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Original Research Article

A randomized controlled trial comparing labor induction at 40 versus 41 weeks in low-risk post-date pregnant women

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ABSTRACT

Background: To determine effect of expectant management till 41 weeks versus labor induction (IOL) at 40 weeks, on spontaneous labor onset (SOL), in low-risk post-date (>40 weeks) women.
Methods: A randomized controlled trial was conducted among low-risk post-date women. At enrolment two hundred women were randomized (group 1; IOL at 40 weeks versus group 2; expectant management till 41 weeks). Demographic and clinical data were collected at enrolment and delivery.
Results: Three-fourth of women (76%) in group 2 had SOL. Additionally, duration of labor (minutes) [median±IQR; 380 (325-417) versus 410 (380-482), p<0.001], delivery within 12 hours (n; 87 versus 45, p<0.001) and within 12-24 hours of admission (n; 1 versus 42, p<0.001) was statistically significantly better in group 2. There was no statistically significant difference regarding mode of delivery (n) [vaginal delivery; 87 vs. 88, or cesarean section (CS); 13 versus 12, p=0.887] and indications of CS (fetal distress; 12 versus 12, and failure of induction of labor 1 versus nil, p=1.000) and maternal and fetal/neonatal outcomes. With an absolute risk of 21% of SOL, five women should be offered expectant management till 41 weeks for one woman to have SOL.
Conclusions: In low- and middle-income countries, low-risk post-date pregnant women should be offered expectant management of pregnancy till 41 weeks awaiting spontaneous labor (76%), with maternal and fetal/neonatal outcomes comparable to routine IOL at 40 weeks.

Keywords: Foley's catheter, Induction of labor, Post-date pregnancy, 40 weeks, 41 weeks

INTRODUCTION

Induction of labor (IOL) is a common procedure in obstetrics worldwide.[1] Proportion of infants delivered at term by IOL is rapidly rising, with one in four births, even in low and middle-income countries (LMIC).[2]

As per WHO guidelines, IOL should be performed only when there is a "clear indication", and the expected benefits outweigh its potential harms.[2] However, there is ambiguity regarding the "timing" of IOL. WHO guidelines stating, "IOL is not recommended in low-risk pregnancy <41 weeks (low-certainty evidence)", is seldom followed, even in LMIC where the majority of women undergo IOL at 40 weeks.[2-4]

High-income countries (HIC) advise elective IOL at 39 weeks in low-risk women {fewer perinatal deaths [0.4/1000 versus 3/1000, risk ratio (RR) 0.31, 95% CI 0.15-0.64] and stillbirths (RR 0.30, 95% CI 0.12-0.75}.[5-11] Number needed to treat with IOL to prevent one perinatal death is 544 (95% CI 441-1042).[3]

Among approximately 140 million births annually, the majority occur in LMIC.[5] An approach of elective IOL, is fraught with overburdening already limited resources. A

low-risk post-date pregnancy (>40 weeks), if followed expectantly, can have spontaneous onset of labor (SOL), thereby reducing unnecessarily load on resources, and subsequently IOL (its inherent logistics issues, in resource-limited LMIC).

Hence, we planned this study to test the hypothesis that with the expectant management of low-risk post-date pregnant women till 41 weeks POG, a significant number of women will have SOL with comparable maternal and fetal/ neonatal outcomes, in comparison to elective IOL at 40 weeks POG.

METHODS

We conducted this randomized controlled trial to compare the effect of expectant management of post-date pregnant women till 41 weeks vs. routine IOL at 40 weeks, on SOL. This trial was conducted in the department of obstetrics and gynecology, Dr. Rajendra Prasad Government Medical College, Kangra at Tanda (HP), India, a tertiary care teaching and training hospital. Institutional ethics committee approved the trial vide letter no. HFW-H(DRPGMC)PRC/2021-109 dated 19.06.2021. Recruitment took place from 01 November 2021 to 05 August 2022. Trial was also registered prospectively in the Clinical Trial Registry of India (CTRI) www.ctri.nic.in (registration number CTRI/2021/10/037550, date; 25-10-2021).

All low-risk post-date women were approached for enrolment. Inclusion criteria were: age 18-40 years, singleton pregnancy, and 40 weeks period of gestation (POG). Exclusion criteria were: any contraindication to vaginal delivery, scarred uterus (previous CS, myomectomy, metroplasty), SOL, non-reassuring fetal heart rate, abnormal bio-physical profile (BPP), oligohydramnios, fetal mal-presentation, multi-fetal gestation, intra-uterine fetal growth restriction, ante-partum hemorrhage, and intra-uterine fetal death, and any medical disorder like hypertension, diabetes, etc.

