Figure 1 illustrates the participation flow. 167 women were assessed after their admission for IOLAC; eight women did not fulfil study criteria, seven opted for prostaglandin ripening and nine patients were already recruited into another study. A further 17 eligible patients declined to participate. 126 consented to participate; 63 were randomized to each arm. Data for analysis was available from all participants.

Table 1 lists the participants' characteristics dichotomized to three-hourly tugging or standard care. Baseline characteristics of Bishop score, maternal age, body mass index, gestational age and parity were similar. There was a significant difference (p=0.047) in indication for IOLAC.

Table 2 reports the primary outcomes of induction (Foley insertion) to birth interval, mean±standard deviation 29.7±9.6vs 29.8±9.1 mean difference -0.1 95% CI -3.4 to 3.2 hours p=0.950 and patient satisfaction with the birth process after IOLAC score (0-10 NRS) median [interquartile range] 8[7-9] vs. 8[7-9] p=0.936 for tugging vs. standard care respectively. The induction to vaginal birth interval was 25.8± 9.4 vs. 28.3±8.6 mean difference -2.6 95% CI -7.8 to 2.7 hours p=0.343. These results were very similar.

Table 3 shows the secondary maternal outcomes. Secondary outcomes with a significant difference across trial arms were the proportion of Foley balloon removed as planned at 12 hours 40/63 (64%) vs. 52/63 (83%) RR 0.77 95% CI 0.62-0.96 p=0.016, the proportion of preplanned Foley displacement due to tugging 20/23 (87%) vs. 0/11 (0%) p<0.001 and the proportion compliant to allocated trial protocol 57/63 (90.5%) vs. 63/63 (100%) p=0.028 for tugging vs. standard care respectively. These findings were as anticipated

and directly driven by tugging and of themselves conferred no clinical benefit. Other secondary outcomes of change in Bishop score at displacement of the index Foley, additional ripening needed, epidural in labor, duration of oxytocin infusion, mode of delivery and indication for operative delivery, delivery blood loss, perineal condition at vaginal birth, maternal fever, length of hospital stay and recommendation of allocated intervention to a friend were all not significantly different across trial arms. Compliance was significantly higher in the standard care arm (100%) but was also high (90.5%) in the tugging arm.

Table 4 displays the secondary neonatal outcomes. Apgar score at 1 minute was significantly different, median [interquartile range] 9[9-10] vs. 9[9-10] p=0.044 but the proportion for Apgar score at 1 min of <4 was 3/63 (5%) vs. 1/63 (2%) RR 3.0 95% CI 0.3-29.1 p=0.619. The clinically more relevant Apgar score at 5 minutes was not different. Umbilical cord artery blood pH, base excess, neonatal admission and their indication for admission) were also not different across trial arms. There were two cases of hypoxic-ischemic encephalopathy (one in each arm, the neonate in the standard care arm needed cooling therapy), two cases of congenital pneumonia (one in each arm) and two cases of cephalhematoma of a severity to require admission (both in tugging arm). The trial was not powered to address these important but uncommon outcomes.

Major harms

There was no anal sphincter injury, maternal ICU admission, cardiopulmonary resuscitation, hysterectomy or uterine rupture. In the newborn, there were two cases of hypoxemic-ischemic encephalopathy, one in each arm and cooling therapy was applied to the case in standard care arm.

Post hoc analysis

As our hypothesis was predicated on expediting birth through earlier discovery of a ripened cervix thus permitting timelier amniotomy and titrated oxytocin infusion to drive contractions, we generated and analyzed the various intervals between induction (balloon insertion), balloon displacement, amniotomy, commencement of oxytocin, second stage and birth across trial arms (Table 5). There were no significant differences and the point estimate differences were small.

We also reanalyze the impact of the interventions on the primary outcomes of induction to birth interval and maternal satisfaction with the birth process, controlling for indication for IOLAC, a characteristic that was significantly across trial arms. There was no material change with this regression analysis compared to the results of main analysis as reported in Table 2.

DISCUSSION

PRINCIPAL FINDINGS

The induction to birth interval with three-hourly tugging of the Foley balloon was a non-significant mean reduction of 0.1 hours compared to standard care. This small point estimate difference is unlikely to be clinically relevant. Similarly, patient satisfaction with the birth process measured with the 0-10 NRS had identical median [interquartile range] values of 8[7-9]. These outcomes suggested that whilst tugging was acceptable, it was ineffective. Although the concept and rationale is different, a 2022 meta-analysis shows that continuous traction compared with no traction in Foley catheter labor induction, the induction to delivery interval (mean difference, 0.25 hours) was not significantly different[33].

