significant association with failed IOL

Distribution of Pre Induction Cervical Ripening:

Table 7:- Relation of cervical ripening and outcome of induction:

Pre-induction cervical ripening	Outcome of induction		OR (95% CI)
	Failed (%)	Successful (%)	
Yes	26 (25.25)	209 (92.08)	2.71 (2.09-3.54)
No	77 (74.75)	18 (7.92)	
Total	103 (100)	227 (100)	P <0.01



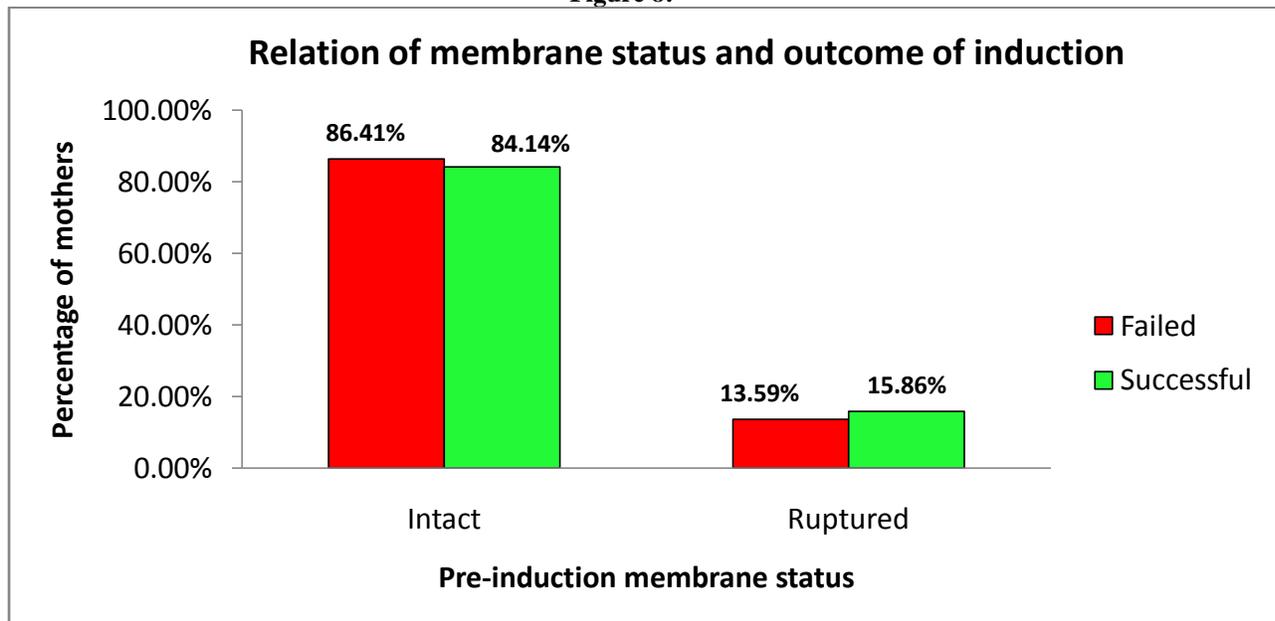
We assessed the odds ratio of non pre induction group found to be 2.71 times greater than the pre induced group. The non pre induction cervical ripening has got significant association with FAILED IOL.

Distribution of Membrane Status

Table 8:- Relation of membrane status and outcome of induction:

Pre-induction membrane status	Outcome of induction		OR (95% CI)
	Failed (%)	Successful (%)	
Intact	89 (86.41)	191 (84.14)	13.64 (7.93 – 23.47)*
Ruptured	14 (13.59)	36 (15.86)	
Total	103 (100)	227 (100)	* P<0.01 (Significant)

Figure 8:-



We observed odds ratio of intact membrane subjects was 13.64 times higher than ruptured membrane status. Hence intact membrane status is significantly associated with FAILED IOL with significant P value.