Consolidated Standards of Reporting Trials (CONSORT) guidelines were followed. After careful assessment by a senior consultant, women were randomized to either of the groups, after written informed consent. In group 1, hundred women underwent IOL with concurrent use of trans-cervical foley catheter (FC) (foley trac; Romsons Group Private Ltd, Uttar Pradesh, India) inflated with 60 ml of normal saline (NS) and vaginal misoprostol ([Misoprost-25 µg; Cipla, Mumbai, India); inserted vaginally every 4h, up to a maximum of five doses or till uterine contractions began, whichever was earlier).[12] If women failed to establish uterine contractions even after five doses of vaginal misoprostol (25 µg each), it was defined as failure of IOL. Subsequently, they were managed as per discretion of the managing team of obstetricians (intention to treat principle).

Allocation concealment was done by sealed, opaque envelopes. Randomization sequence was computer-generated in blocks of four or eight. In group 1 (n=100), IOL was done with concurrent use of FC (18-french, inflated with 60 ml NS) and vaginal misoprostol (25 µg every 4-hour) under sterile aseptic precautions. Subsequently, women were observed in the pre-labor ward. Pelvic examination was repeated 4-hour or earlier if women had leakage per vaginum (PV), bleeding PV, the expulsion of FC, or any other unusual symptom. Nursing staff on duty noted the spontaneous expulsion of FC. If not expelled spontaneously, FC was removed 12 hours post-insertion. When the women had regular uterine contractions, insertion of a vaginal misoprostol tablet was withheld, and they were shifted to the labor ward, where a separate team of obstetricians managed them.[12]

Women randomized to group 2 were advised follow-up after three days (or earlier in case of labor pains, leakage PV, bleeding PV, decreased fetal movements, or any other unusual symptom). On the follow-up visit (40+3 weeks), a detailed examination, including a non-stress test (NST) and ultrasonography (bio-physical profile; BPP), was done. If there was any abnormality in NST or BPP, they were admitted and managed accordingly. If no abnormality was detected, follow-up was advised at 41 weeks (or earlier in case of labor pains, leakage PV, bleeding PV, decreased fetal movements, or any other unusual symptom). Women were observed for SOL. IOL was done at 41 weeks (as described in group 1; if they didn't have SOL).

Women were observed for chorioamnionitis (temperature ≥38°C on at least two occasions 6 hours apart up to 7 days after delivery), hemorrhage, need for subsequent hospitalization, or, maternal morbidity (admission to ICU, or septicemia) or death.

Sample size was calculated based on the basis of a previous study by Soni et al.[1] As per the available literature, 21% of women undergoing IOL had CS. To achieve 90% power while detecting a 40% increase in women having SOL, with α-error of 0.05 using a two-sided t-test, 192 women were required (96 in each group). In addition, to account for any loss to follow-up, we randomized 200 women (i.e., 100 in each group).

Statistical analysis was carried out based on the intention-to-treat principle. Data were entered into software [Microsoft excel (Microsoft, Redmond, WA, USA)] and analyzed using Epi-info7. Parametric and non-parametric tests were used whenever considered appropriate. The normality of distribution was assessed by Kolmogorov-Smirnov test. Continuous data were analyzed with the t-test (normal distribution) and Mann-Whitney U test (non-normal distribution), whereas Fisher's exact test analyzed categorical variables. $P<0.05$ was considered statistically significant. Kaplan-Meier survival analysis estimated the proportion of women not delivered in two groups.

RESULTS

Figure 1 shows the CONSORT flow chart. From 01 November 2021 to 05 August 2022, a total of 200 women were randomized to either of the study groups. In group 1, IOL was done at 40 weeks POG and in group 2, expectant management was done till 41 weeks.

