OUTCOMES OF INDUCTION VERSUS SPONTANEOUS ONSET OF LABOUR WHEN PERFORMED AT 40 AND 41 GESTATIONAL WEEKS: FINDINGS FROM A PROSPECTIVE INDIVIDUAL PATIENT DATABASE IN SRI LANKA

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Abstract

Objectives The World Health Organization (WHO) recommends induction of labour (IOL) for low risk pregnancy from 41+0 gestational weeks (GW). Nevertheless, in Sri Lanka IOL at 40 GW is common practice. This study aimed to compare maternal/newborn outcomes after IOL versus spontaneous onset of labour (SOL) at 40 GW (IOL40) and 41 GW (IOL41). Design Observational study. Setting De Soysa Teaching Hospital for Women, Colombo, the largest maternity hospital in Sri Lanka. Population Low risk pregnancies at 40 or 41 GW. Methods Data from a routine prospective individual patient database were analysed. IOL and SOL groups were compared using logistic regression. Main Outcome Measures Births with one or more negative maternal/newborn outcome/s; maternal/newborn complications; caesarean section (CS); operative vaginal delivery. Results Of 13670 deliveries, 2359 (17.4%) were singleton and low risk at 40 or 41 GW. Of these, 456 (19.3%) women underwent IOL40, 318 (13.5%) IOL41, and 1585 (67.2%) SOL. Both IOL40 and IOL41 were associated with an increased risk of any maternal/newborn negative outcomes (OR=2.21, 95%CI=1.75-2.77, $p<0.001$ and OR=1.91, 95%CI=1.47-2.48, $p<0.001$ respectively), maternal complications (OR=2.18, 95%CI=1.71-2.77, $p<0.001$ and OR=2.34, 95%CI=1.78-3.07, $p<0.001$ respectively) and CS (OR=2.75, 95%CI=2.07-3.65, $p<0.001$ and OR=3.01, 95%CI=2.21-4.12, $p<0.001$ respectively). Results did not change in secondary and sensitivity analyses. Conclusions Both IOL groups were associated with higher risk of negative outcomes compared to SOL. These findings, though potentially explained by selection bias, local IOL protocols and CS practices, are valuable for the Sri Lankan context, particularly given contradictory findings from other settings.

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Short title: Outcomes of induction of labour from a prospective database, Sri Lanka

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List of abbreviations

AOR= Adjusted odds ratio

APH= Antepartum haemorrhage

BMI= Body mass index

CI= confidence interval

CS= Caesarean section

GW= gestational weeks

IOL= Induction of labour

IUGR= Intrauterine growth restriction at ultrasonography

LMIC= Low and middle-income countries

NICE= National Institute for health and Care Excellence

OT= operating theatre

OVD= operative vaginal delivery

PPH= Postpartum haemorrhage

RCT= randomized clinical trial

SGA= Small for gestational age

SOL= Spontaneous onset of labour

STROBE= STrengthening the Reporting of OBservational studies in Epidemiology

UK= United Kingdom

US= United States

WHO= World Health Organization

ABSTRACT WORD COUNT=245/250

ABSTRACT

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Design Observational study.

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Results Of 13670 deliveries, 2359 (17.4%) were singleton and low risk at 40 or 41 GW. Of these, 456 (19.3%) women underwent IOL40, 318 (13.5%) IOL41, and 1585 (67.2%) SOL. Both IOL40 and IOL41 were associated with an increased risk of any maternal/newborn negative outcomes (OR=2.21, 95%CI=1.75-2.77, p<0.001 and OR=1.91, 95%CI=1.47-2.48, p<0.001 respectively), maternal complications (OR=2.18, 95%CI=1.71-2.77, p<0.001 and OR=2.34, 95%CI=1.78-3.07, p<0.001 respectively) and CS (OR=2.75, 95%CI=2.07-3.65, p<0.001 and OR=3.01, 95%CI=2.21-4.12, p<0.001 respectively). Results did not change in secondary and sensitivity analyses.

Conclusions Both IOL groups were associated with higher risk of negative outcomes compared to SOL. These findings, though potentially explained by selection bias, local IOL protocols and CS practices, are valuable for the Sri Lankan context, particularly given contradictory findings from other settings.

