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Original Research Article

Fetomaternal outcome in post dated pregnancy

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ABSTRACT

Background: The risks to the fetus increase after 41 weeks mainly due to increasing fetal weight, decline in placental function, oligohydramnios which increase chances of cord compression, and meconium aspiration. Perinatal mortality after 42 weeks is twice as compared to the perinatal mortality at 40 weeks and by 44 weeks the rate is increased up to threefold. In cases of prolonged pregnancy, fetus is more at risk of hypoxia during labor than a fetus at term.

Methods: This cross sectional observational study of feto-maternal outcome in post dated pregnancy (Women beyond 40 weeks of gestation) was carried out in the department of obstetrics and gynaecology in a rural based tertiary care centre from October 2016 to September 2018, willing to participate and fulfilling the inclusion and exclusion criteria in the study period.

Results: Majority i.e. 45 patients (46.9%) went into spontaneous labour and delivered vaginally, whereas 16 patients (16.7%) required caesarean section. Among all 45 participants who were given induction, maximum 26 (57.78%) were induced by Dinoprostone gel, 4 patients (8.89%) were induced by Tab. Misoprostol.

Conclusions: The present study, we conclude that, the post dated pregnancy can be considered as a high risk factor from the point of view of fetal outcome as there is more fetal morbidity.

Keywords: High risk pregnancies, Maternal mortality, Outcomes, Perinatal mortality, Postdated pregnancy

INTRODUCTION

Post dated pregnancy is gestation longer than 40 weeks or 280 days. Prolonged pregnancy is defined as any pregnancy that lasts 294 days or more. Pregnancy between 41 and 42 weeks is late term pregnancy. The objective of every obstetrician is the delivery of a healthy baby to a healthy mother at the end of each pregnancy.

Term pregnancy was defined as a pregnancy with gestational age from 3 weeks before till 2 weeks after the estimated date of delivery and post term pregnancy as a pregnancy with a gestational age of 42 completed weeks or more. Term is a period of five weeks from 37 to 42 weeks that is 260 to 294 days. Expected date of delivery is calculated from the first day of the last menstrual period to the end of 40 weeks or 280 days. In late 2012, a work group including representatives from the American

College of Obstetricians and Gynaecologists (ACOG), the Society for Maternal-Fetal Medicine (SMFM) and other professional societies recommended that the label term be replaced by early term, full term, late term and post term to more accurately describe deliveries occurring at or beyond 37 weeks of gestation.^{2,3}

The period after 41 weeks of gestation is valuable for patient and obstetrician. Inadequate counselling regarding expected date of delivery may create undue anxiety and distress for the patient.⁴ The frequency of adverse neonatal outcome is observed to be lowest among uncomplicated pregnancies delivered between 39 and 40 weeks of gestation. The most frequent cause of prolonged pregnancy is inaccurate dating.^{5,6} The risk factors are primiparity, maternal genetic factors, prior history of postdatism, obesity and male gender of the fetus. Criteria for diagnosing postdates are correlation of menstrual

history, clinical findings and USG. Ultrasonographic dating in early pregnancy can improve reliability of EDD.^{7,8}

In post dated pregnancy, there are chances of fetal hypoxia, asphyxia, intracranial damage, meconium aspiration syndrome (MAS), macrosomia, atelectasis, hypoglycaemia and stillbirths. These perinatal risks increase with increase in the gestational age beyond 40 weeks. 9,10 The maternal risks include an increase in labor dystocia, an increase in severe perineal injury related to macrosomia and operative vaginal delivery and an increase in the rate of caesarean delivery and postpartum haemorrhage. 11,12 The risks to the fetus increase after 41 weeks mainly due to increasing fetal weight, decline in placental function, oligohydramnios which increase chances of cord compression, and meconium aspiration. Perinatal mortality after 42 weeks is twice as compared to the perinatal mortality at 40 weeks and by 44 weeks the rate is increased up to threefold. In cases of prolonged pregnancy, fetus is more at risk of hypoxia during labor than a fetus at term. All these factors compel the obstetrician to induce labor once 41 weeks are completed, even in the absence of any valid indication.^{5,6}

In the present study, maternal and fetal outcome was studied in pregnancy beyond 40 weeks of gestation to find out the frequency of post dated pregnancies, to study the maternal outcome in pregnancies beyond expected date of delivery (EDD) and to know the fetal morbidity and mortality.