Although tugging resulted in a statistically significant difference in Foley displacement rates before scheduled removal at 12 hours, 11/20 (55%) of the balloons were tugged out were at 12 hours, just prior to scheduled balloon deflation for removal. As a result, there was no impact of three-hourly tugging on the induction to balloon displacement interval as 79%-81% of the balloons were still within the vagina-lower uterus at 12 hours.

The requirement for additional ripening was high 65%-73% across our trial arms compared to 31.7% in the 12 hour arm of another IOLAC trial that inflated the Foley balloon to 50 ml compared to the 30 ml balloon volume in this trial. Balloon volumes larger than 30 mL during Foley catheter IOL reduce total time to delivery by approximately 2 hours.[32] However, in IOLAC specifically, inflating the Foley balloon to 30 or 80 ml resulted in similar duration of labour and delivery rate within 24 hours.[35]

It was plausible that providers tug with insufficient force to retrieve a dislodged and retained 30 ml balloon. This sensibility could be driven by the objective of not causing pain or out of concern about a balloon re-insertion if the cervix was not as ripened as possible. The later point of getting the cervix as ripened as possible and for contractions was especially pertinent in the context of high-risk IOLAC where there would be concern to start oxytocin[36] or use it for a prolonged period at a high dose[34].

Consequently, the downstream induction to amniotomy and commencement of oxytocin intervals were not shortened with tugging. The balloon can be retained as supported by findings that six vs. 12 hour planned Foley placements hastened birth in the labour induction nulliparas[21], multiparas[22] and after one previous cesarean[6] indicating that six hour placement was sufficient to ripen the cervix.

Cesarean delivery was high at 59%-65% in our trial but consistent with cesarean rates following IOLAC in recent trial reports of 50%-69%[5-8]. In contemporary practice, these high unplanned cesarean rates following IOLAC, preponderantly indicated by failure to progress is plausibly due to a cautious and duration-sensitive approach with oxytocin use[34,36] coupled to a low threshold recourse to cesarean delivery.

Patient satisfaction with tugging was not increased nor were they more likely to agree to recommend their allocated intervention. A shorter induction to delivery interval, amniotomy, vaginal delivery, no postpartum hemorrhage, and no neonatal admission are independently predictors of patient satisfaction at IOL[25]; these outcomes were not different across our trial arms.

CLINICAL IMPLICATIONS

Our findings did not support periodic tugging during Foley IOLAC. Tugging was tolerated well and there was no adverse inference to it from our data. Hence, as our method was novel, it is not implausible that better instruction or training on the tugging technique might still benefit.

Routine Foley catheter tugging at IOLAC for the retrieval of the balloon to serve as marker of a ripened cervix should not applied outside a clinical trial. However, with signs of ongoing balloon expulsion such as obvious external lengthening of the catheter tubing and a bloody show, tugging would be a reasonable first-line clinical response.

STRENGTHS AND LIMITATIONS

The strengths of this study were the randomized controlled design, sample size calculated using guidance data from another IOLAC trial[6] and the sample size target was achieved, complete primary outcome ascertainment and high compliance rate. Trials about techniques for IOLAC have been sparse. Limitations of this study included evaluating a novel technique of catheter tugging without guidance data on how it should be best performed and these details could have contributed to a negative result for this trial. For compliance, we assessed that tugging was attempted but not that sufficient force or time was applied as intended in the instruction. Our trial was conducted in a single center which could limit generalizability of its findings.

Figure 1: Recruitment flow chart into a randomised trial of 3-hourly tugging vs standard care (no tugging) of Foley balloon in induction of labour after one previous cesarean.