TWEETABLE ABSTRACT WORD COUNT=109/110

Tweetable abstract. Induction of labour in low risk pregnancy at 40/41 GW increases risk of negative birth outcomes in Sri Lanka.

Keywords. Induction of labour; Full term pregnancy; Late term pregnancy; Pregnancy outcomes; Low risk pregnancies

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INTRODUCTION WORD COUNT= 785/400

DISCUSSION AND CONCLUSION WORD COUNT =1067/1200

INTRODUCTION

Over the past decades, induction of labour (IOL) rates have continued to rise, with a reported average incidence of one out of four births at term (from 37+0 GW) in high-income countries, and very similar rates in low and middle-income countries (LMIC)[1]. According to the World Health Organization (WHO), IOL should be performed only when there is a clear medical indication and the expected benefits outweigh its potential harms[2]. As perinatal risks increase with gestational age, the current recommendation from WHO, the National Institute for health and Care Excellence (NICE), and most scientific societies is to perform IOL in women who are known with certainty to have reached 41 GW (i.e., from 41+0).[3-7]

However, especially in the last few years, the debate on optimal timing for IOL and, specifically, whether IOL around term improves birth outcomes, has become very lively. The most recent Cochrane review (2018) including 30 randomized clinical trials (RCTs), seven conducted in southeast Asia, highlighted that IOL from 37 GW compared to expectant management is associated with fewer perinatal deaths, neonatal intensive care unit admissions, babies with low Apgar scores and caesarean sections (CS), but also with more operative vaginal delivery (OVD).[8] Authors concluded that further investigation is needed into optimal timing of IOL, together with exploration of women's risk profiles and preferences.[8]

More recently, other evidence has emerged. In 2019, a meta-analysis of cohort studies including 15 million pregnancies in high-income countries reported that stillbirth increases slightly but significantly from 37 GW onward with a 64% increase in the risk of stillbirth at 41 GW compared to 40 GW,[9] thus suggesting the opportunity of elective IOL even before the traditional cut-off of 41 GW.

Other relevant RCTs were published in parallel. A single-centre RCT in the UK among nulliparous women over 35 years old without complications showed no significant difference in maternal and newborn outcomes between IOL at 39 GW and expectant management.[10] More recently, the ARRIVE trial, a multicentre RCT conducted by Grobman et al. among 6106 low-risk nulliparous women in the US compared IOL at 39 GW to expectant management and found lower incidence of CS with IOL (RR 0.84; 95%CI 0.76-0.93) and no significant differences in perinatal deaths or severe neonatal complications (RR 0.80; 95%CI 0.64-1.00).[11] A meta-analysis of cohort studies[12] confirmed the results of this trial.[11]

Two other RCTs in uncomplicated singleton pregnancies - INDEX, a Dutch trial enrolling 1801 women,[13] and SWEPIS, a Swedish multicentre trial in 14 hospitals including 2760 women[14] - found that IOL at 41 GW was associated with fewer adverse perinatal outcomes than expectant management until 42 GW.[13,14] Notably, the SWEPIS study was stopped early because of higher perinatal mortality with SOL.[14]

On the other hand, a national retrospective register-based cohort study evaluating the effects of changes in routine elective IOL policies in Denmark (42 GW versus 41+3 and 41+5 GW) found no differences in neonatal outcomes including stillbirth, despite the number of women with IOL increasing significantly.[15] Additionally, a systematic review reported that IOL at 41 versus 42 GW was associated with an increased risk of CS (RR 1.11; 95%CI 1.09-1.14) and adverse maternal outcomes.[16]

In conclusion, evidence is still contradictory and the debate is quite polarized. No clear context-specific evidence exists on women's preferences on IOL. The ARRIVE trial reported that American women in the IOL group had a positive perception of increased control over birth,[11,17] while other qualitative systematic reviews concluded that the majority of women feared medical intervention, preferring a physiological birth promoting their physical and psychosocial capacities.[17, 18]

In addition, literature on outcomes of IOL around term versus expectant management in LMIC is very scarce. According to the WHO Global Survey on Maternal and Perinatal Health, IOL was performed in Asia in 12.1% of deliveries and associated with negative neonatal outcomes.[19]According to existing estimates, Sri Lanka has the highest IOL rate in Asia (about 35.5% of total deliveries)[1,19] with 77.2% of all IOL being elective.[19] Elective IOL at 40 GW is often justified by local professionals on the basis of supposed earlier foeto-placental maturation in South Asian populations compared with Caucasian women or Asian counterparts, and on the fear of increased risk for the baby.[20-22]Nevertheless, no study from Sri Lanka has so far explored outcomes of women with IOL at 40 GW versus 41 GW.