METHODS

This cross sectional observational study of feto-maternal outcome in post dated pregnancy (Women beyond 40 weeks of gestation) was carried out in the Department of Obstetrics and Gynaecology in a rural based tertiary care centre from October 2016 to September 2018, willing to participate and fulfilling the inclusion and exclusion criteria in the study period. Approval of the Institutional Ethics Committee was taken prior to commencement of the study.

The sample size was calculated on the basis of a pilot study over a period of 3 months from November 2016 to January 2017 to know the hospital frequency of postdated pregnancies. Depending on the pilot study, frequency of postdated pregnancy was calculated as 3 to 4 per month. The approximate sample size of the present study was pre decided in the range of 74 to 96 subjects. The post dated pregnancy cases reporting to the hospital after completion of the sample size were also included, the study being time bound.

Inclusion criteria

 Post dated women with regular menstrual cycles and known first day of last menstrual period or with first trimester ultrasonography

- Singleton pregnancy with vertex presentation.
- Uncomplicated Antenatal cases beyond 40 weeks of gestation, willing to participate in the study.

Exclusion criteria

- High risk pregnancies like diabetes, antepartum haemorrhage (APH), premature rupture of membranes (PROM) and pregnancy induced hypertension (PIH), heart disease, chronic hypertensive disease, chronic renal disease
- Previous caeserean sections
- Congenital anomalies
- Irregular menstrual cycles and unknown LMP and not having 1st trimester ultrasonography
- Multiple gestation
- Non-vertex presentation
- Not willing to participate in the study.

The data was collected using a case record form after taking informed consent of the participants during the study period. Total 96 patients were selected according to the clinical examination of the patient.

Detailed clinical history like menstrual history, obstetrics history, past history, personal history, marital history, family history was noted. Exact gestational age was calculated using the Naegele's formula in women with regular menstrual cycles. In case, if a woman has menstrual cycles, her 1st ultrasonography report was used for calculation of gestational age. If there was a difference of more than 5 days between the first day of the last menstrual period and the first trimester ultrasonography, the estimated date of delivery was calculated as per the first trimester ultrasonography. When there have been, the first and second trimester ultrasonography, the gestational age was calculated as per the first trimester ultrasound.

The patient's general condition, temperature, pulse, blood pressure, pallor, icterus, height and weight were noted. Systemic examination was done. Per abdominal examination was carried out to know the presentation and the position of the fetus, the amount of liquor amnii and the fetal heart rate. Sterile per speculum examination was conducted to visualize the cervix and the vagina, any discharge per vaginum, any leaking or bleeding per vaginum. Sterile per vaginal examination was done to assess cervical dilatation, cervical length (or effacement), station, consistency and position of cervix and Modified Bishop's score was calculated. Adequacy of the pelvis was assessed.

Bishops score >=6 was regarded as favourable and score of <6 was regarded as unfavourable. Decision for instrumental delivery or caesarean section was taken according to the fetal heart rate and the progress of labour. Record was kept about the mode of delivery and if any post partum maternal complications that occurred and they were labelled under maternal morbidity. The

baby was attended by the paediatrician after delivery, APGAR score was noted in 1 minute and 5 minutes, baby weight, any gross congenital anomaly, whether there was any necessity for NICU admission was recorded. If yes then cause of NICU admission was noted. Any neonatal deaths, that occurred, were recorded.

RESULTS

There Total deliveries in the tertiary health care centre in the period of 2 years from October 2016 to November 2018 were 5110. Out of those, total numbers of cases of postdated pregnancies were 260. Out of the 260 women, total number of cases selected in the present study after applying inclusion and exclusion criteria were 96. Therefore, the frequency of post-dated pregnancy according to the present study is 260/5110 x 100 = 5.09%.

Out of the total 96 patients studied, majority 84 (87.5%) were registered in our health care centre for their ANC visits, whereas 12 (12.5%) were unregistered. The mean age of study participants was 26.34 years (SD±5.4) within range of 17 to 40 years of age and maximum participants 77 (80.2%) were included in the age group of 20 to 35 years of age. The least number, 8 patients were

in the age group >35 years (8.3%). 11 patients (11.5%) were in the age group of <20 years. Majority 67 (69.8%) of the study participants were included in the group of gestational age of 40 week to 40+6 week. 26 (27.1%) patients had gestational age from 41 to 41+6 weeks, only 3 patients (3.1%) were more than 42 weeks (Table 1).