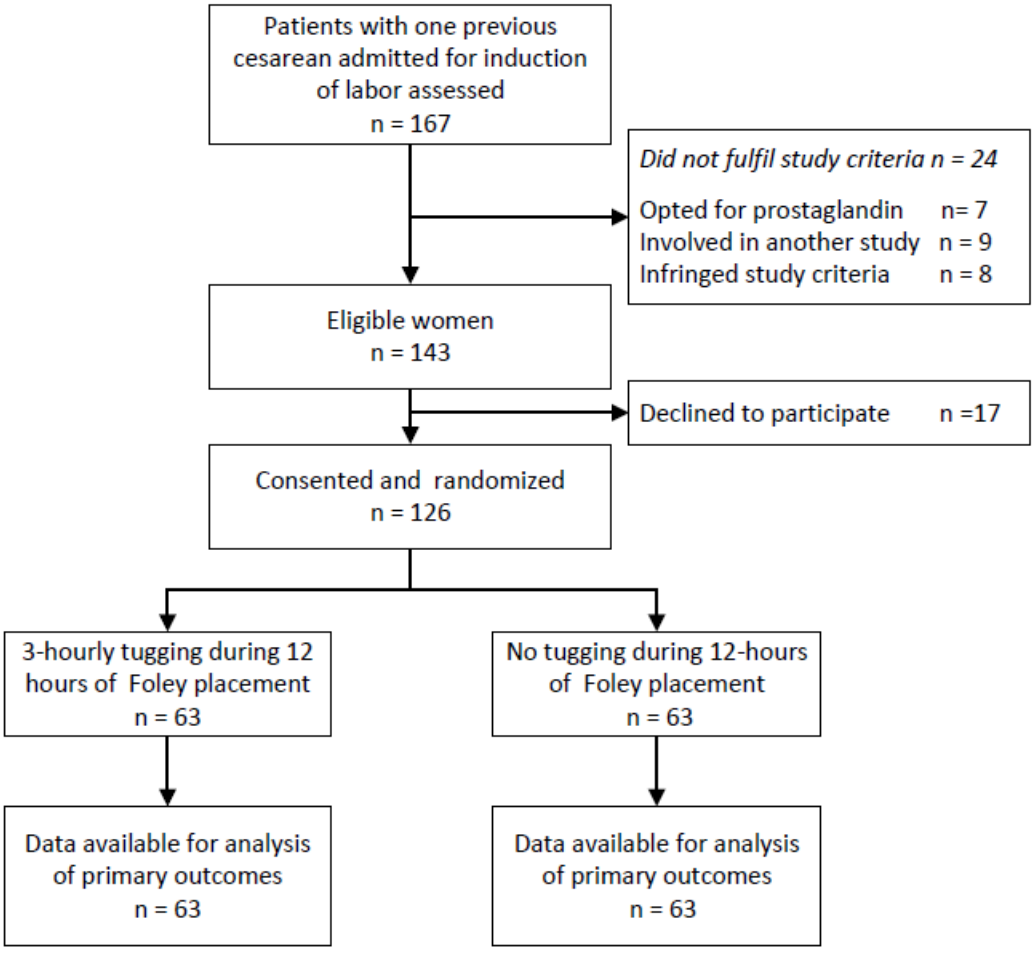

Table 1: Characteristic of participants in a randomized trial of 3-hourly tugging vs. standard care (no tugging) of Foley balloon in induction of labor induction after one previous cesarean

	Tugging n = 63	Non-Tugging n = 63	p value
Age (years)	32.2 ± 3.9	33.0 ± 4.2	0.326
Body mass index	30.9 ± 5.0	31.0 ± 5.3	0.906
Gestation (weeks)	38.4 ± 1.0	38.4 ± 1.0	0.917
Parity:			0.847
1	44 (70%)	43 (68%)	
≥2	19 (30%)	20 (32%)	
Education Level:			0.741
Up to secondary	11 (18%)	13 (21%)	
Diploma	24 (38%)	20 (32%)	
Degree and above	28 (44%)	30 (48%)	
Occupation:			0.327
Employed	51 (81%)	48 (76%)	
Self Employed	0 (0%)	3 (5%)	
Home Maker	12 (19%)	12 (19%)	
Ethnicity:			0.662
Malay	48 (77%)	50 (79%)	
Chinese	5 (8%)	3 (5%)	
Indian	7 (11%)	9 (14%)	
Others	3 (5%)	1 (2%)	
Induction indication			0.047
Prolonged Pregnancy	20 (32%)	13 (21%)	
Non-reassuring Fetal Status[1]	26 (41%)	18 (29%)	
Diabetes In Pregnancy	8 (13%)	19 (30%)	
Hypertension In Pregnancy	4 (6%)	2 (3%)	
Prolonged Latent Phase	1 (2%)	5 (8%)	
Others[2]	4 (6%)	6 (9%)	
Bishop Score	5 [4-5]	5 [5-5]	0.112
5	45 (71%)	52 (83%)	0.118
4	8 (13%)	8 (13%)	
≤3	3 (5%)	10 (16%)	

Data represented as number (%), mean±standard deviation and median[interquartile range]. Analysis was by t Test for normally distributed continuous data, Mann-Whitney U test for non-normally distributed or ordinal data and Chi-Square test for categorical and nominal data (Fisher exact test applied if ≥ 20% of cells has expected cell size < 5).