The objective of this study was to assess adverse maternal and neonatal outcomes in low risk women undergoing IOL at 40 and 41 GW versus women with a spontaneous onset of labour (SOL) giving birth at the largest maternity hospital in Sri Lanka. Data for this study were collected over four years in a prospective individual patient database established in 2015 at the De Soysa Teaching Hospital for Women, Colombo.

METHODS

Study design

This is an observational study reported according to the STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) statement (**Table S1**).[23]

Population and setting

Data collection, data quality assurance procedures and standard operating procedures used for the individual patient database are reported elseswhere.[24]Briefly, 150 variables (i.e., maternal sociodemographic characteristics, risk factors, process indicators, maternal and neonatal outcomes) were collected for each birth on two wards of the University Obstetric Unit at De Soysa Teaching Hospital for Women, using a standardised two-page form, and entered in real time in an electronic database. De Soysa is the largest referral hospital for maternity care in Sri Lanka and all deliveries occurring in these two wards from May 2015 to May 2019 were entered in the database and considered for inclusion. Overall data quality was routinely monitored with external independent random review of 5% of forms and 5% of entered births to maintain an error rate in data collection below 0.02%.[24] Data were also externally monitored for completeness and internal consistency at roughly 4-month intervals.[24]

We included "low risk women" with singleton pregnancies and a foetus in cephalic presentation whose delivery occurred between 40+0 and 41+6 GW. We excluded all cases with any maternal or foetal characteristics which may have affected outcomes, such as: maternal obesity (Asian criteria-based body mass index -BMI-more than 27.5[25]), previous CS, macrosomia at ultrasonography (defined as estimated birthweight exceeding the 90$^{\text{th}}$centile for gestational age), hypertension disorders during pregnancy (e.g. pregestational or gestational hypertension, preeclampsia, eclampsia, HELLP syndrome), chorioamnionitis, major foetal malformations, intrauterine growth restriction at ultrasonography (IUGR), small for gestational age (SGA), pregestational diabetes, gestational diabetes with the need of drug therapy, maternal cardiac disease, maternal hypothyroidism, polyhydramnios, oligohydramnios, antepartum haemorrhage (APH), major placenta praevia, placental accretism, severe anaemia (haemoglobin <7.0 g/dl) and other foetal and maternal pathological conditions, i.e. systemic lupus erythematosus, pre-pregnancy deep venous thrombosis, epilepsy, suspected cephalo pelvic disproportion, recurrent infection, pancreatitis or glomerulonephritis in pregnancy, chickenpox disease, chronic disease, signs of potentially impaired foetal wellbeing (non-reassuring or pathological cardiotocography, reduced foetal movement, meconium stained amniotic fluid). We also excluded macerated stillbirth from the IOL40 group, as these births are always induced. All women with a reported indication for IOL suggesting the presence of maternal or foetal characteristics described above, such as diabetes, macrosomia at ultrasound, IUGR/SGA, were excluded from the analysis.

Comparison groups and outcomes

We compared women with IOL at 40 GW (40+0 to 40+6 GW), women with IOL at 41 GW (41+0 to 41+6 GW), and women with SOL in between 40+0 to 41+6 GW. Artificial separation of membranes alone was not considered induction.

The incidence of births with one or more negative outcome(s) was our primary outcome. In line with previous literature,[2,3,8] we defined negative outcomes as any birth that included an intervention (i.e. CS, OVD) and/or a maternal or neonatal complication (i.e., was not completely physiological) (see list in **Table S2**).

Data analysis

Categorical variables were expressed as absolute numbers and compared among groups with χ^2 or Fisher exact test as appropriate.

We evaluated the association between each group and negative outcome(s), CS, and OVD using multiple logistic regression models adjusting for baseline characteristics (e.g., age, parity, education, BMI, neonatal weight). Results of logistic regression are also presented for CS and OVD since they were evaluated as clinical outcomes related to failed induction in Sri Lanka.[26] A one-sided Cochran-Armitage test for trend was performed to assess the influence of changes of clinical protocols and staff training practices[27, 28]over different semesters of the study on CS and OVD.

