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Induction of normal labor using folly catheter

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Abstract: Background: Foley catheters are used for cervical ripening during induction of labor. Labor induction is one of the most commonly performed obstetrical interventions. **Aim and objectives**: the aim of the study was to investigate the induction of normal labor by folly catheter, and to determine role of folly catheter in induction of normal labor. **Subjects and methods**: This study was a randomized clinical trial, which was carried out at the Gynecology in AL-Azhar University Assyut hospitals, from March 2020 till September 2020, participants were randomized online to either group A (Foley's catheter group) or group B (placebo). Cervical assessment was performed by principle investigator with modified Bishop Score. **Results**: results of the study revealed that in group A there were 54(67.5%) with NVD, 26(32.5%) with CS, 19(73.1%) with fetal distress, 1(3.8%) with poor progress, 6(23.1%) with other, In group B there were 40(50%) with NVD, 40(50%) with CS, 16(40%) with fetal distress, 6(15%) with poor progress,9(22.5%) with failed IOL, 9(22.5%) with others, and there is significant difference between 2 groups as regard Mode of delivery and as regard Indication of caesarean section. **Conclusion**: For women with an unfavorable cervix at term, induction of labor with a Foley catheter is safe and effective. Higher balloon volume (80-mL vs. 30-mL) and longer ripening time (24 hours vs. 12 hours) would not shorten induction to delivery interval or reduce cesarean section rate.
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1. Introduction:

Childbirth most often is viewed as a joyful event and most commonly culminates in a happy outcome. However, it is also a major life change for the pregnant woman that frequently produces anxiety, stress, and fear, and is associated with considerable pain and a need for substantial physical and emotional exertion. Women have described childbirth pain as severe, with 60% of women reporting labor pain as the most intense that they had ever experienced (Escott et al., 2009; Niven et al., 1984). Some authors have described pregnancy and childbirth as having a crisis character, similar in some ways to the crisis character of surgery. Thus, the pregnant patient must, in some way, cope with the critical nature of childbirth (Miquelutti et al., 2013; Sieber et al., 2006). And her ability to cope with the pain and stress of childbirth can determine whether she views it as a positive or a negative experience.

Labor and delivery are physiological processes that begin with the onset of regular uterine contractions and end with the expulsion of the products of conception from the uterus (American College of Obstetricians and Gynecologists, 2003). Labor is characterized by the presence of uterine contractions of sufficient intensity, frequency, and duration to bring about demonstrable effacement and dilation of the cervix. The progress of labor is measured by changes in cervical dilatation and fetal descent. Detection of deviations from normal progress in labor allows for timely and appropriate intervention to optimize maternal and fetal well‐being (World Health Organization, 2010). However, defining normal labor progression has been a long‐standing challenge (Zhang et al., 2010).

Friedman was the first to depict a labor curve and divide the labor process into three stages (first, second, and third) in a continuous process (Iams, 2006). The first stage of labor, from the onset of uterine contractions to full cervical dilation, is further divided into the latent phase (the presence of uterine contractions resulting in progressive effacement and dilatation of the cervix to 4 cm) and the active phase (regular uterine contractions accompanied by cervical dilatation and effacement from 4 cm until full dilatation and effacement of the cervix).

The second stage of labor is from full dilatation and effacement of the cervix to birth of the neonate. The third stage of labor refers to the period following the completed delivery of the newborn until the

completed delivery of the placenta **(Iams, 2006).** The prospective diagnosis of labor of spontaneous onset relies on the presence of regular uterine contractions, progressive cervical effacement and dilation, and "show" (discharge of cervical mucus). Cervical insufficiency may be indicated when there is cervical dilation without regular uterine contraction. Conversely, uterine contractions without cervical change may be due to "false labor" or uterine irritability **(Selman et al., 2013).** Neither of these two latter scenarios meets the clinical criteria for true labor. Labor onset may be either spontaneous or induced. The latter may be further classified as induced labor with or without medical indication **(Bailit et al., 2010)**.