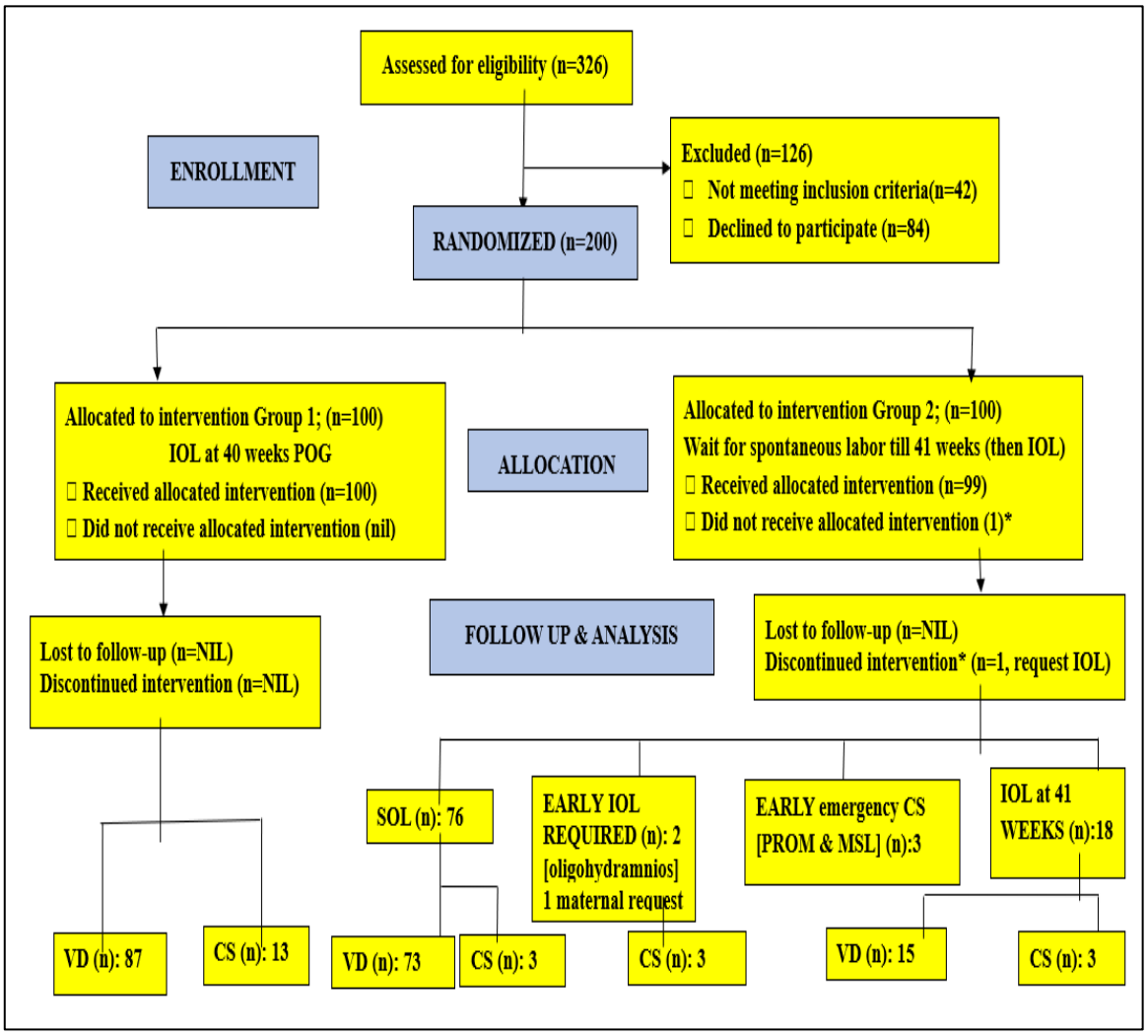

Figure 1: CONSORT flow diagram.

*: One patient in group 2 was kept on expectant management at 40 weeks gestation, she reported at 40 weeks 3 days with decreased fetal movements, her fetal assessment was normal, however on maternal request induction of labor was done.

As shown in Table 1, demographic characteristics were similar in both the groups. There was no statistically significant difference between the groups regarding age, BMI, parity, previous vaginal delivery, Bishop score at randomization, birth weight and sex of the neonates.