As secondary analyses we compared IOL at 40 GW to a group composed of IOL at 41 GW and SOL, in line with analyses by Rydahl and collegues.[16] This allowed comparison between IOL group at 40 GW and spontaneous labour at the same gestational age, and simultaneously took into account the risks of the ongoing pregnancy including all births at 41 GW, reducing possible bias.

In addition, we performed a sensitivity analysis including all cases with reported hypertensive disorders (pregestational hypertension, preeclampsia, eclampsia, HELLP syndrome), chorioamnionitis, oligohydramnios, APH, and signs of potentially impaired foetal wellbeing (non-reassuring or pathological cardiotocography, reduced foetal movement, meconiumstained amniotic fluid) from 41 GW, considering these as negative birth outcomes rather than as possible risk factors.

Data were analysed using STATA version 14.0 (Stata Corporation, College Station TX) and SAS/STAT® software version 9. All statistical tests were two-sided and a p-value less than 0.05 was considered statistically significant.

Ethical considerations

The study was approved by the Ethics Review Committee of the Faculty of Medicine, University of Colombo. Confidentiality was maintained by de-identifying all files before database entry. Human subjects were not directly involved in the study. Informed consent was not requested by the Ethics Review Committee.

RESULTS

Women's characteristics

A total of 13,670 women delivered in the hospital during the study period. Of these, 2359 (17.4%) matched our inclusion criteria of low risk singleton pregnancy from 40+0 to 41+6 GW with the foetus in cephalic presentation (**Figure 1**). Among the included women SOL was observed in 1585 women (67.2%), while among 774 cases of IOL, 456 (58.9%) were induced from 40+0 to 40+6 GW, and 318 (41.1%) from 41+0 to 41+6 GW.

Some imbalances among groups were observed (**Table 1**). Women undergoing IOL at 40 GW had a significantly higher level of education compared to the SOL group (20.0% vs 13.3%, p=0.001). Significantly more women were unmarried and overweight in the IOL at 41 GW group compared to SOL, and more women were overweight comparing IOL at 41 and 40 weeks (unmarried women: 2.2% vs 0.9%, p=0.040; overweight women: 29.9% vs 23.2% in IOL at 40 GW vs 23.0 in SOL, p=0.031). IOL group at 41 GW had an increased frequency of newborns with a birth weight between 3500 and 4000 grams (19.2% vs 12.5% in IOL at 40 GW vs 14.8% in SOL, p=0.035) and above 4000 grams (2.5% vs 2.4% in IOL at 40 GW vs 0.8% in SOL, p=0.006). Women with SOL were most often multiparous (52.4% vs 43.0% in IOL at 40 GW vs 37.7% in IOL at 41 GW, p<0.001) and more frequently assisted at delivery by nurses (56.7% vs 44.9% vs 36.5%, p<0.001), while mid-level medical staff (either senior house officers or registrars) was more often involved in IOL groups (30.7% vs 30.2% vs 14.1%, p<0.001).

Primary outcomes

The overall incidence of births with one or more negative outcome (including CS and OVD) is reported in **Figure 2** . The rate was significantly lower in the SOL group (27.1%, p<0.001), compared to IOL, without significant difference among IOL at 40 GW and IOL at 41 GW (47.1% versus 45.2%, p= 0.609). As further detailed in **Table S3 and S4** , the CS rate was significantly higher among women undergoing IOL either at 40 GW (25.4%) or at 41 GW (28.6%) when compared with SOL (10.3%, p<0.001). OVD rate was significantly higher in IOL at 40 GW (7.0%) compared to IOL at 41 GW (2.8%, p=0.010) whereas no significant difference was found with SOL. The proportion of births with complications different from CS and OVD was not significant among groups (p=0.222).

The trend analysis (**Figure S1**) showed an increasing CS rate over semesters in the group with IOL at 40 GW only (trend test p=0.021), whereas OVD rate decreased overall (trend test p=0.016) and in IOL at 40 GW (p=0.036).