For women with healthy pregnancies who expect a normal labor and who have a choice of care provider, the question arises as to the optimal care model to select. A recently updated Cochrane review by Sandall et al. compared midwife led care to other forms of care, including doctor‐led care **(Chapman, 2016).** Women who had midwife‐led continuity models of care were less likely to experience regional analgesia (RR 0.83, 95% CI 0.76–0.90), episiotomy (RR 0.84, 95% CI 0.76– 0.92), and instrumental birth (average RR 0.88, 95% CI 0.81–0.96), and were more likely to experience no intrapartum analgesia/anesthesia (average RR 1.16, 95% CI 1.04–1.31), spontaneous vaginal birth (average RR 1.05, 95% CI 1.03–1.08), attendance at birth by a known midwife (average RR 7.83, 95% CI 4.15–14.80), and a longer mean length of labor (hrs) (mean difference (hrs) 0.50, 95% CI 0.27–0.74). There were no differences between groups in cesarean births (average RR 0.93, 95% CI 0.84–1.02). Maternal satisfaction tended to be high in the midwife‐led care groups.

Labor induction is one of the most commonly performed obstetrical interventions. Although multiple methods for cervical ripening and labor induction exist, the search for the optimal method is ongoing. Mechanical methods for cervical ripening, specifically cervical balloon catheters, have the advantage of ripening the cervix without inducing simultaneous uterine contractions (Delaney et al., 2010; Grabiec et al., 2015; Jozwiak et al., 2012; Tenore, 2003; Vogel et al., 2017). The frequency of labor induction has been increasing in the United States and worldwide. In 2006, more than one in five pregnant women underwent induction of labor (Osterman et al., 2011). Transcervical Foley catheter placement has been established as a safe and effective modality in the setting of labor induction (Wing, 2015).

Potential mechanisms of cervical ripening include mechanical dilation of the cervix as well as release of endogenous prostaglandins from the fetal membranes. Foley catheter placement before the initiation of oxytocin has been shown to decrease the risk of cesarean delivery when compared with oxytocin alone (Gelber & Sciscione, 2006; Grabiec et al., 2015; Subramanian & Penna, 2009). The latest Practice Bulletin published by the American College of Obstetricians and Gynecologists (Bonsack et al., 2014). On induction of labor reports that there is no difference in the duration of induction to delivery or risk of cesarean delivery when the efficacy of a Foley catheter was compared with that of intravaginal prostaglandins. However, Foley catheter use decreases the risk of tachysystole (with or without fetal heart rate changes) and offers the advantage of lower cost, reversibility, and stability at room temperature (Jozwiak et al., 2012; Levine et al., 2016; Ramirez, 2011).

Potential side effects of Foley catheter for induction of labor include premature rupture of membranes, chorioamnionitis, bleeding, increased patient discomfort, displacement of the presenting part, and future risk of preterm birth (Sherman et al., 1996). Multiple studies have shown no consistent association between Foley catheter use and these risks, although is it generally accepted that low-lying placenta is a relative contraindication for Foley catheter placement because of concern for potential disruption of the placental edge resulting in maternal hemorrhage (Abramovici et al., 1999; Carbone et al., 2013; Dalui et al, 2005; El-Khayat et al., 2016; Kashanian & Fekrat, 2009; Meyer et al., 2005). In our study we aim to further investigate the induction of normal labor using folly catheter.

Aim of the work

Further investigate the induction of normal labor by folly catheter.

Objectives

Determine role of folly catheter in induction of normal labor.

2. Patients and methods

Setting:

Thestudy will take place in the Gynecology in AL-Azhar University –Assyut hospitals.

Patients

Patients admitted to assyut hospital for normal labor.

Study type:

Prospective cohort study.

Inclusion criteria:-

Patients who are about to normal deliver.

Exclusion criteria:

Patients not willing to be a part of the study.

Patients has any medical disorder that would affect the normal delivery process.

Patients who have had medical problems in previous pregnancies.

3. Results

Table (1) shows that in group A the mean maternal age 30.4(± 5.45 SD) with range (22-40), the mean Gestational age 39.24(±1.35 SD) with range (37-41), the mean parity 1.93(±1.4 SD) with range (0-5), the mean BMI 28.2(±3.43 SD) with range (23-34), the mean Bishop score pre induction 3.28(±1.01 SD) with range (2-5).

