ORIGINAL RESEARCH

To compare the maternal and perinatal outcome with elective induction of labour at 40 weeks and with expectant management until 41 weeks of gestation

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ABSTRACT

Background: Timing of Induction of labour in low-risk pregnancies continues to be a matter of debate with perinatal risks such as fetal hypoxia, shoulder dystocia, meconium aspiration syndrome (MAS), macrosomia in postdated pregnancies and fear of litigation on one side and increasing stress on de-medicalisation of labour process on other side. **Materials and Methods:** This was a randomized controlled trial that included the low risk pregnant women at or beyond 39 weeks of gestation age. Eligible participants were randomized to group A (induction at 40 weeks gestation) and group B (expectant management at 41 weeks gestation) and outcomes were compared. **Results:** Out of 174 total participants recruited, 56 (32.18%) participants were randomised to group A. 118 (67.82%) participants were allotted group B. Majority of participants, 78.57% and 78.81% delivered vaginally in both group A and group B respectively. Most common indication for caesarean section was fetal distress in both group A and B. There was no maternal and neonatal mortality in either group. There was no significant difference in caesarean rate amongst group A (21.43%) and group B (21.19%).Chi-Square = 0.001, df = 2, p-value = 0.999. Expectant management till 41 weeks is not associated with increased adverse neonatal outcome. **Conclusion:** A policy of induction of labour at 40 weeks of gestation in low risk pregnancies was not associated with any statistically significant change in caesarean rates irrespective of parity or Bishop score. This intervention did not result in any statistically significant reduction in perinatal morbidity (MAS, need of hospitalisation, APGAR score <7, birth weight > 4 kg).

Keywords: Meconium aspiration syndrome, non stress test, APGAR score,induction of labour,expectant management.

INTRODUCTION

The guiding principles for health care providers attending to pregnant women are regular screening for risk factors and complications, counseling and evidence based intervention when indicated. Induction of labour is one such intervention that precedes 20% of all births.[1] In high-risk pregnancies, the balance often shifts in favor of delivery between 37 to 39 weeks of gestation, but the optimal timing of delivery in low-risk pregnancies is still not clear.

Most of the guidelines agree on induction at 42 weeks gestation while others recommend that women with uncomplicated singleton pregnancy should be offered induction at 41 weeks.[2]

Perinatal risks such as fetal hypoxia, asphyxia, intracranial damage, shoulder dystocia, meconium aspiration syndrome (MAS), macrosomia, atelectasis, hypoglycemia, and stillbirths are possible in post-dated pregnancies and increases as the gestational age exceeds 40 weeks.[3,4,5]

It remains a matter of debate if active management of low risk pregnancy at term through preventive labour induction may improve perinatal outcomes.

AIMS AND OBJECTIVES

To determine if elective induction at 40 week of gestation in low risk pregnancies is associated with

1. Decrease in perinatal complications

2. Increase in operative delivery (operative vaginal delivery/caesarean section)
3. compared to the policy of expectant management till 41 week of gestation.

MATERIALS AND METHODS

This study was conducted at Government Medical College, Amritsar from January 2021 to March 2022 after approval from institutional ethical committee. This was a randomized controlled trial that included the low risk pregnant women who attended the antenatal clinic and labour room. Patients were assessed at or beyond 39 weeks of gestation for the following inclusion and exclusion criteria.

INCLUSION CRITERIA

- Maternal age group 20-35 years.
- Singleton low risk pregnancy with the cephalic presentation, membrane intact, AFI>5.
- Reliable dates, previous regular menstrual cycles, not conceived during lactational amenorrhea.
- Pregnancy with gestation dating confirmed by ultrasonography done at (<22 weeks).

EXCLUSION CRITERIA

- Maternal age group <20 and >35 years.
- Multifetal gestation, Mal-presentation, PROM.
- Contraindication to vaginal delivery (e.g. placenta previa, cephalopelvic CPD), maternal instability),
- Need of urgent birth e.g. APH, fetal distress, Non-reassuring fetal status (no fetal movements, abnormal fetal heart rate at time of randomisation).
- Unknown dates, irregular menstrual cycle, No USG available at less than 22 weeks gestation.
- Maternal diseases like severe anemia, diabetes and pre-existent maternal heart or kidney diseases.
- Evidence of fetal hypoxia or placento-fetal insufficiency in Doppler, severe oligohydramnios.
- Intrauterine fetal death (IUFD) or fetal anomalies
- Pregnancy with previous Caesarean section.
- Hypertensive disorders of pregnancy
- Rh negative pregnancy

Those patients fulfilling the criteria were briefed about the study and those giving the written informed consent were randomized to either of the study group.
Randomization in ratio 1:1 with random number table was done between 39 – 40 weeks.
Eligible patients who presented for the first time after 40 weeks of gestation were automatically allotted to group B.