[1]Comprising oligohydramnios (10), reduced fetal movement (8), increased umbilical artery pulsatility index (7) or small for gestational age (19) and all with reassuring fetal heart rate tracing at labour induction
[2]Comprising polyhydramnios (3), large for gestational age (2), suspicion of hind water rupture (2), prior suspicion of preterm membrane rupture (1), previous early neonatal demise (1), gestational thrombocytopenia (1), suspicion of meconium staining in vaginal discharge

Table 2: Primary outcomes of a randomized trial of 3-hourly tugging vs. standard care (no tugging) of Foley balloon in induction of labor induction after one previous cesarean

	Tugging n=63	No tugging n=63	Mean Difference	95% CI	P value
Maternal satisfaction[1]	8[7-9]	8[7-9]			0.936
Induction[2] to all births (hours)	29.7±9.6	29.8±9.1	-0.1	-3.4 to 3.2	0.950
Induction[2] to vaginal birth[3] (hours)	25.8± 9.4 n=26	28.3±8.6 n=22	-2.6	-7.8 to 2.7	0.343

Data represented as mean ± standard deviation and median [interquartile range]. Analysis was by Student t test for normally distributed data, Mann-Whitney U test for ordinal data. Two-sided P<0.025 (Bonferroni corrected) was taken as level of significance for two primary outcomes of maternal satisfaction and .

[1]Maternal satisfaction with birth process scored with the 0-10 numerical rating scale
[2]Induction start was defined as from insertion of the Foley balloon
[3]Including instrumental vaginal births

Table 3 : Secondary outcomes (maternal) of a randomized trial of 3-hourly tugging vs. standard care (no tugging) of the Foley balloon in induction of labor after one previous cesarean

	Tugging	No tugging	Relative Risk	95% CI	p value
	n=63	n=63			
Bishop score change[1]	2[1-3]	2[1-3]			0.996
Additional ripening[2]	41 (65%)	46 (73%)	0.89	0.71-1.13	0.335
Foley	39 (95%)	45 (5%)	0.97	0.90-1.06	0.600
Prostaglandin	2 (5%)	1 (2%)			
Foley removed as planned	40 (64%)	52 (83%)	0.77	0.62-0.96	0.016
Foley expelled or tugged out	23 (21%)	11 (17%)			
Spontaneously expelled	3 (13%)	11 (100%)			<0.001
Tugged out	20 (87%)	0 (0%)			
Tugged out at 3 hours	2				
Tugged out at 6 hours	5				
Tugged out at 9 hours	2				
Tugged out at 12 hours	11				
	n = 20				
Compliance to trial protocol[3]	57 (90.5%)	63 (100%)			0.028
Oxytocin infusion duration (hour)	6.1±2.8	6.2±2.7	-0.1	-1.1 to 1.0	0.861
	n=53	n=51			
Epidural in labor	37 (60%)	38 (61%)	0.97	0.73-1.29	0.854
Mode of delivery					0.238
Vaginal, spontaneous	21 (33%)	21 (33%)			
Operative vaginal	5 (8%)	1 (2%)			
Cesarean section	37 (59%)	41 (65%)			
Indication Of Cesarean:					0.915
Failure to Progress	24 (65%)	24 (59%)			
Non reassuring fetal status	10 (27%)	13 (32%)			
Maternal request	2 (5%)	2 (5%)			
Non cephalic	1 (3%)	2 (5%)			
	n=37	n=41			
Estimated Blood Loss	300[300-500]	400[300-500]			0.407
PPH ≥ 500ml	20 (32%)	25 (40%)	0.80	0.50-1.28	0.353
Perineal Condition[4]					0.742
Intact	3 (12%)	1 (5%)			
First Degree	8 (31%)	10 (46%)			
Second Degree	5 (19%)	4 (18%)			
Episiotomy	10 (39%)	7 (32%)			
	n=26	n=22			
Maternal fever (≥38^{0}C)	1 (1%)	2 (3%)	0.5	0.05-5.38	>0.99
Antibiotics (during labor and birth)	42 (67%)	49 (79%)	0.84	0.68-1.05	0.120
Indication for Antibiotics[5]					0.191
Caesarean prophylaxis	27 (43%)	34 (54%)			
GBS carrier	11 (18%)	10 (16%)			
Instrumental Delivery	4 (6%)	1 (2%)			
Postpartum hemorrhage	0 (0%)	1 (2%)			
Intrapartum fever	0 (0%)	3 (5%)			
Recommends intervention[7]					0.626