In group B the mean maternal age 30.58(± 6.12 SD) with range (21-41), the mean Gestational age 39.5(±1.35 SD) with range (37-42), the mean parity 1.98(±1.41 SD) with range (0-5), the mean BMI 28.03(±3.53 SD) with range (22-34), the mean Bishop score pre induction 3.15(±1.02 SD) with range (2-5).

There is no significant difference between 2 groups.

Table (1): Comparison between the two studied groups according to maternal data

	Group A (n = 80)	Group B (n = 80)	Test of Sig.	p
Maternal age				
Min. – Max.	22.0 – 40.0	21.0 – 41.0		
Mean ± SD.	30.40 ± 5.45	30.58 ± 6.12	t= 0.191	0.849
Median (IQR)	30.0 (26.0 – 35.0)	29.0 (26.0 – 26.0)		
Gestational age				
Min. – Max.	37.0 – 41.0	37.0 – 42.0		
Mean ± SD.	39.24 ± 1.35	39.50 ± 1.35	t= 1.229	0.221
Median (IQR)	39.0 (38.0 – 40.0)	40.0 (38.0 – 41.0)		
Parity				
Min. – Max.	0.0 – 5.0	0.0 – 5.0		
Mean ± SD.	1.93 ± 1.40	1.98 ± 1.41	U= 3132.0	0.811
Median (IQR)	2.0 (1.0 – 3.0)	2.0 (1.0 – 3.0)		
BMI				
Min. – Max.	23.0 – 34.0	22.0 – 34.0		
Mean ± SD.	28.20 ± 3.43	28.03 ± 3.53	t= 0.318	0.751
Median (IQR)	28.0 (25.0 – 31.0)	28.0 (25.0 – 31.0)		
Bishop score pre induction				
Min. – Max.	2.0 – 5.0	2.0 – 5.0		
Mean ± SD.	3.28 ± 1.01	3.15 ± 1.02	t= 0.780	0.436
Median (IQR)	3.0 (2.0 – 4.0)	3.0 (2.0 – 4.0)		

t: Student t-test U: Mann Whitney test p: p value for comparing between the studied groups

Table (2) shows that in group A the mean Difference in BS 4.21(±1.17 SD) with range (2-6).

In group B the mean Difference in BS 3.84(±1.52 SD) with range (1-6) There is no significant difference between 2 groups.

Table (2): Comparison between the two studied groups according to difference in BS

Difference in BS	Group A (n = 80)	Group B (n = 80)	t	p
Min. – Max.	2.0 – 6.0	1.0 – 6.0		
Mean ± SD.	4.21 ± 1.17	3.84 ± 1.52	1.750	0.082
Median (IQR)	4.0 (3.0 – 5.0)	4.0 (2.0 – 5.0)		

t: Student t-test p: p value for comparing between the studied groups

Table (3) shows that in group A with Favorable cervix there were 49(65.3%) with Vaginal delivery, 26(34.7%) with Caesarean section, with unfavorable cervix there were 3(27.3%) with Vaginal delivery. 8(72.7%) with Caesarean section.

In group B with Favorable cervix there were 40(57.1%) with Vaginal delivery, 30(42.9%) with Caesarean section, with unfavorable cervix there were 5(38.5%) with Vaginal delivery. 8(61.5%) with Caesarean section.

There is no significant difference between 2 groups.

Table (3): Comparison between the two studied groups according to cervix

Cervix	Group A		Group B		2	p
	No.	%	No.	%		
Vaginal delivery=NVD	**54**	**67.5**	**40**	**50.0**		
Favorable cervix	50	92.6	40	100.0		
Unfavorable cervix	4	7.4	0	0.0	3.095	0.134
Caesarean section=CS	**26**	**32.5**	**40**	**50.0**		
Favorable cervix	26	100.0	30	75.0		
Unfavorable cervix	0	0.0	10	25.0	7.661*	0.005*

2: **Chi square test** FE**: Fisher Exact** p: p value for comparing between the studied groups

Table (4) shows that in group A there were 54(67.5%) with NVD, 26(32.5%) with CS, 19(73.1%) with fetal distress, 1(3.8%) with poor progress, 6(23.1%) with others.