Table S4 details the incidence of maternal and neonatal complications by type of labour. Maternal complications, as defined in **Table S1** , were more frequent in IOL groups (36.2% and 39.3% in IOL group at 40 GW and 41 GW respectively vs 19.1% in SOL, p<0.001). Postpartum haemorrhage (PPH) was the most frequent complication after CS and OVD (2.6% vs 5.7% vs 1.9% respectively, p=0.001). The incidence of newborn complications was higher in births with IOL at 40 GW when compared to SOL (22.4% vs 13.4%, p<0.001), particularly admissions to Special Care Baby Unit (15.8% in IOL at 40 GW vs 10.7% in IOL at 41 GW vs 8.6% in SOL group, p<0.001). Newborn infections, neurological complications and respiratory distress syndrome were significantly more frequent in the group with IOL at 40 GW than SOL (respectively, 5.0% vs 2.2%, p=0.002; 3.1% vs 1.3%, p=0.009; 2.4% vs 0.9%, p=0.002). Perinatal deaths and stillbirth rates were low across all groups (one stillbirth in IOL at 41 GW and less than five perinatal deaths in each group).

In multivariate analysis (**Table 2**) with SOL as reference and controlling for age, parity, education, BMI and neonatal weight, both IOL groups were positively associated with higher odds of any negative birth outcome (AOR=2.21, 95%CI=1.75-2.77, p<0.001 for IOL at 40 GW and AOR=1.91, 95%CI=1.47-2.48,p<0.001 for IOL at 41 GW), all maternal complications (AOR=2.18, 95%CI=1.71-2.77, p<0.001 for IOL at 40 GW and AOR=2.34, 95%CI=1.78-3.07, p<0.001 for IOL at 41 GW) and CS (AOR=2.75, 95%CI=2.07-3.65, p<0.001 for IOL at 40 GW and AOR=3.01, 95%CI=2.21-4.12, p<0.001 for IOL at 41 GW). IOL at 40 GW was associated with a higher number of neonatal complications (AOR=1.63, 95%CI=1.24-2.16, p<0.001) and IOL at 41 GW was positively associated with maternal complications other than CS or OVD (AOR=1.83, 95%CI=1.19-2.80, p=0.006).

Secondary and sensitivity analyses

IOL at 40 GW was positively associated with increased numbers of negative birth outcomes (AOR=1.95, 95%CI=1.56-2.44, p<0.001), maternal complications (AOR=1.82, 95%CI=1.44-2.30, p<0.001), CS (AOR=2.09, 95%CI=1.60-2.74, p<0.001), and neonatal complications (AOR=1.58, 95%CI=1.21-2.06, p<0.001) when compared with IOL at 41 GW and SOL combined (**Table S6**). No other significant association was found (**Table S5 and S6; Figure S2**).

We explored a sensitivity analysis including women with risk factors for IOL (oligohydramnios, APH and impaired foetal wellbeing), resulting in an additional 4 women eligible for analysis **Table S7**). Results did not differ from the primary analysis (**Table S8**).

DISCUSSION

Main Findings

Findings from this study in Sri Lanka suggest that the practice of elective IOL at 40 GW or induction at 41 GW is associated with a higher risk of negative maternal and neonatal outcomes, particularly maternal complications, compared to SOL. Both IOL groups were also associated with increased odds of CS compared to SOL.

Strengths and Limitations

To our knowledge this is the first published study on the association between timing of IOL and maternal and newborn outcomes in low-risk pregnancies in Sri Lanka. It is also the first study from a setting with limited resources reporting on the use of a prospective individual-patient database to analyse practices and outcomes of IOL.[24] This study contributes to current international and local debate on the appropriateness of IOL near term. These study findings are extremely relevant locally both for clinicians, researchers and policy makers, as IOL at 40 GW is a common practice in Sri Lanka and has a significant economic impact on the health system and healthcare resources.

We acknowledge some limitations of this study. As an observational study, we could only assess associations between IOL and birth outcomes and not causation. Generalizability of study results may be limited by the characteristics of the local context and population in this single centre study. Larger sample sizes are required to detect significant differences in rare adverse events including stillbirth or maternal or perinatal death. Although gestational age was mostly determined by ultrasound examination, for 12% of the included women gestational age was estimated by menstrual dating.

