



Poster Code

EP.0550

Elective Induction Of Labour Vs Expectant Management At 39 Weeks Among Low Risk Nulliparous Pregnant Women – A Randomized Controlled Trial [Elite -39 Trial]

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RCOG WORLD
CONGRESS 2022
13 - 15 JUNE

INTRODUCTION

- High risk pregnancies are delivered between 37-38 weeks or even earlier
- Optimal timing of delivery in low risk pregnancies is not known
- There is a strong evidence that the perinatal mortality rate (PNMR) increases with increasing gestational age at or 37 weeks.¹
- Risk of oligohydramnios, birth injury, macrosomia, meconium aspiration syndrome and still birth are more beyond 42 weeks.²
- Over decades, it has been a common practice among obstetricians to avoid labour induction before 41 weeks of gestation without an appropriate indication
- Risks associated with induction of labour like sepsis, hemorrhage and increased caesarean section rate

OBJECTIVES

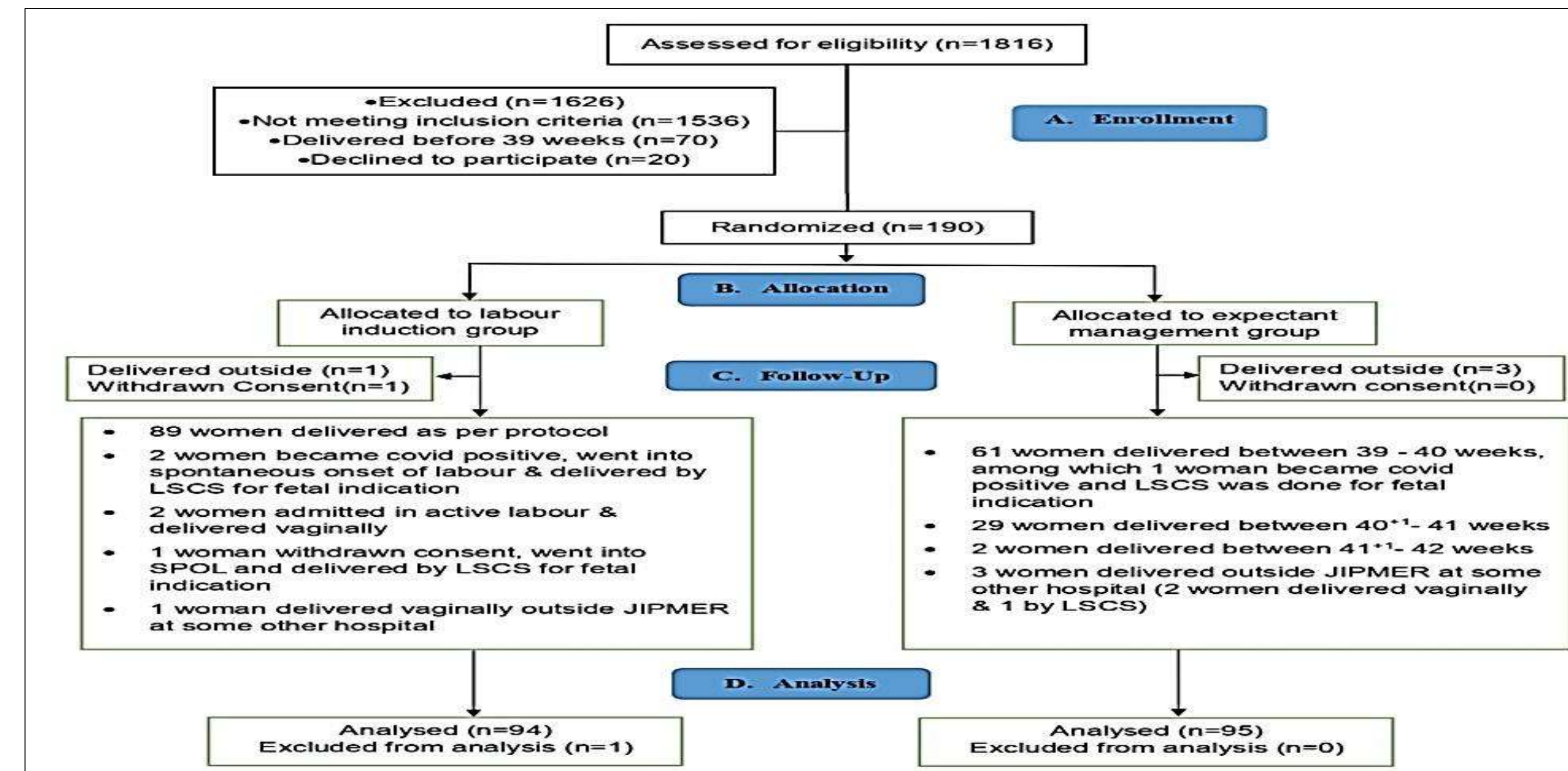
- To compare the rate of caesarean section in elective induction of labour (E-IOL) vs expectant management (EM) at 39 weeks
- To compare maternal and perinatal outcomes between women undergoing E-IOL vs EM at 39 weeks