As shown in Figure 1, out of 100 women in group 2 (expectant management of pregnancy till 41 weeks), 76 (76%) had SOL. Out of these 76 women in SOL, a majority (n=73; 96%) had vaginal delivery (the remaining three had CS). On follow-up of women in group 2 (at 40+3 weeks), three women presented with premature rupture of membranes and MSL (they had emergency CS), two women had oligohydramnios [(AFI<5); IOL was done, and they had emergency CS for acute fetal distress (AFD)]. Additionally, one woman complained of decreased fetal movements at 40+5 weeks POG. Detailed examination, including NST and BPP, was normal. However, on maternal request, IOL was done (intention to treat principle). Subsequently, she had emergency CS for non-progress of labor. The remaining 18 women in group 2 had IOL at 41 weeks; 15 (83%) had vaginal delivery and 3 (17%) had emergency CS for AFD with MSL, as shown in Figure 1. In group 1 (IOL at 40 weeks POG), 87 (87%) women had vaginal delivery and 13 (13%) had CS. There was no statistically significant difference (p=0.887) with respect to the mode of delivery (n) [vaginal delivery (85 in each group), operative vaginal delivery (2 versus 3), or CS (13 versus 12)] in the two groups respectively, as shown in Table 2.

Table 1: Demographic characteristics of women in study.

Characteristics	Group 1 (n=100)	Group 2 (n=100)	P value
Age (years)*	26.3±3.6	25.8±3.4	0.267
BMI* (kg/m^2) #	24.3±1.0	24.5±1.0	0.228
Parity (N)			
No abortion	80	80	1.000
Previous 1 abortion	15	18	0.704
Previous 2 abortions	5	2	0.445
Previous vaginal delivery			
Nil	65	55	0.194
1	27	35	0.284
2	7	9	0.795
3	1	1	1.000
Bishop Score at randomization (40 weeks)	3 (3-4)	3 (3-4)	0.895
Birth weight* (grams)	2853±338	2843±369	0.827
Neonate sex (N)			
Male	45	49	0.671
Female	55	51	0.671

(*: mean±standard deviation, #: kilogram per meter square)

Table 2: Outcomes of women in the study.

	Group 1 (n=100)	Group 2 (n=100)	OR (95% CI)	P value
Mode of delivery (N)				
Vaginal delivery	85	85	1 (2.1-0.4)	1.000
Operative vaginal delivery	2	3	0.6 (4.03-0.1)	1.000
CS	13	12	1.0 (2.5-0.4)	1.000
Indications of caesarean delivery (N)				
Acute fetal distress	12	12	-	1.000
Failure of IOL[#]	1	0	-	1.000
Duration of labor[$] (minutes)	410 (380-482)	380 (325-417)	-(332-401)	<0.001
Bishop score at admission	3 (3-4)	5 (4-6)	-	<0.001
Meconium stained liqor (N)	10	12	0.8 (0.33-1.98)	0.821
Admission delivery Interval (N)				0.001
<12 hours	45	87	0.07 (0.564-0.01)	<0.001
12-24 hours	42	1		<0.001
Doses of misoprostol required (N)	2 (1-3)	1 (1-2)	-	0.005
Chorio-amnionitis (N)	4	1	-	0.368
NICU[@] admission (N)	1	1	1 (0.06-16.21)	1.000
Apgar score at 1 minute[$]	7 (7-8)	7 (7-8)	-	0.786
Apgar score at 5 minutes[$]	8 (8-9)	8 (8-9)	-	1.000

$: median±inter-quartile range, # (IOL): induction of labor, @ (NICU); neonatal intensive care unit.

Duration of labor (in minutes) (after exclusion of women with CS) was also statistically significantly lower in group 2 [median (inter-quartile range): 380 (325-417) versus 410 (380-482), p<0.001, respectively], as shown in Table 2. Bishop score at admission [median (inter-quartile range): 5 (4-6) versus 3 (3-4), p<0.001, respectively] was statistically significantly better (p<0.001) in group 2 (expectant management till 41 weeks). There was no statistically significant difference with respect to MSL in the two groups (n) (12 versus 10, p=0.821, respectively). Number of women (n) with admission delivery interval (both SOL/IOL) <12 hours and 12-24 hours was statistically significantly better in group 2 (87 versus 45 and 42 versus 1, p=0.001, respectively), with the number of doses of misoprostol required (n) [median (IQR): 1 (1-2) versus 2 (1-3), p=0.005, respectively], was statistically significantly lesser in group 2. There was no statistically significant difference with respect to chorioamnionitis (n: 4 versus 1, p=0.368), NICU admission (n: 1 versus 1, p=1.000), Apgar score at 1 minutes [median (IQR): 7 (7-8) versus 7 (7-8), p=0.786] and Apgar score at 5 minutes [median (IQR): 8 (8-9) versus 8 (8-9), p=1.000], in two groups.