Socio-cultural background and women's empowerment may have affected both requests for induction and the type of care offered by physicians. Specifically, early induction (IOL at 40 GW) occurred more often in women with a high level of education. Unmarried women, still subjected to social stigma in Sri Lanka,[29] were significantly more represented in the group undergoing IOL at 41 GW. Thus, numbers of CS and neonatal complications may have been influenced by socio-economic status. Other authors have described similar results, where unmarried women could have limited access to care[29] while higher social status or economic condition is related to an increasing medicalization of birth.[30,31] However, in our study, since these imbalances among groups affect results in different directions, there may be limited risk of bias.

Though results were corrected for confounding, we cannot exclude that induced women may have differed on characteristics not captured or not reported in the data collection form (such as unreported small for gestation foetuses, mild oligohydramnios, etc.). We were not able to explore specific practices related to IOL (such as safe use of uterotonics, appropriate maternal-foetal monitoring or CS indications), therefore we cannot exclude a difference among the groups for these variables. We had no information on the level of women's participation in the decision process during labour care, nor specific choices, inclinations or skills of operators which may have had a substantial role in the differences observed.[27, 32-34] Notably, most of the evidence that we actually rely on may have some of these biases. Observational studies may not capture these aspects of care, while RCT, even though controlling these with randomization, may suffer from study effect.

Finally, another limitation related to the database is the absence of timing for risk factor onset. Hence it was impossible to differentiate between high-risk pregnancy (with risk factors before 40+0 GW) and low risk women at 40+0 GW that developed complications due to prolonged pregnancy (after 40+0 GW). A sensitivity analysis was performed to assess this limitation and results showed that it did not affect the overall findings.

Interpretation

Our findings are partially in line with the most recent Cochrane systematic review, confirming that there is evidence of higher OVD rate in IOL at 40 GW vs IOL at 41 GW.[8] Discrepancies between our results for CS rates and other studies[8, 10, 13, 15, 35] could be accounted for by differences in setting, study design, and different definitions of comparison groups. Our study was set in Sri Lanka and includes recent data from a maternity hospital registry, evaluating optimal timing of IOL in routine circumstances in a LMIC setting at predefined GW. Only 9 of 30RCTs included in the Cochrane review were conducted in LMIC, while 13 (43%) studies were published from 1960s-1980s.[19] Furthermore, comparison groups in the Cochrane review are not directly comparable since timing of IOL differed among included trials as well as group definition, timing, and monitoring of expectant management.

Moreover, while RCT would be the most appropriate study design to address the question of optimal timing of IOL, this design has potential limitations. As shown in the two most recent RCTs comparing IOL at term versus expectant management[11, 14], recruiting women for such trials is extremely difficult. In both trials a high number of women declined participation (73% in the US study and 78% in the Swedish study). This could have affected the characteristics of the sample and the generalizability of findings. Moreover, it highlights the fact that the views of women on onset of labour can be strong, both in refusing or requesting induction. This underscores the need for patient-centered care which takes into account the perspective of patients,[36] as well as for more research on women's preferences and views. Another limitation of RCTs is that the intervention cannot be masked, thus being open to possible bias due to differences in treatment/monitoring by allocation group. The availability of a prospective database capturing characteristics and outcomes of each delivery provides the opportunity to easily monitor indicators over time and compare practices and results in a real world setting.

Overall, findings of this study highlight the need for caution in generalizing the results of RCT conducted in high income settings to different clinical settings and populations. More studies should be conducted to further explore the ideal timing of IOL in LMICs.

CONCLUSIONS

Women with low risk pregnancies who underwent elective induction at 40 GW or induction at 41 GW in Colombo, Sri Lanka had significantly increased risk of negative birth outcomes (CS, OVD or any complication) compared to women with spontaneous onset of labour. While more evidence is needed on a global level to further understand the optimal timing of IOL in settings with low resources, these findings should be used to improve monitoring and routine practices in Sri Lanka, as well as in other LMIC where IOL is frequent practice.

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DISCLOSURE OF INTERESTS

No competing interests.

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AUTHOR CONTRIBUTIONS

HS and ML conceived the study and procured funds.

IM analysed data.

HS, IM, EPV, BA, MP, CB, MR, BC, and ML interpreted data and contributed to the manuscript.

All authors revised and approved the final manuscript.