METHODOLOGY

- Low risk nulliparous pregnant women who attended JIPMER OPD between 36-38⁺⁶ weeks were screened for eligibility criteria
- Women after fulfilled eligibility criteria & gave consent ,were randomly assigned into either E-IOL or EM group
- Pelvic assessment was done at 38 weeks
- Based on bishop score, induction process started in E-IOL group (39-39⁺⁴)
- Women assigned to EM group were managed according to department protocol
- Labour details, maternal and perinatal outcomes were analysed & compared

STATISTICAL METHODS

- Intention to treat analysis was performed
- Normality test was done using K-S test
- Continuous variables were expressed as mean $\pm$ SD or median with inter quartile range & compared between the groups using Mann Whitney U test
- Categorical variables were compared by Chi-square test/Fishers exact test
- P<0.05 was considered significant
- The statistical test was done using SPSS version 19.0

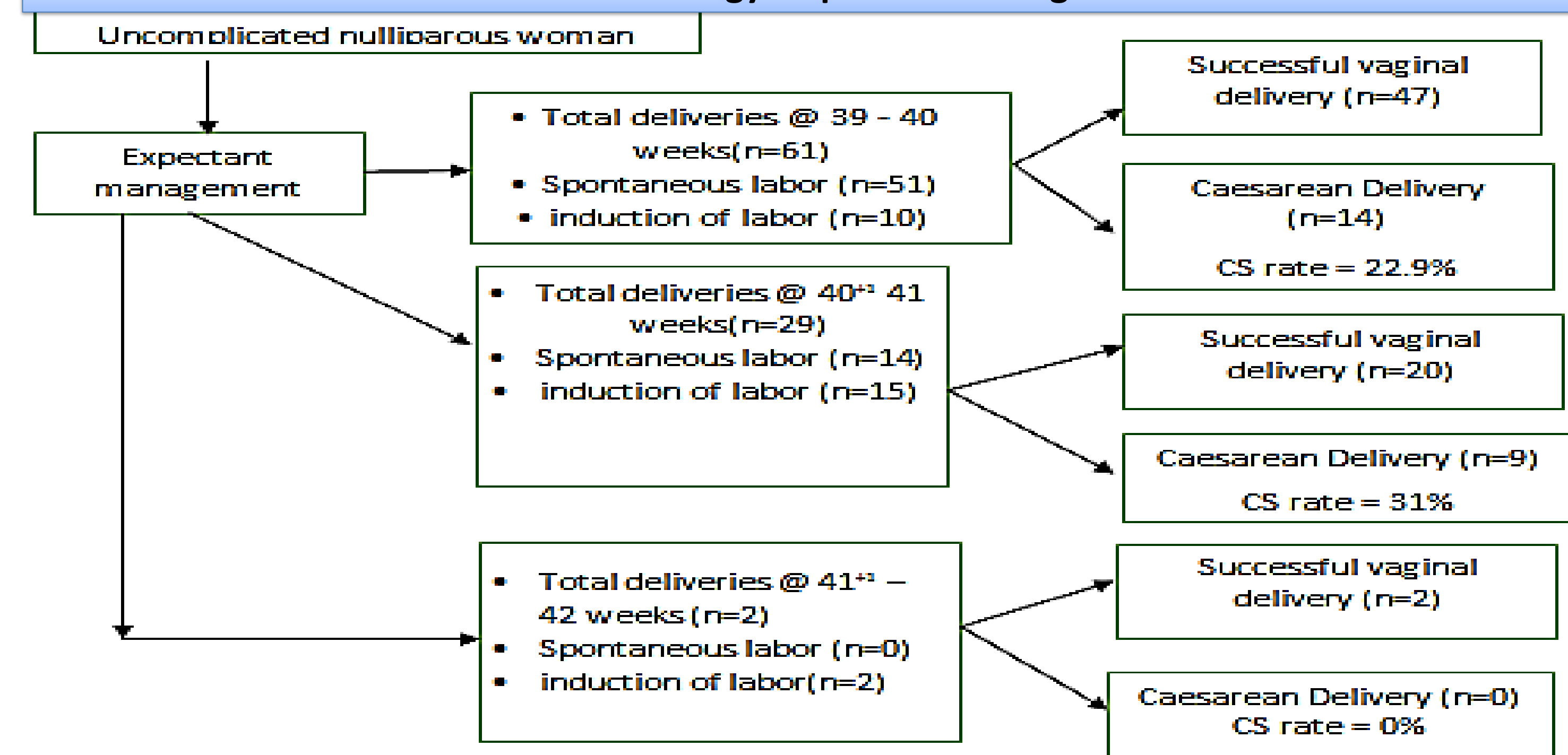


RESULTS

BASELINE CHARACTERISTICS

Sl. No.	Parameters studied (Mean $\pm$ SD / Median with IQR)	Study Group N=94 (%)	Control Group N=95 (%)	p Value
1	Maternal age (years)			
	Median with IQR	24 (22 – 26)	24 (21 – 27)	0.707
2	Maternal BMI (Kg/m²)			
	Mean $\pm$ SD	27.3 $\pm$ 1.58	27 $\pm$ 1.67	0.171
3	Gestational age at randomization			
	Median with IQR	39 ⁺² (39-39 ⁺⁴)	39 ⁺² (39-39 ⁺⁴)	-
4	Method of conception			
	Spontaneous	90 (95.7 %)	93(97.9 %)	0.682
	Assisted conception	4 (4.25 %)	2 (2.1 %)	
5	Previous pregnancy loss			
	<12 weeks	5 (5.31%)	3 (3.15 %)	0.394
	>12 weeks	1 (1.06%)	0	
6	Bishop score at randomization			
	Median with IQR	4 (3 – 4)	3 (3-4)	0.246

Decision Strategy: Expectant Management



3 women delivered outside JIPMER at some other hospital (2 SVDs and 1 LSCS), the exact gestational age of those delivered outside is not known

RESULTS (CONT.) MODE OF DELIVERY

Mode of delivery	Study group N= 94 (%)	Control group N= 95 (%)	OR (95% CI)	p value
Vaginal delivery	80 (85.1%)	71 (74.7 %)	0.587 (0.285 – 1.211)	0.149
Caesarean section	14 (14.9 %)	24 (25.3 %)		

MATERNAL OUTCOMES

Maternal Outcomes	Study group N= 94 (%)	Control group N= 95 (%)	OR (95 % CI)	p Value
Intrapartum Fever	3 (3.2%)	7 (7.4%)	0.69(0.45– 1.07)	0.194