In group B there were 40(50%) with NVD, 40(50%) with CS, 16(40%) with fetal distress, 6(15%) with poor progress,9(22.5%) with failed IOL, 9(22.5%) with others.

There is significant difference between 2 groups as regard Mode of delivery and as regard Indication of caesarean section.

Table (4): Comparison between the two studied groups according to mode of delivery

	Group A (n = 80)		Group B (n = 80)		2	p
	No.	%	No.	%		
Mode of delivery						
NVD	54	67.5	40	50.0		
CS	**26**	**32.5**	**40**	**50.0**	5.055*	0.025*
Indication of caesarean section	**(n = 26)**		**(n = 40)**			
Fetal distress	19	73.1	16	40.0		
Poor progress	1	3.8	6	15.0		
Failed IOL	0	0.0	9	22.5	11.289*	MCp= 0.008*
Other	6	23.1	9	22.5		

2: **Chi square test** MC: **Monte Carlo** p: p value for comparing between the studied groups
*: Statistically significant at $p \leq 0.05$

Table (5) shows that in group A the mean insertion 1.09(±0.64 SD) with range (0-2), the mean removal 0.76(±0.8 SD) with range (0-2).

In group B the mean insertion 1(±0.64 SD) with range (0-2), the mean removal 0.58(±0.52 SD) with range (0-2).

There is no significant difference between 2 groups.

Table (5): Comparison between the two studied groups according to maternal pain score

Maternal Pain Score	Group A (n = 80)	Group B (n = 80)	U	p
Insertion				
Min. – Max.	0.0 – 2.0	0.0 – 2.0		
Mean ± SD.	1.09 ± 0.64	1.0 ± 0.64	2976.0	0.385
Median (IQR)	1.0 (1.0 – 1.50)	1.0 (1.0 – 1.0)		
Removal				
Min. – Max.	0.0 – 2.0	0.0 – 2.0		
Mean ± SD.	0.76 ± 0.80	0.58 ± 0.52	2896.5	0.255
Median (IQR)	1.0 (0.0 – 1.0)	1.0 (0.0 – 1.0)		

U: Mann Whitney test p: p value for comparing between the studied groups

Table (6) shows that in group A the mean Baby birth weight 3.02(±0.34 SD) with range (2.38-3.61).

In group B the mean Baby birth weight 3.07(±0.38 SD) with range (2.44- 3.65).

There is no significant difference between 2 group.

Table (6): Comparison between the two studied groups according to baby birth weight (kg)

Baby birth weight (kg)	Group A (n = 80)	Group B (n = 80)	t	p
Min. – Max.	2.38 – 3.61	2.44 – 3.65		
Mean ± SD.	3.02 ± 0.34	3.07 ± 0.38	0.968	0.334
Median (IQR)	3.07 (2.75 – 3.26)	3.08 (2.71 – 3.43)		

t: Student t-test p: p value for comparing between the studied groups

Table (7) shows that in group A the mean Apgar score at 1 minute 7.9(± 1.09 SD) with range (3-9), at 5 minute 8.8(± 1.05 SD) with range (4-10), there were 2(2.5%) with NICU admission.

In group B the mean Apgar score at 1 minute 7.91(± 1.3 SD) with range (3-9), at 5 minute 8.89(± 1.3 SD) with range (3-10), there were 4(5%) with NICU admission.

There is no significant difference between 2 groups.