Baseline assessment at >39 week of gestation: History and general examination, Obstetric examination, Pelvic assessment. Review of Routine antenatal investigation including Hb, DIPSI results, Blood grouping, Urine examination, Third trimester USG for FWB and AFI.
After randomization, patients were asked to report at 40 weeks of gestation or earlier if they went in labour or had bleeding, leakage, decreased fetal movements. Those remaining undelivered at 40 weeks gestation and allotted to group A were admitted for induction of labour at 40 weeks of gestation.
Those allotted to group B were assessed in OPD at 40 weeks, 40 weeks 3 days and finally admitted at 41 weeks for induction. At visit at 40 weeks and 40 weeks 3 days gestation, all patients of group B were subjected to obstetric examination and NST. Those with persistent non reactive NST were induced before 41 weeks of gestation.

Outcomes

Primary

1. Perinatal mortality and neonatal morbidity (5-minute Apgar-score below 7, meconium aspiration syndrome, birth asphyxia, weight > 4kgs, plexus brachialis injury and/or NICU admission.
2. Rates of operative delivery (caesarean and operative vaginal deliveries)

Secondary

Maternal outcomes such as post-partum haemorrhage ≥ 1000 ml and severe perineal injury (third- or fourth-degree perineal tear), puerperal sepsis, wound infection,length of hospital stay.