Table 3: Sub-group analysis of women in group 2 (expectant management till 41 weeks gestation).

	Group 2 (SOL*) (n=76)	Group 2 (IOL#) (n=21)	P value
Age$ (years)	26 (24-29)	25 (23-25)	0.100
BMI$ (kg/m^2)	24.6 (24-24.9)	24.9 (23.9-26)	0.241
Parity (n)			
No abortion	62	18	1.000
≥ 1 abortion	14	3	1.000
Birth weight@ (grams)	2823.9±378.2	2903.3±341.0	0.362
Neonate sex (N)			
Male	37	12	0.623
Female	39	9	0.623
Duration of pregnancy$ (days)	282 (281-283)	287 (287-287)	<0.001
Bishop Score at admission	5 (4-6)	3 (3-4)	0.031
Mode of delivery (N)			
Vaginal delivery	73	15	0.003
Cesarean delivery	3	6	0.003
Indications of CS (N)			
Acute fetal distress	3	6	0.003
Duration of labor$ (in minutes)	340 (320-380)	390 (344-420)	0.044
Meconium stained liqor (N)	4	8	0.001
Chorio-amnionitis (N)	1	0	1
NICU## admission (N)	1	0	1
Apgar score at 1 minute$	7 (7-8)	7 (7-8)	0.864
Apgar score at 5 minutes$	8 (8-9)	8 (8-9)	0.978

*Group 2: (100 women) 76 had spontaneous onset of labor (SOL) on expectant management till 41 weeks gestation, 3 women had emergency cesarean section for premature rupture of membranes with meconium-stained liquor, #; 21 remaining women induction of labor (IOL) was done as per study protocol at completion of 41 weeks gestation, $: median±inter quartile range, @: mean±standard deviation, ##: neonatal intensive care unit.

Table 4: Sub-group analysis of women undergoing IOL* in the study.

	Group 1 (n=100)	Group 2 (n=21)	OR (95% CI)	P value
Demographic characteristics				
Age$ (years)	26 (25-28)	25 (23-25)	-	0.243
BMI$ (Kg/m^2)	24.3 (23-24.5)	24 (23.3-25.4)	-	0.386
Parity (N)				
No abortion	80	17	1 (1.9-0.5)	1.000
Previous 1 abortion	15	2	0.8 (1.7-0.3)	0.734
Previous 2 abortions	5	2	2.5 (13.6-0.4)	0.350
Previous vaginal delivery				
Nil	65	15	1.5 (2.6-0.8)	0.623
1	27	3	0.6 (1.2-0.3)	0.276
2	7	2	0.7 (2.1-0.2)	0.654
3	1	1	1 (16.2-0.06)	1.000
Birth weight (grams)$	2854±339	2843±369	-	0.827
Neonate sex (N)				
Male	45	11	-	0.632
Female	55	10	-	0.335
Outcomes of women				
Doses of misoprostol required (N)				
1	50	17	-	0.014
2	29	4	-	0.423
3	15	0	-	0.071
4	4	0	-	1.000
5	2	0	-	1.000

Continued.

	Group 1 (n=100)	Group 2 (n=21)	OR (95% CI)	P value
Mode of delivery (N)				
Vaginal delivery	87	15	-	0.097
Caesarean delivery	13	6	-	0.097
Induction delivery interval (in minutes)#	674 (541-870)	446 (354-604)	-	<0.001
Chorio-amnionitis (N)	4	1	-	0.368
NICU## admission (N)	1	1	-	1.000
Apgar score at 1 minute$	7 (7-8)	7 (7-8)	-	0.838
Apgar score at 5 minutes$	8 (8-9)	8 (8-9)	-	0.942

*: Induction of labor, as per study protocol all women in group 1 (n=100) had IOL at 40 weeks gestation, in group 2 expectant management till 41 weeks, if women don't have spontaneous labor then IOL done at completion of 41 weeks (2 women in group 2 required early IOL at 40 weeks 3 days gestation due to oligohydramnios and one on maternal request), #: median ± inter quartile interval, $: mean±standard deviation.