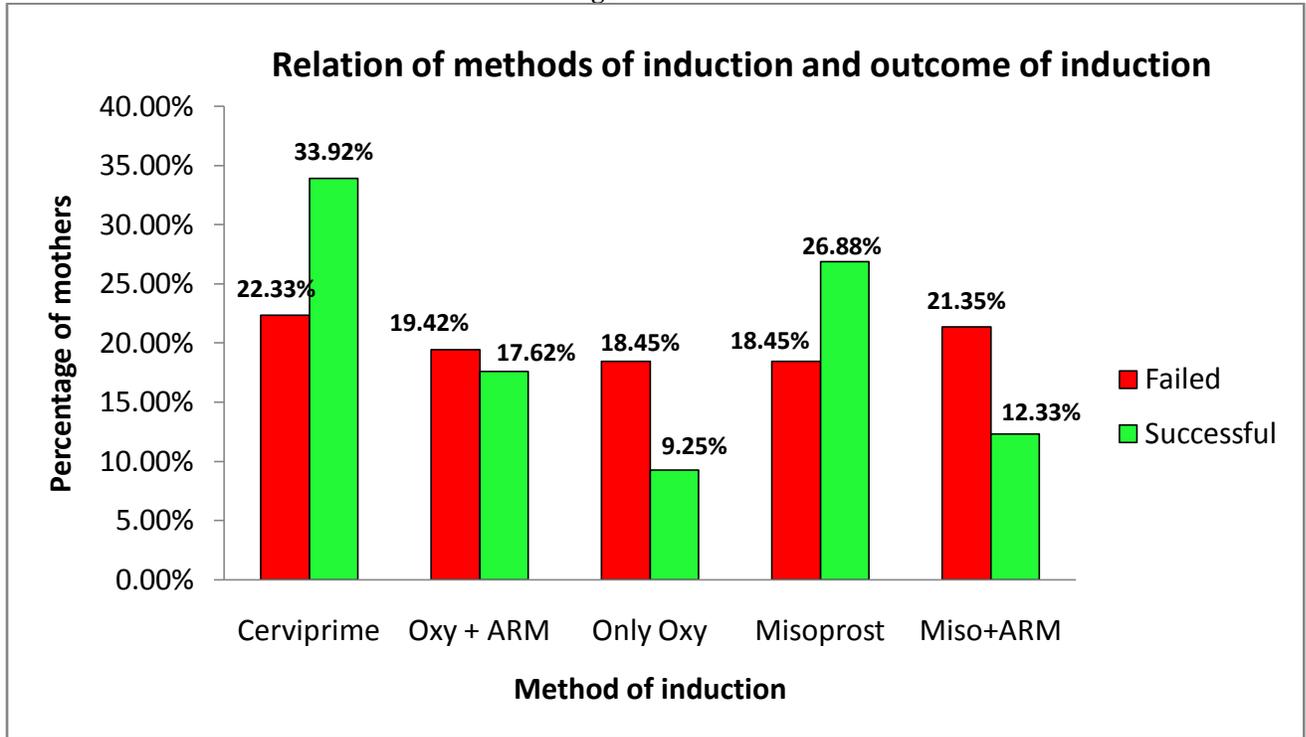
Distribution of Methods of IOL:

We assessed distribution method of IOL in failed group. Most of the participated subjects were subjected to cerviprime gel based on the dictum that SELECTION CRITERIA FOR METHOD OF IOL IS INDIVIDUALISED.

Table 9:- Relation of methods of induction and outcome of induction:

Method of induction	Outcome of induction		OR (95% CI)
	Failed (%)	Successful (%)	
Cerviprime	23 (22.33)	77 (33.92)	1.13 (0.82-1.48) *
Oxy + ARM	20 (19.42)	40 (17.62)	1
Only Oxy	19 (18.45)	21 (9.25)	
Misoprost	19 (18.45)	61 (26.88)	
Miso+ARM	22 (21.35)	28 (12.33)	
Total	103 (100)	227 (100)	* P>0.05 (Not Significant)

Figure 9:-



We assessed odds ratio of cerviprime induced subjects is 1.13 times higher and contributing for significant FAILED IOL.