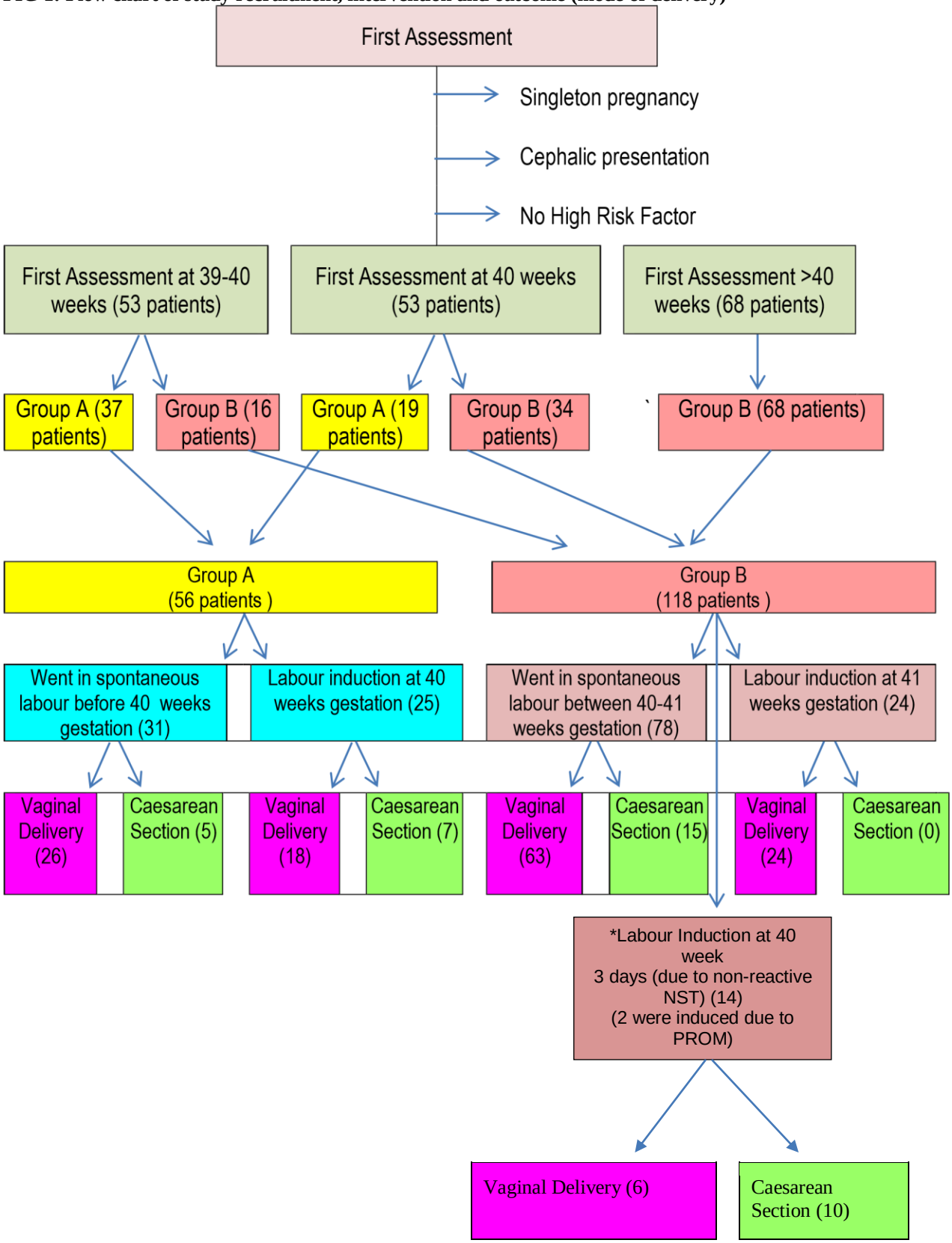
Data Analysis

The results were analysed according to the intention to treat principle. The outcomes were assessed by calculating relative risks and 95% confidence intervals. We investigated significance using $\chi 2$ test, Fisher's exact test, t test, or Mann-Whitney U test statistics. The log-rank test statistic was used to evaluate the difference in time to birth.
Statistical analyses were performed the using statistical programmers SPSS version 24 for Windows. The p value < 0.05 considered statistically significant.

RESULTS

Out of 174 total participants recruited, 56 (32.18%) participants were randomised to group A (induction planned at 40 weeks of gestation).118 (67.82%) participants were allotted group B (expectant management planned till 41 weeks of gestation).
In group B, 14 participants had to be induced before completion of 41 weeks of gestation due to non-reactive NST while 2 were induced due to PROM. (Fig 1)

FIG 1: Flow chart of study recruitment, intervention and outcome (mode of delivery)



Both the groups were comparable in terms of maternal age (mean age 24.68±3.66 years in group A, 24.64±3.45 years in group B, p-value = 0.7876) and parity (Group A 53.57% nulliparous, Group B 55.93% nulliparous, p value= 0.9581)

There was no significant difference in caesarean rate amongst group A (21.43%) and group B (21.19%). $\chi 2$ = 0.001, df = 2, p-value = 0.99 (Table1)

Thus proving the null hypothesis that the intervention i.e. induction at 40 weeks is not associated with an increased caesarean rate compared to expectant Management till 41 weeks of gestation is true.