Table 1: Distribution of participants according to their demographic data.

Demographic data		Number of participants	Percent (%)
	<20	11	11.5
Age group	20-35	77	80.2
(Years)	>35	8	8.3
	Total	96	100
	40-40W6D	67	69.8
Gestational	41-41W6D	26	27.1
age	≥ 42 W	3	3.1
	Total	96	100
Canadity	Primigravida	61	63.5
Gravidity	Multigravida	35	36.5
Previous Present		25	26
history of post-datism	Absent	71	74

Table 2: Distribution of participants according to their clinical parameters (mother).

Clinical parameters		Number of participants	Percent (%)
Presentation on admission	In labour	41	42.7
Presentation on admission	Not in labour	55	57.3
	Spontaneous vaginal	45	46.9
Mode of delivery	Successful induction	35	36.5
	Caesarian section	16	16.7
	Tab Misoprostol 25 mcg	4	8.89
Type of induction	Dinoprostone PGE2 gel	26	57.78
	Oxytocin infusion	15	33.33
	Fetal distress	6	37.5
Indication of caesarean section	Failure of induction	5	31.25
indication of caesarean section	CPD	4	25
	Transverse lie	1	6.25
	<4	71	74
Bishop scoring	4-6	19	19.8
	>6	6	6.4
Instance and allies and	Outlet forceps	4	80
Instrumental delivery	Vacuum	1	20

Majority 61 (63.4%) of the study participants were belonging to primigravida group and 35 patients (36.5%) were multigravida 25 out of the 35 multigravidas had history of postdatism in previous Pregnancy. Maximum 55 (57.3%) patients were not in labour, whereas 41 (42.7%) of the patients were in labour at the time of admission. Out of the 55 patients who were not in labour,

45 were induced of which 35 (36.5%) delivered successfully vaginally.

Majority i.e. 45 patients (46.9%) went into spontaneous labour and delivered vaginally, whereas 16 patients (16.7%) required caesarean section. Among all 45 participants who were given induction, maximum 26 (57.78%) were induced by Dinoprostone gel, 4 patients

(8.89%) were induced by Tab. Misoprostol and 26 (33.33%) were augmented by oxytocin infusion Among all participants who had undergone caesarean section, indication for caesarean section was fetal distress in 6 patients (37.5%) out of which 5 were fetal distress in induced patients and 1 patient was directly taken for emergency LSCS in view of non-reassuring fetal heart. Failure of induction was the indication in 5 cases (31.25%), which were followed by cephalo-pelvic

disproportion in 4 cases (25%) and transverse lie in 1 patient (6.25%) (Table 2).

Poor Bishop's score is associated with failure of induction and lesser chances of vaginal delivery. In patients with Bishop's score <4, maximum underwent caesarean section in view of failure of induction and fetal distress. Amongst all 96 participants, bishop score was <4 in 71 (74%) participants.

Table 3: Distribution of participants according to their clinical parameters (newborn).

Clinical parameter	rs	Number of participants	Percent (%)
	<2.5 kg	13	13.5%
Birth weight	2.5-3.5 kg	77	80.2%
	>3.5 kg	6	6.3%
APGAR score at 1	<4	4	4.2%
min	4-7	6	6.2%
111111	>7	86	89.6%
ADCAD assus at 1	<4	3	3.1%
APGAR score at 1 min	4-7	3	3.1%
111111	>7	90	93.8%
NICU admission	Yes	12	12.5%
NICU admission	No	84	87.5%
	Respiratory distress with MSL	4	4.17%
Indications for NICU admission	Low birth weight	2	2.08%
	Respiratory distress	4	4.17%
	Hyperbilirubinemia	2	2.08%
No		84	87.5%

Table 4: Distribution of participants according to their morbidity indicators.