Perineal Tear	5 (5.31%)	1 (1.1%)	2.54 (0.438 – 14.7)	0.368
PPH	8 (8.5%)	8 (8.4%)	1 (0.59 – 1.66)	1
Puerperal Pyrexia	1 (1.06%)	3 (3.2%)	0.659 (0.632–1.18)	0.621
Blood Transfusion	1 (1.06%)	4 (4.2%)	0.615 (0.38 – 0.97)	0.368

COMPOSITE PERINATAL OUTCOMES

Parameters Studied	Study group N= 94 (%)	Control group N= 95 (%)	Relative Risk	P-value
Composite perinatal outcome	5(5.3%)	11(11.6%)	2.23(0.93-5.32)	0.022
Still Birth	1 (1.1%)	0	0.49 (0.43 – 0.57)	
5 APGAR < 7	2 (2.1 %)	4 (4.2 %)	0.74 (0.41 – 1.33)	
HIE stage II/III	0	2 (2.1%)	0.49 (0.42 – 0.57)	
NICU stay > 48 hours	2 (2.1%)	5 (5.26%)	0.62 (0.26 – 1.48)	

DISCUSSION

- There was decreased caesarean section rate in elective induction group compared to expectant management but it was not statistically significant (p = 0.14)
- The composite perinatal outcome was 5.3% in study group vs control group was 11.6 % with relative risk of 2.23 (p = 0.02)

- A total 53.7% went into spontaneous labour before 40 weeks in expectant management arm and it became 68.4% before 41 weeks (No spontaneous labour after 41 weeks)
- One still birth in intervention arm is a concern and polices for induction and guidelines for monitoring the woman in labour are essential

LIMITATIONS

- We could randomize only 50% of the proposed sample as there were logistic difficulties in recruiting low risk nulliparous pregnant women in this ongoing COVID pandemic
- Though the Bishop score was assessed by single observer at randomization in study group, further management after labour induction was left to the discretion of treating unit
- The trial was not powered to study the differences in adverse maternal and perinatal outcome

CONCLUSION

- Elective induction in low risk women at 39 weeks was not associated with increased caesarean section rate compared to expectant management
- Elective induction at 39 weeks was not associated with greater frequency of adverse maternal and perinatal outcome

REFERENCES

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- 2.ACOG Practice Bulletin. Clinical management guidelines for obstetricians-gynecologists. Number 55, September 2004 (replaces practice pattern number 6, October 1997). Management of Postterm Pregnancy. Obstetrics and gyne.pdf.