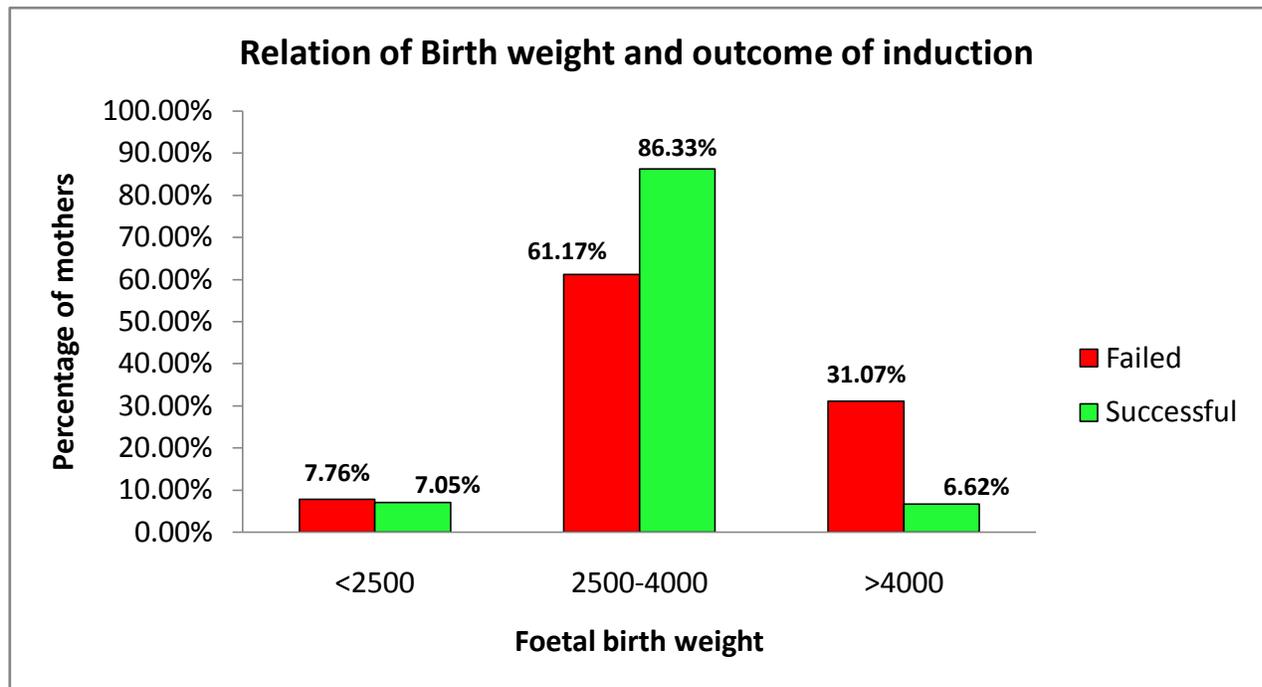
Distribution of Birth weight in IOL:

In the present study we assessed birth weight association with failed IOL.

Table 10:- Relation of Birth weight and outcome of induction:

Birth weight (grams)	Outcome of induction		OR (95% CI)
	Failed (%)	Successful (%)	
<2500	08 (7.76)	16 (7.05)	1
2500-4000	63 (61.17)	196 (86.33)	0.25 (0.14-0.43)
>4000	32(31.07)	15 (6.62)	6.125 (4.21-8.90)*
Total	103 (100)	227 (100)	* P<0.01 (Significant)

Figure 10:-



We found odds ratio of B.wt 4000gms is 6.125 times higher and significantly associated with failed IOL with P value <0.01.

Discussion:-

Even though there is no standard definition for the failure of IOL, it is stated that failure to achieve regular uterine contractions (every 3 minutes) after one cycle of completion of cervical ripening consisting of insertion of three intra cervical PGE2 gel at 6th hrly interval and 12 to 24 hr of oxytocin administration after rupture of membrane, if feasible.

Overall magnitude of failed IOL among women who underwent IOL is found to be 31.2%. It is similarly in line with 29.6% according to EnkuAfeeworkDemssie, et al. conducted at adama medical hospital, Ethiopia.⁹

TsionTadesse,et al.¹⁰ it is 24.4% in his study at north west Ethiopia WoubishetGirma, et al.¹¹ prevalence is 21.4% .

Failure rate was higher than 50% in the studies conducted by RT Rayamajhidone et al at Kathmandu iniversity and at south Africa (49.3%)¹², OromiaEthiopia (42.1%)¹³, Odisha of Eastern india (50.5%)¹⁴.

The lower prevalence comparatively in this study is because mothers who were induced and got delivered through caesarean sections for indications other than failed induction were excluded from the study. The other possible justifications for discrepancies in prevalence is due to lack of a universally accepted definition of failed IOL along with descripencies in participation of different parous mothers and availability of methods of induction.

Age

It is evident from this study that, age group less than 20yrs odds ratio is 2.22 higher than other groups and is significantly related to the failure of induction of labour.