Morbidity indicat	tors	Number of participants	Percent (%)
	PPH	5	5.20
	Para-urethral tear	2	2.08
Maternal	Shoulder dystocia	1	1.04
morbidity	Episiotomy gape	1	1.04
	Wound gape	1	1.04
	None	86	98.58
Perinatal	Still birth	2	66.66%
mortality	Neonatal death	1	33.33%

Among all participants (5 out of 96) who needed instrumental delivery, 4 (80%) participants delivered by assistance of outlet forceps and 1 (20%) participant needed assistance of vacuum The majority 77 (80.2%) of the babies born to participants weighed between 2.5 to 3.5 kg. Only 6 (6.3%) babies had birth weight of >3.5 kgs. 13 babies (13.5%) had birth weight <2.5 kgs. The majority 86 (89.6%) of the babies born to participants had Apgar score of >7 after 1 minute of birth, 6 babies (6.2%) had Apgar score of <4 at 1 minute of birth The majority 90 (93.8%) of the babies born to participants were having Apgar score of >7 counted at 5 minutes after birth, 3 babies (3.1%) had Apgar score of 4-7, and 3 babies (3.1%) had

Apgar score <4 at 5 minutes after birth. In the present study, 5 (5.20%) patients had post partum haemorrhage. 2 patients (2.08%) had paraurethral tear, 1 patient (1.04%) had wound gape and 1 patient (1.04%) had episiotomy gape and 1 patient (1.08%) had shoulder dystocia. There was no maternal mortality in our study (Table 3).

The majority 84 (87.5%) babies born to participants did not need admission to NICU, while 12 (12.5%) babies were admitted to neonatal intensive care ward. In the present study, 12 (12.5%) of the neonates were admitted to NICU after delivery. The primary reason was respiratory distress syndrome in 4 babies (33.33%); and respiratory distress with meconium stained liquor (MSL)

in 4 babies (33.33%) followed by low birth weight in 2 babies (2.08%) and hyperbilirubinemia in 2 babies (2.08%). NICU admission rate is high as compared to general population (12.5%) There was 1 neonatal death and 2 still births (Table 3).

Neonatal death was because of Meconium Aspiration Syndrome (MAS) and the other two were fresh stillbirths, causes of which were unknown. The only 1 neonatal death in the present study was because of negligence in the part of the patient as she was advised admission at 40 weeks for safe confinement but she came later in labour with leaking per vaginum having thick meconium stained liquor since 12 hours. Her caesarean section was done in view of non reassuring fetal heart with thick meconium stained liquor and baby died on day 7 of life due to meconium aspiration syndrome (MAS). Perinatal mortality rate in the present study is 1.04% (Table 4).

DISCUSSION

The aim of this study was to find out the frequency of post dated pregnancies and to know the maternal and fetal outcome beyond the expected date of delivery (EDD).

According to the age of the patient

In the present study, the mean age of study participants was 26.34 years (SD±5.4) within range of 17 to 40 years of age and maximum participants 77 (80.2%) were included in the age group of 20 to 35 years of age. The least number, 8 patients were in the age group >35 years (8.3%), and 11 patients (11.5%) were <20 years of age. It seems that there is no correlation with maternal age and postdated pregnancy. Paliulytė V et al, studied age distribution among pregnancy beyond 41 weeks of gestation and found no age relation.13 Mahapatro AK et al, observed in their study on pregnancy beyond 41 weeks of gestation that 55% cases were in the age group of 21 to 25 years.14 Akhtar P et al, observed in their study on pregnancy beyond 41 weeks of gestation that 82% of cases were in the age group of 18 to 29 years. 15 In study by Dobariya PV et al, there were 58 (69.05%) patients in age group 20 to 30 years, and in study by Patel N et al. there were 32 (64%) cases in age group 20 to 30 years. 16,17

According to gestational age of the patient

khtar P et al, studied that maximum patients (52%) lies within 41 to 42 weeks. ¹⁵ Akhter S et al, from Bangladesh studied that maximum patients (80%) were within 40+6 to 42 weeks, Dobariya PV et al, studied that maximum patients are within 41 to 42 weeks. ¹⁶ In studies done by Francis S et al, Patel N et al, maximum patients were between 40 to 40.6 weeks which is similar to our study in which 67 patients (69.8%) patients are between 40 to 40.6 weeks of gestation, 26 patients (27.1%) are between 41 to 41.6 weeks and 3 patients (3.1%) are 42 weeks and

beyond.^{17,18} It's because of induction of labour is at 41 weeks of gestation.