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TABLE/FIGURE CAPTION LIST

Figure 1. Study sample selection

Table 1. Characteristics of the study population

Figure 2. Births with negative outcomes by type of labour

Table 2. Adjusted odds ratios for negative birth outcomes by type of labour

Table 1. Characteristics of the study population

Population	IOL at 40 GW (40+0 to 40+6) N=456 n (%)	IOL at 41 GW (41+0 to 41+6) N=318 n (%)	SOL (40+0 to 41+6) N=1585 n (%)
Maternal Age < 35 years [?] 35 years	401 (87.9) 55 (12.1)	290 (91.2) 28 (8.8)	1424 (89.8) 161 (10.2)
Education None Primary Secondary Higher Missing	1 (0.2) 10 (2.2) 353 (77.4) [1,3] 91 (20.0) [1] 1 (0.2)	2 (0.6) 4 (1.3) 266 (83.6) 46 (14.5) 0	2 (0.1) 26 (1.6) 1341 (84.6) 211 (13.3) 5 (0.4)
Working status Working Housewife Missing	81 (17.8) 370 (81.1) 5 (1.1)	48 (15.1) 270 (84.9) 0	227 (14.3) 1344 (84.8) 14 (0.9)
Marital status Married Unmarried Unmarried living together Missing	451 (98.9) 3 (0.7) 1 (0.2) 1 (0.2)	311 (97.8) 7 (2.2) [2] 0 0	1570 (98.6) 14 (0.9) 2 (0.1) 6 (0.4)
Parity 0 [?]1	260 (57.0) [1] 196 (43.0) [1]	198 (62.3) [2] 120 (37.7) [2]	754 (47.6) 831 (52.4)
Asian criteria-based BMI [25] Underweight (<18.4) Normal (18.5-22.9) Overweight (23-27.4)	38 (8.3) 312 (68.4) 106 (23.2)	33 (10.4) 190 (59.7) [2, 3] 95 (29.9) [2,3]	159 (10.0) 1061 (67.0) 365 (23.0)
Operator delivering care Nurse Midwife House Officer Mid-level staff * Consultant Missing	200 (43.9) [1] 110 (24.1) 4 (0.9) 140 (30.7) [1] 2 (0.4) 0	116 (36.5) [2, 3] 101 (31.8) [3] 4 (1.3) 96 (30.2) [2] 1 (0.3) 0	899 (56.7) 431 (27.2) 24 (1.5) 224 (14.1) 3 (0.2) 4 (0.3)
Neonatal weight at birth <2000 2000 to 2499 2500 to 3499 3500 to 4000 >4000 Missing	0 13 (2.9) 374 (82.0) 57 (12.5) 11 (2.4) [1] 1 (0.2)	0 3 (0.9) [2] 246 (77.4) 61 (19.2) [2, 3] 8 (2.5) [2] 0	0 55 (3.5) 1278 (80.6) 234 (14.8) 13 (0.8) 5 (0.3)

Notes: [1] Significant p value ($p<0.05$) in the comparison IOL at 40 GW vs SOL; [2] Significant p value ($p<0.05$) in the comparison IOL at 41 GW vs SOL;[3] Significant p value ($p<0.05$) in the comparison IOL at 40 GW vs IOL at 41 GW; * Mid-level staff defined as Senior House Officer or Registrar.

Abbreviations: BMI= body mass index; GW= gestational weeks; IOL= induction of labour; SOL= spontaneous onset of labour.

Table 2. Adjusted odds ratios for negative birth outcomes by type of labour

	IOL at 40 GW (40+0 to 40+6) N=456	IOL at 40 GW (40+0 to 40+6) N=456	IOL at 4
	Adj OR (95% CI)	p value	Adj OR
Any negative outcome	2.21 (1.75-2.77)	**<0.001**	1.91 (1.4
All maternal complications	2.18 (1.71-2.77)	**<0.001**	2.34 (1.7
Caesarean section	2.75 (2.07-3.65)	**<0.001**	3.01 (2.2
Operative vaginal delivery	1.27 (0.82-1.98)	0.285	0.48 (0.2
Other maternal complications	0.88 (0.55-1.42)	0.606	1.83 (1.1
All neonatal complications	1.63 (1.24-2.14)	**<0.001**	1.16 (0.8

Notes: ORs are adjusted for age, parity, education, BMI and neonatal weight.

Abbreviations: GW= gestational weeks; IOL= induction of labour; SOL= spontaneous onset of labour.

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