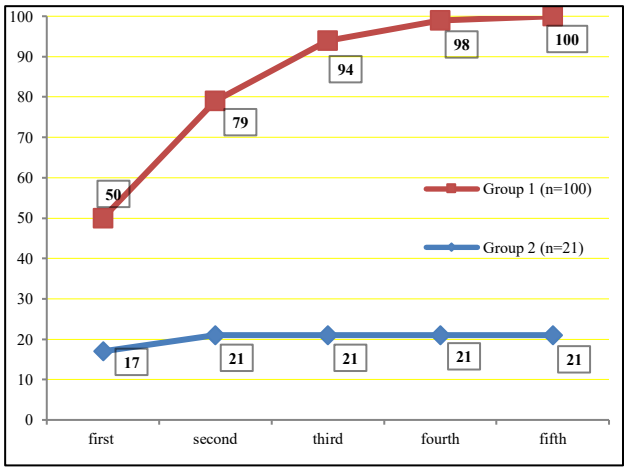

Figure 2: Women undergoing induction of labor with vaginal misoprostol (n; number of doses) in the study.

Group 1: 100 women induction of labor at 40 weeks gestation with [FC (60 ml) and vaginal misoprostol (25 µg every 4 hours)]; group 2: 100 women expectant management at 40 weeks gestation, 76 women had spontaneous labor, 3 required emergency cesarean delivery, 3 women required IOL at 40 weeks 3 days, 18 women had induction of labor at 41 weeks [FC (60 ml) and vaginal misoprostol (25 µg every 4 hours)].

On sub-group analysis of women (n) in group 2 [SOL 76 versus IOL 21 (remaining 3 had emergency CS for AFD with MSL)], there was no statistically significant difference with respect to age, BMI, parity, birth weight or neonatal sex, as shown in Table 3. However, there was a statistically significant difference with respect to the duration of pregnancy (days) {group 1 versus 2 [median (IQR)]: 282 (281-283) versus 287 (287-287), p<0.001]}, Bishop Score at admission {group 1 versus 2 [median (IQR)]: 5 (4-6) versus 3 (3-4), p<0.031]}, mode of delivery (n) [vaginal delivery; 73 versus 15, OR 9.73 (2.18-43.32), and CS; 3 versus 6, p=0.002], the indications of CS (n: AFD 3 versus 6, p=0.003), duration of labor [median (IQR); 340 (320-380) versus 390 (344.5-420), p=0.044], and MSL [n; 4 versus 8, OR (95% CI) 0.09 (0.02-0.34), p<0.001], respectively, with comparable maternal, fetal/neonatal outcomes, as shown in Table 3.

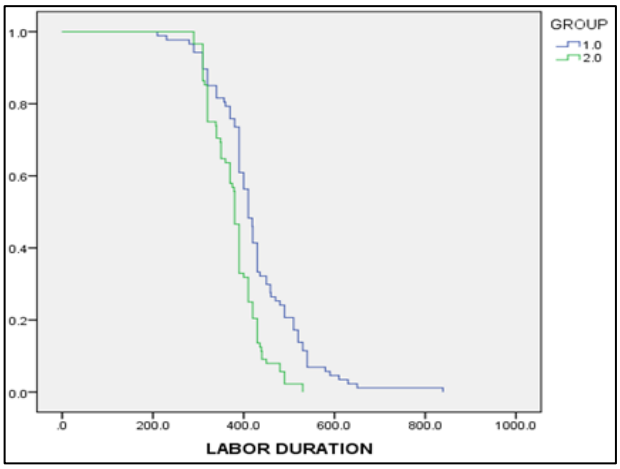

Figure 3: Kaplan Meier survival analysis curve for vaginally delivered women in the study.

On sub-group analysis concerning women undergoing IOL in two study groups {group 1; n=100 (IOL at 40 weeks) and group 2; n=21 [IOL at 40+3 weeks for three women (two for oligohydramnios and one on maternal request) and IOL at 41 weeks for 18 women]}, there was no statistically significant difference with respect to age, BMI, parity, previous vaginal delivery, birth weight, and neonatal sex, as shown in Table 4. There was a statistically significant difference with respect to doses of misoprostol required (n) (one dose; 50 versus 17, two doses; 29 versus 4, three doses; 15 versus nil, four doses; 4 versus nil and five doses; 2 versus nil, p<0.001, respectively as shown in Table 4 and Figure 2), mode of delivery (n) (vaginal delivery; 87 versus 15 and CS; 13 versus 6, p<0.001 respectively) and induction delivery interval (in minutes) [median (IQR); 674 (541-870) versus 446 (354-604), p<0.001 respectively], with comparable maternal and fetal/neonatal outcomes.