According to gravidity of the patient

Nulliparity increases risk of prolonged pregnancy, but in various recent studies incidence of late term and postterm is equal or slightly increased in multigravida. Marahatta et al, studied distribution of parity and found 54% patients were multigravida. Amina FN et al, in their study found maximum (54%) patients were multigravida. Mahapatro et al, found maximum (72%) of patients were primigravida. Akhter S, also found in his study that maximum (53%) patients were multigravida. However, in the present study maximum patients 61 (63.5%) were primigravida and 35 patients (36.5%) patients were multigravida.

According to history of post datism in previous pregnancy

Annette Wind Olesen BMJ studied that there were 19.9% patients who had previous history of postdatism. Farhat Naz et al, found in their study that 38.3% patients had previous history of postdatism. Woman with previous postdates have increased risk of postdated pregnancy. (Odds ratio 4.4) (Anna S. Oberg 2013). In the present study, there were 25 out of the 35 multigravidas (26%) who had history of postdatism in their previous pregnancy. ²⁰

According to presentation at the time of admission

In the present study, out of 96 participants, 41 (42.7%) patients were in labour on admission and the rest 55 (57.3%) were not in labour. There were no other studies available previously, doing similar discussion.

According to mode of delivery

In the present study, maximum patients 80 (78.12%) underwent vaginal delivery, of which 45 (46.9%) delivered spontaneously and 35 (36.5%) delivered vaginally after successful induction, 16 (16.7%) patient underwent LSCS correlating with above studies. Among all participants (5 out of 96) who needed instrumental delivery, 4 (80%) participants delivered by assistance of outlet forceps and 1 (20%) participant needed assistance of vacuum. Our study shows caesarean section rate of 16.7%.

Caughey AB et al, studied that maximum patients (68%) underwent spontaneous vaginal delivery, 17% patient required instrumental delivery and 14% patient required primary caesarean section.²⁰ Shinge N et al, studied that maximum patients (53.7%) underwent spontaneous vaginal delivery, 9.5% patients required instrumental delivery and 37% patients required caesarean section as mode of delivery.²²

According to the type of induction

In the present study, maximum induction was done by Dinoprostone gel in 26 patients (57.78%) followed by augmentation with Oxytocin Infusion after artificial rupture of membranes (ARM) in 15 patients (33.33%) and least by Tab. Misoprostol in 4 patients (8.89%). Foley's induction was not tried in our cases. In study conducted by Nikita Patel et al, showed maximum induction by Tab Misoprostol 25 mcg in 12 patients (57.14%) followed by Dinoprostone PGE2 gel in 9 patients (42.85%).¹⁷

According to the indication of caeserean section

In the present study, indication for caesarean section was fetal distress in 6 patients (37.5%) and failure of induction in 5 cases (31.25%), which were followed by cephalo-pelvic disproportion in 4 cases (25%) and transverse lie in 1 patient (6.25%).

Incidence of caesarean section for fetal distress by Caughey AB et al, is 23.5% and 21.4% underwent caesarean section for CPD (21.4%).²¹ In the study by Akhtar P et al, caesarean section was done in view of fetal distress in 32% cases, non progress of labour in 25.3% cases and failure of induction in 24% cases.¹⁵

According to Bishop's score

Poor Bishop's score is associated with failure of induction and lesser chances of vaginal delivery. In our study, maximum patients had Bishop's score less than 4 and they needed further intervention by induction of labour by either Tab. Misoprostol or Dinoprostone gel or augmentation of labour by oxytocin infusion after artificial rupture of membranes (ARM). In patients with Bishop's score <4, maximum underwent caesarean section in view of failure of induction and fetal distress.

In present study, 77 babies (80.2%) had birth weight between 2.5 to <3.5 kg and 13 (13.5%) babies had their birth weight <2.5 kg. Only 6 babies (6%) had birth weight between >=3.5kgs. Mean birth weight in present study is 3.005 kg. Mean birth weight reported by various authors in postdated pregnancy according to Virginija Paliulytė et al, is 3.6 kg, Akshaya Kumar et al, is 3.6 kg and Agata Szpera Gozdziewicz Tomasz Gozdziewicz is 3.6 kg. 14.23 The present study correlates with the above studies.

According to Apgar score at 1 minute

The majority 86 (89.6%) of the babies born to participants had Apgar score of >7 after 1 minute of birth, 6 babies (6.2%) had Apgar score of 4-7, and 4 babies (4.2%) had Apgar score of <4 at 1 minute of birth.