Strongly Agree	7 (11%)	12 (19%)	
Agree	38 (60%)	33 (52%)	
Neutral	16 (25%)	15 (24%)	
Disagree	2 (3%)	3 (5%)	
Induction to discharge (days)	3.2[2.9-4.0]	3.2[3.0-4.0]	0.849

Data represented as mean±standard deviation, median[interquartile range] and number (%). Normal distribution of continuous data checked with the 1-sample Kolmogorov Smirnov test. Analyses by Student t test for comparison of means in normally distributed data, Mann-Whitney U test for not normally distributed and ordinal data, and Chi-Square test for categorical data sets (Fisher exact test substituted instead if ≥20% cells analyzed had expected cell number <5).

[1] From pre-induction to expulsion/retrieval or planned removal at 12 hours
[2] Additional ripening after the index (first) Foley balloon
[3] Compliance defined as tugging performed at every scheduled point (if catheter still in place) in the tugging arm and no tugging performed at any stage of balloon placement in the no tugging arm
[4]Vaginal delivery only (exclude cesarean) After vaginal
[5]Indication of the first antibiotic given from induction to birth
[6]Satisfaction with the birth process measured using an 11-point 0-10 numerical rating scale
[7]Recommends allocated intervention of tugging or no tugging to a friend

Table 4: Secondary neonatal outcomes of a randomized trial of 3-hourly tugging vs. standard care (no tugging) of the Foley balloon in induction of labor after one previous cesarean

	Tugging	No Tugging	Relative Risk	95% CI	p value
	n=63	n=63			
Apgar score					
At 1 min	9[9-10]	9[9-10]			0.044
At 1 minute <4	3 (5%)	1 (2%)	3.0	0.3-29.1	0.619
At 5 min	10[10-10]	10[10-10]			0.362
At 5 min <7	3 (5%)	2 (3%)	1.5	0.3-8.6	>0.99
Umbilical cord artery blood					
pH	7.30[7.23-7.34]	7.30[7.26-7.33]			0.800
≤7.10	3 (5%)	3 (5%)	1.00	0.2-4.8	>0.99
Base excess (mmol/l)	-2.4[-4.6 to -1.2]	-3.1[-4.4 to -1.5]			0.729
≤-12	1 (2%)	1 (2%)	1.00	0.1-16.6	
Neonatal admission	18 (29%)	11 (18%)	1.64	0.9-3.2	0.138
Intensive care	8 (44%)	2 (18.2%)			0.199
Special care nursey	7 (39%)	4 (36%)			
Postnatal ward nursery	3 (17%)	5 (46%)			
Neonatal admission (indication)					0.476
Transient tachypnea	6 (33%)	2 (18%)			
Maternal diabetes (drug therapy)	3 (17%)	3 (27%)			
Maternal fever	0 (0%)	3 (27%)			
Fetal dilated renal pelvis	2 (11%)	1 (9%)			
HIE[1]	1 (6%)	1 (9%)			
Congenital pneumonia	1 (6%)	1 (9%)			
Cephalhematoma	2 (11%)	0 (0%)			
Respiratory (opioid)	1 (6%)	0 (0%)			
Respiratory (general anesthesia)	1 (6%)	0 (0%)			
Neonatal purpura	1 (6%)	0 (0%)			
	n=18	n=11			
HIE[1]	1 (2%)	1 (2%)	1.00	0.1-15.6	>0.99
Cooling therapy for HIE[1]	0 (0%)	1 (2%)			>0.99
Birth trauma	2 (3%)	0 (0%)			0.496
Neonatal sepsis	1 (2%)	1 (2%)	1.00	0.1-15.6	>0.99
Birthweight (kg)	3.00[2.71-3.31]	2.95[2.40-3.28]			0.775

Data represented as median[interquartile range] or mean±standard deviation and number (%). Normal distribution of continuous data checked with the 1-sample Kolmogorov Smirnov test. Analyses were by Student's t-test for comparison of means and Mann-Whitney U test for non-normally distributed and ordinal data and Fisher exact test for nominal data.

[1]Hypoxic-ischemic encephalopathy