In multivariate analysis, there was a nearly two-fold increase in the relative risk [RR 1.98, (95% CI 1.473-2.186), p value <0.001] of SOL in group 2. With an absolute risk of 21% of women undergoing SOL, five women were required to be offered expectant management till 41 weeks (number needed to treat) for one to have SOL.

DISCUSSION

Three-fourths of low-risk post-date (>40 weeks) pregnant women (76%) offered expectant management till 41 weeks POG had SOL. Therefore, with an absolute risk of 21% of women having SOL, five women should be offered expectant management till 41 weeks for one woman to have SOL.

Our findings of SOL in women undergoing expectant management till 41 weeks have also been observed in the available literature.[4-6] These findings can have tremendous implications regarding reduced "need and duration" of hospitalization, especially in LMIC. Additionally, admission delivery interval (p=0.001), duration of labor (p<0.001), Bishop score at admission [5 (4-6) versus 3 (3-4), p<0.001], duration of labor in (minutes) [380 (325-417) versus 410 (380-482), p<0.001, as shown in Figure 3], number of women with delivery within 12 hours of admission (n; 87 versus 45, p<0.001) and within 12-24 hours of admission (n; 1 versus 42, p<0.001) was statistically significantly better in women undergoing expectant management till 41weeks, thereby implying a significant reduction in duration of hospitalization. Also, women with SOL have a statistically significant reduction in admission delivery interval (p=0.001) compared to IOL at 40 weeks. With a hefty load of obstetric patients and limited resources available, proper logistics management of hospital beds assumes tremendous importance in LMIC.[4]

Further, women having SOL (as compared to IOL) in group 2 have statistically significantly higher chances of vaginal delivery [n; 73 (out of 76) versus 15 (out of 21), OR 9.73 (95% CI 2.18-43.32), p=0.002], respectively. Also, MSL [n; 4 (out of 76) versus 8 (out of 21), OR 0.09 (95% CI 0.02-0.34), p=0.002, respectively] and CS for AFD [n; 3 (out of 76) versus 6 (out of 21), p=0.003], was significantly lower in women having SOL as compared to IOL in group 2. Women in SOL (as compared to IOL) have better chances of vaginal delivery and lesser need for CS (including that for AFD).[4-6,10]

Additionally, among women undergoing IOL, induction-delivery interval (p<0.001) and doses of misoprostol required (p<0.001), were statistically significantly lower in IOL at 41 weeks as compared to 40 weeks. Although, the majority of data on IOL is from HIC the situation in LMIC is entirely different where IOL (40 or 41 weeks) per se is associated with an increased risk of adverse newborn outcomes (OR=2.21, 95% CI=1.75-2.77, p<0.001), maternal complications (OR=2.18, 95% CI=1.71-2.77, p<0.001) and CS (OR=2.75, 95% CI=2.07-3.65, p<0.001).[3-6] However, it is pertinent to mention that our study was not adequately powered to assess these outcomes. A sample size of 94 women in each group (i.e. IOL at 40 versus 41weeks) is required to detect a 30% reduction in induction delivery interval using a two-sided t-test and to accept an error of 0.05 and 80% power (EPI INFO 7).

One limitation of our study is that five women (5%) (3; PROM with MSL and 2; oligohydramnios) required emergency intervention during the waiting period from 40 to 41weeks. This stresses the need for the round-the-clock availability of obstetric services with early and easy access to the same.[2,12] Timely managing these women led to optimum results with no significant maternal, fetal/neonatal complications. However, it is prudent to mention that there is an urgent need of a large multi-centric trial regarding timing of IOL in low-risk post-date pregnant women, especially in LMIC with limited resources.

Nonetheless, all low-risk pregnant women require meticulous observation between 40-41 weeks. Detailed examinations, including NST and BPP, should be offered twice weekly, during this period.[2,12] Furthermore, these women should be counselled regarding the signs and symptoms for seeking emergency health care services at the earliest without any unwarranted delay.

CONCLUSION

To conclude, we opine that the standard adage of "watchful expectancy" should be adhered to rather than IOL as a primary policy of labor management in low-risk post-date (>40 weeks) pregnant women in LMIC as the majority of them have SOL (76%), with comparable maternal and fetal/neonatal outcomes.

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Ethical approval: The study was approved by the Institutional Ethics Committee vide letter no. HFW-H(DRPGMC)PRC/2021-109 dated 19.06.2021

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