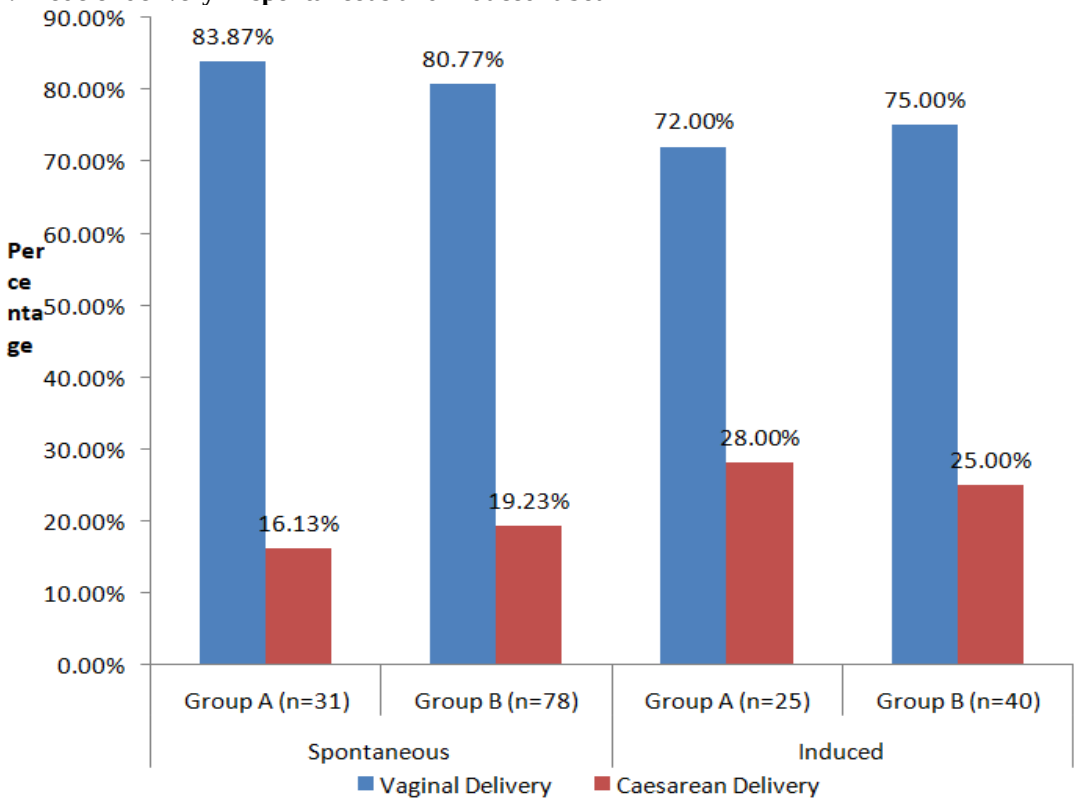
TABLE 1: Mode of delivery

Vaginal Delivery and Caesarean Section	Group A		Group B		Total	
	No. of cases	%age	No. of cases	%age	No. of cases	%age
Vaginal Delivery	44	78.57	93	78.81	137	78.74
Caesarean section	12	21.43	25	21.19	37	21.26
Total	56	100.00	118	100.00	174	100.00

Chi-Square = 0.001, df = 2, p-value = 0.999

Participants who went spontaneously in labour were 55.35% in group A and 66.10% in group B. There was no statistically significant difference in caesarean rates amongst participants who went spontaneously in labour (18.34%) and induced group (26.2%)of participants in both group A and group B although overall rate of caesarean delivery was higher among induced labour participants in both groups.. $\chi 2$= 1.482, df=1, p-value=0.224 (Fig 2)

FIG 2: Mode of delivery in spontaneous and induced labour



Although caesarean section rate were higher among those with Bishop score<6, both nulliparous and parous women,it wasn't statistically different in both the groups.(table 2 and table 3)

TABLE 2: Effect of parity and Bishop Score (at the time of first assessment) on mode of delivery in group A

Bishop Score and Mode of delivery		Group A			
		Nulliparous		Parous	
		Number of cases	Percentage	Number of cases	Percentage
<6	Vaginal Delivery	14/16	87.50	6/10	60.00
	Caesarean section	2/16	12.50	4/10	40.00
>6	Vaginal Delivery	10/14	71.43	14/16	87.50
	Caesarean section	4/14	28.57	2/16	12.50

Vaginal delivery= Chi-square=3.532, df=1, p-value=0.060
Caesarean section= Chi-square=1.333, df=1, p-value=0.348

TABLE 3: Effect of parity and bishop score (at the time of first assessment) on mode of delivery in group B

Bishop Score and mode of delivery		Group B			
		Nulliparous		Parous	
		Number of cases	Percentage	Number of cases	Percentage
<6	Vaginal Delivery	18/27	66.67	10/13	76.92
	Caesarean section	9/27	33.33	3/13	23.08
>6	Vaginal Delivery	30/39	76.92	35/39	89.74
	Caesarean section	9/39	23.08	4/39	10.26

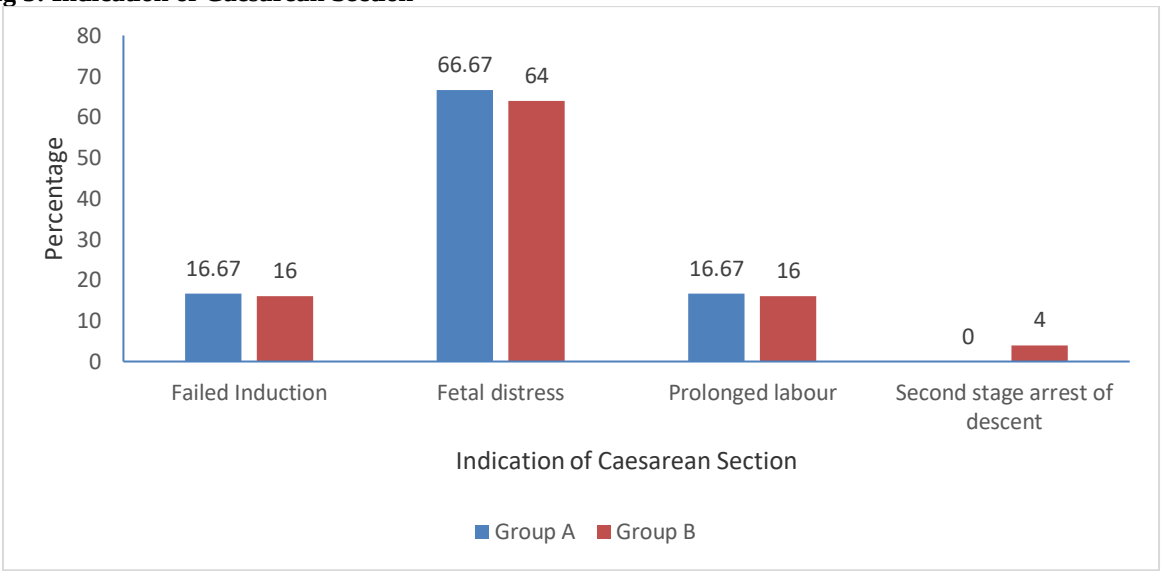
Vaginal delivery=Chi-square=2.576, df=1, p-value=0.109
Caesarean section= Chi-square=0.103, df=1, p-value=0.748