It is in line with study done by Tsiontadesse etal. Yimer Mohammed Beshir, et al.¹⁵

Parity

The study reveals that odds ratio of nulliparous is 2.14 times greater than multi parous group with significant P value associating with failed IOL.Nulli parity as an independent predictor for failed induction was also seen in most of the studies reviewed by Leah R. Battista, et al.¹⁶, F. Gary Cunningham ,et al.¹⁷ Woubishet Girma etal.¹¹ Neelofubabar khan

, et al.¹⁸ & Muhdin Mohammed et al.¹⁹. This may be due to the fact that nulliparous women has different pre-induction cervical status and its response to induction methods when compared to multiparous women.¹⁵ In addition, the nulliparous cervix is immature and requires longer time and effort to stimulate through induction compared with multiparous women. One study conducted in Eastern Ethiopia explained that as parity increases, the likelihood of failed IOL because uterine muscles can be easily stimulated and contracted in multipara women.¹⁰ This may be as well due to nature of cervix in multiparous women which is a wide, uneven and bulky appearance that makes cervix easy to dilate.

Bishop Score

This study revealed Odds ratio of subjects with unfavourable score is 8.26 times greater than the subjects with favourable bishops score. Hence unfavourable bishop score with significant P value is highly associated risk factor for failed IOL. This is in line with MUHDIN MOHAMMED, ET AL.¹⁹ STUDY, TSIONTADESSE, ET AL.¹⁰ KHAN NB, ET AL.¹⁸ DILNESSA T, ET AL.²⁰

EnkuAfeworkdemssie, et al.¹⁰ study was contradictory to this study . This contrast might be related to the subjective assessment of the Bishop score.

Indications

This study assessed HDP odds ratio found to be 1.79 times higher than any other indication with significant P value <0.01. Hence HDP is significantly associated with FAILED IOL.

It is in line with TsionTadasse, et al.¹⁰ Demisse, et al.⁹ Mary Catherine Tolcher, et al.²¹ The possible explanation may be MGSO4 which is given for management of PE/Eclampsia acts like a tocolytic agent and effects the progress of labour. The other explanation may be due to HDP increasing the risk of utero placental insufficiency leading to compromised placental function, leading to decreased response to uterotonics & eventual increase of likelihood of failed IOL.

Membranes

The current study observed odds ratio of intact membrane subjects was 13.64 times higher than ruptured membrane status. Hence intact membrane status is significantly associated with failed IOL with significant P value which is in line with BikilaTeferaDebelo, et al. study. It may be due to the contents of amniotic fluid, prostaglandins, which are responsible for cervical dilatation and eventual successful birth.²² But contrary to EnkuAfework Demssie, et al.⁹ study.

BMI

This study reveals the odds ratio of pre obese and obese is higher than normal BMI with P value <0.01 contributing for the significant association with failed IOL. This is in line with the studied as per Ellis, et al. study²³ Beckwith , et al.²² Amare Genetuejigu , et al.²⁵ The possible explanation can be that Women with obesity may need higher doses as well as longer duration of exposure to prostaglandins to complete labour initiation and birth compared to the women of normal weight. Femke Frederiks, et al.²⁶ study is little contradictory to our study stating that BMI has less of a risk factor than anticipated for failed IOL, as independent risk factor , more or less restricted to the morbidly obese women.

Pre Induction Cervical Ripening

This study assessed the odds ratio of non pre induction group found to be 2.71 times greater than the pre induced group. It is supported by the study done by T Tadasse, et al.¹⁰, Amare Genetuejigu, et al.²⁵

Birth Weight

The current study revealed that odds ratio of B.wt 4000gms is 6.125 times higher and significantly associated with failed IOL with P value <0.01. It is supported by Demisse , et al.⁹ Ejiu, et al. study.²⁵ were statistically associated with failure of IOL.

With the above discussion , the present study revealed that Maternal age, Nulliparity, BMI, Poor bishop score, membrane status, Pre Induction Cervical Ripening , Hypertensive disorder of pregnancy, Birth weight are significantly associated with the failure of Induction of Labour.

Conclusion:-

The prevalence of failure of induction of labour in this study is 31.2% of total induced subjects. Determinants like Maternal age, Nulliparity, BMI, Poor bishop score, membrane status, Pre Induction Cervical Ripening, Hypertensive disorders of pregnancy, Birth weight are significantly associated with the failure of Induction of Labour.

Considering the above determinates making standard definitions and universal protocols are recommended for reducing the failure rate of induction of labour.

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