According to Appar score at 5 minutes

Table 5: Apgar score at 5 minutes.

Author	Score < 7	Score > 7
Nikita Patel et al ¹⁷	30%	70%
Dobariya PV et al ¹⁶	11.25%	88.75%
Present study	6.2%	93.8%

In study by Patel N et al, 15 babies (30%) had Apgar score <7 at 5 minutes and 35 babies (70%) had Apgar score >7 at 5 minutes. 17 In study by Dobariya PV et al, 9 babies (11.25%) had Apgar score <7 at 5 minutes and 71 babies (88.75%) had Apgar score >7 at minutes. 16 In the present study, the majority 90 (93.8%) of the babies born to participants were having APGAR score of >7 counted at 5 minutes after birth, 3 babies (3.1%) had APGAR score of 4-7, and 3 babies (3.1%) had APGAR score <4 at 5 minutes after birth. There is no difference of Apgar score at 5 min among pregnancies at 41 or 42 weeks of gestation as per various studies.

According to maternal morbidity

In the present study, 5 (5.20%) patients had post partum haemorrhage. 2 patients (2.08%) had paraurethral tear, 1 patient (1.04%) had wound gape and 1 patient (1.04%) had episiotomy gape and 1 patient (1.08%) had shoulder dystocia. There was no maternal mortality. This present study correlates with study conducted by Aaron B.

Caughey, found that the risk of maternal peripartum complications increase beyond 40 weeks of gestation. Rates of 3rd or 4th degree perineal lacerations, chorioamnionitis, postpartum haemorrhage and prolonged labour were all increased among women with gestational age more than 40 weeks compared to 39 weeks of gestation.²¹ In study conducted by Patel N et al, maximum morbidity was because of perineal tears/cervical tears in 10 patients (34.44%) and prolonged labour/shoulder dystocia in 10 patients (34.44%) followed by post partum haemorrhage in 6 patients (20.47%).¹⁷

According to NICU admission of the babies

In the present study, 12 (12.5%) of the neonates were admitted to NICU after delivery. The primary reason was respiratory distress syndrome in 4 babies (33.33%); and respiratory distress with meconium stained liquor in 4 babies (33.33%) followed by low birth weight in 2 babies (2.08%) and hyperbilirubinemia in 2 babies (2.08%). NICU admission rate is high as compared to general population. (12.5%) As per various studies, NICU admission rate is increased in postdated pregnancies. Most common indication being of NICU admission being asphyxia neonatarum.

According to perinatal mortality rate

There was 1 neonatal death and 2 still births in the present study. Neonatal death was because of Meconium Aspiration Syndrome and the other two were fresh stillbirths, causes of which were unknown. The only 1 neonatal death in the present study was because of negligence in the part of the patient as she was advised admission at 40 weeks for safe confinement but she came later in labour with leaking per vaginum having thick meconium stained liquor since 12 hours. Her caesarean section was done in view of non reassuring fetal heart with thick meconium stained liquor and baby died on day 7 of life due to meconium aspiration syndrome. Perinatal mortality rate in present study is 1.04%.

Table 6: Perinatal mortality rate.

Author	Total number of babies	Perinatal mortality rate
Akhter S ²⁴	100	3%
Present study	96	1.04%

Perinatal mortality according to Akhter S and Thakur et al, is 5.4%, is 3%. 24,25 In our study it's quite low because high risk pregnancies like pregnancy induced hypertension, ante partum haemorrhage, gestational diabetes mellitus, bad obstetric history, and hypothyroidism are excluded.

CONCLUSION

From the present study, we conclude that, the post dated pregnancy can be considered as a high risk factor from the point of view of fetal outcome as there is more fetal morbidity. Most of the women with post dated pregnancy were having Modified Bishop's score <6. Induction of labor can be safely practised at 41 weeks of gestation. Fetal distress is the most common indication of caesarean section in both, spontaneous as well as induced labour in post dated pregnancy. Considering the above mentioned reasons of maternal and perinatal outcome, most of the patients will be benefited from more aggressive induction of labour at 41 weeks. Though the correct choice of management remains controversial, according to the present study, it seems reasonable to induce labour at 41 weeks of gestation as perinatal morbidity is significantly more in > 40 weeks of gestation.

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Institutional Ethics Committee

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