RR of caesarean section amongst participants with Bishop score<6 was 1.5 and p-value =0.13, not statistically significant.

In both groups A and B, majority of participants were delivered in < 24 hours of duration, irrespective of whether the participants spontaneously went into labour (84.62% from group A, 85.71% from group B) or were induced (92% from group A and 90% from group B).

Most common indications for caesarean section in both group A and B were similar as shown in figure 3.

Fig 3: Indication of Caesarean Section



Labour abnormalities (prolonged labour and second stage arrest of descent) leading to caesarean section were more commonly seen among induced labour in both group A(100%) and B(80%) compared to those who went spontaneously in labour with RR=10.06, p value=0.03 hence, statistically significant.

In group A, 3 (5.36%) and in group B, 5 (4.24%) participants delivered newborn with birth weight >4.0kg. RR= 0.78, p-value=0.7419 in expectant management group and thus expectant management didn't increase the risk.

No incidence of intrauterine fetal demise, intrapartum stillbirth, neonatal and maternal mortality was observed in both group A and B.

No incidence of hypoxic encephalopathy, neonatal sepsis, neonatal mortality, shoulder dystocia, brachial plexus injury was seen in both the groups.

Majority of newborns had APGAR score at 5 minute >7 in group A(96.43%)and B (94.07%). No advanced neonatal resuscitation was required in any of the neonates in both groups. The expectant management till 41 weeks is not associated with increased risk of Apgar score<7 with RR=1.66, p value=0.518.

Presence of meconium stained liquor was similar in group A (32.14%) and group B (33.89%),$\chi 2$=0.053, df=1, p-value=0.819

In group A, meconium aspiration syndrome (MAS) was present in 1 (1.78%) newborn while in group B, MAS was present in 3 (2.54%) newborns. Incidence of MAS was very low and was slightly higher in induced participants in both group A and B compared to those who had spontaneous labours.

3.57% in group A and 1.69% in group B suffered lower genital tract injuries (cervical tear, vaginal tear or perineal tear) that needed suturing. The blood loss was not significantly increased in any of these cases and none of the patients required blood transfusion.

There was no case of puerperal Sepsis in either group although single episode of puerperal pyrexia was seen

in1.78% cases of group A and 0.84% cases of group B. Surgical site infections were observed in 16.67% cases in group A and 10.15% cases in group B .

Majority of participants (77.27% from group A and 83.87% from group B) remained hospitalized for <2days in case of vaginal delivery while majority of participants (75% and 92% in group A and B respectively) had a hospital stay of 6-10 days in case of caesarean delivery

DISCUSSION

In our study, rate of caesarean section were not different amongst group randomized to elective induction at 40 weeks of gestation (21.43%) and group randomized to expectant management till 41 weeks of gestation. (21.19%) and were not affected by the fact whether labour was spontaneous in onset or induced which is similar to the conclusion made by Bapoo[6] who found no differences in caesarean rates (OR 1.02) or other adverse pregnancy outcomes when IOL was done near 40 weeks as compared with expectant management in low-risk pregnancies.

Our observation of caesarean delivery rate of 21.19 % in group B is similar to Caesarean rates of 24.2% observed by Hemkanta,[2] between 40-41 weeks gestation. Similarly Lataet al[7] reported 26.47% caesarean rate between 40 week 1 day - 41 weeks along with 5.85% had operative vaginal delivery.

On the other hand, Patil et al[8] reported caesarean rates to be 12% amongst low risk pregnancies induced at 40 weeks vs 30% amongst those induced at 41 weeks which was statistically significant (p =0.007).

Our caesarean rates were much lower than many of contemporary studies because we included only low risk pregnancies. Caughey[11] reported the caesarean rate to be 14.1% at 40 weeks gestation and 19.8% at 41 weeks gestation.

Although we found caesarean rates were slightly higher amongst induced labours 26.1% as compared to 18.34% in spontaneous onset labours, it was not statistically insignificant (p=0.22).

Dobariya et al[10] observed that amongst postdated pregnancies, amongst those undergoing spontaneously in labour 30.95% needed LSCS, while those undergoing labour induction 33.34% needed LSCS but this included cases beyond 41 weeks as well.

Mode of delivery with respect to Bishop score and parity was not statistically different in both the groups in our study.

RR of caesarean delivery was 1.5 amongst participants with Bishop score< 6 with p=0.13 and hence not statistically significant. Cochrane[11] review by Gülmezoglu[12] in 2022 reported the RR for caesarean delivery amongst induced labours near or beyond term to be 1.12 amongst women with Bishop score<6.

In our study, fetal distress was most common indication of caesarean section in both group A and B and accounts 66.67% and 64% respectively followed by failure of induction of labour (16.67% in group A and 16% in group B) and prolonged labour (16.67% in group A and 20% in group B).

Dobariya[10] mentions similar results with fetal distress as the most frequent cause if cesarean section in 27(32.14%) of patients followed by failure to progress in 22.22%. Lata et al[7] also showed comparable results with 37.5% of cases indicating failure of induction, 25% indicating fetal distress, 21.87% indication non progress of labour. Senthilpriya[13] also mentioned as most common reason for cesarean section was fetal distress (10%) followed by failure of induction of labour (6%) and prolonged labour (4%) amongst postdated pregnancies.

Failed induction rates observed by Tondage et al[14] were 9% at 40 weeks vs 12% at 41 weeks. Failed induction rates amongst postdated pregnancies were as high as 37.5% in study by Lata et al.[7] and 31.25% in study by Kandalgaoker et al[15] and 21.44% in study by Dobariya et al.[10] our rates of failed induction were much lesser than most of these studies which may be due to different protocols of induction being followed and may be a contributory factor towards our lower caesarean rates in both groups compared to other contemporary studies.

We found labour induction to be a significant risk factor for labour abnormalities leading to caesarean deliveries. (RR 10.06, p =0.03)

In our study both group A and B had equal incidence of meconium stain liquor (32.14%, 33.89% respectively. It was in fact higher amongst those undergoing spontaneous labour compared to induced labour in both groups.

Rates of meconium staining were 25.8% at 40 weeks gestation vs 31.9% at 41 weeks as reported in a the large retrospective cohort study conducted by Caughey. In our study meconium aspiration syndrome rate was very low and it was present more in group B but RR of MAS by expectant management was 1.42, p=0.75, hence not statistically significant. RR of MAS was 0.27 at 41 weeks gestation in large Cochrane study done by Gülmezoglu.[12] Caughey[11] reported serious neonatal complications including MAS to be 2.31% at 40 weeks vs 3.14% at 41 weeks gestation.Maternal morbidity in our study was very low and there was no maternal mortality.

The incidence of PPH, third/fourth degree perineal tears and febrile morbidity have been reported by Caughey[11] to be 3.1%, 4.6% and 2% respectively at 4.1%, 6.7% and 2.7% respectively at 41 weeks gestation.

Tondage[14] showed that PPH, cervical tear, perineal tear and sepsis were 2 vs 3 %, 2 vs 2%, 1 vs 2% and 2 vs 3% in 40 week and 41 week gestation respectively.Our rates of PPH and lower genital tract injuries were comparable to other studies but rates of surgical site infections were higher.

STRENGTH

The result analysis was done with intention to treat basis, thus resembling the real life scenarios

WEAKNESS

In order to increase the number alloted to group B we had to allow for inclusion of low risk pregnancies referred to our institute after 40 weeks of gestation. These patients were not really randomised by us but rather by natural chance.

CONCLUSION

A policy of induction of labour at 40 weeks of gestation in low risk pregnancies was not associated with any statistically significant change in caesarean rates irrespective of parity or Bishop score. This intervention did not result in any statistically significant reduction in perinatal morbidity (MAS, need of NICU, APGAR score <7, birth weight > 4 kg).

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