Table (7): Comparison between the two studied groups according to neonatal condition

Indications	Group A (n = 80)		Group B (n = 80)		Test of Sig.	p
Apgar score						
At 1 minute						
Min. – Max.	3.0 – 9.0		3.0 – 9.0			
Mean ± SD.	7.90 ± 1.09		7.91 ± 1.30		U= 3021.5	0.520
Median (IQR)	8.0 (7.0 – 9.0)		8.0 (7.0 – 9.0)			
At 5 minutes						
Min. – Max.	4.0 – 10.0		3.0 – 10.0			
Mean ± SD.	8.80 ± 1.05		8.89 ± 1.30		U= 2782.5	0.121
Median (IQR)	9.0 (8.0 – 9.0)		9.0 (9.0 – 10.0)			
NICU admission	**No.**	**%**	**No.**	**%**		
No	78	97.5	76	95.0	^{2}= 0.693	FEp= 0.681
Yes	2	2.5	4	5.0		

2: **Chi square test** FE**: Fisher Exact** **U: Mann Whitney test**
p: p value for comparing between the studied groups

Table (8): Relation between mode of delivery with Bishop Score pre induction and maternal pain score in group A (n = 80)

	Mode of delivery		Test of sig.	p
	Vaginal delivery (success) (n = 54)	Caesarean section (failed) (n =26)		
Maternal Pain Score				
Insertion				
Min. – Max.	0.0 – 2.0	0.0 – 2.0		
Mean ± SD.	1.06 ± 0.68	1.15 ± 0.54	U= 652.0	0.560
Median	1.0	1.0		
Removal				
Min. – Max.	0.0 – 2.0	0.0 – 2.0		
Mean ± SD.	0.76 ± 0.82	0.77 ± 0.76	U= 688.50	0.881
Median	1.0	1.0		
Bishop score pre induction				
Min. – Max.	2.0 – 5.0	2.0 – 5.0		
Mean ± SD.	3.30 ± 1.02	3.23 ± 0.99	t=0.271	0.787
Median	3.0	3.0		

U: Mann Whitney test **t: Student t-test**

4. Discussion

Labor induction is a frequently used method in the management of high-risk pregnancy. At present, both medical and mechanical methods have been applied for cervical ripening in women with an unfavorable cervix. As the oldest methods to induce labor, mechanical methods were developed to promote cervical ripening and the onset of labor by dilating the cervix. Hygroscopic and osmotic dilators are effective, but they might be associated with an increase in maternal infection and are seldom used in the term labor induction. Currently, Foley catheter balloon is the most commonly used mechanical device for labor induction, which acts not only as a mechanical dilator of the cervix but also a stimulator of endogenous prostaglandins release from the fetal membranes (**Gondkar et al., 2018).**

The incidence of induction of labor (IOL) is rising worldwide, with a rate of 20−30% in developed countries at present. The increasing rates of IOL may be explained by increasing maternal age, obesity, and medical conditions, as well as improved fetal monitoring. Several clinical guidelines and recommendations on indications and optimal timing for IOL exist. The most common indications for IOL are post-term pregnancy and premature rupture of membranes (PROM) (**McMahon et al., 2020).**

The exact mechanism of initiation of parturition is not completely understood. Cell-free fetal DNA has been suggested to trigger the biochemical process of cervical ripening, leading to onset of labor. The role of cervical ripening in success of IOL is well established; an unripe cervix is associated with high risk of induction failure, failure to progress in labor, cesarean section (CS), infections, fetal distress, and postpartum hemorrhage (**Kruit et al., 2017).**

Double-balloon catheter has been designed and introduced recently for labor induction. However, two studies showed that double-balloon catheter could not improve outcomes and might be associated with more operative deliveries compared with Foley catheter balloon. Compared with vaginal prostaglandin E2 gel in term labor induction, Foley catheter achieved similar vaginal delivery rates, with fewer maternal and neonatal side effects. Cost-effectiveness analysis alongside the trial showed that Foley catheter and prostaglandin E2 labor induction resulted in comparable costs. In the Foley catheter group, the induction material was cheaper but induction to delivery interval was longer, which generated higher costs due to longer labor ward occupation (**Young et al., 2020).**

To improve the efficacy of induction, different balloon inflation sizes and ripening time have been compared. Balloon inflation sizes of 30–80 mL have been reported and two randomized controlled trials showed that larger balloon volume was associated with shorter induction to delivery interval without affecting cesarean section rate. As to the time limitation for exposure to extra-amniotic balloon, some practitioners set a maximum time limit, while others wait until spontaneous expulsion of the balloon catheter. Cromi et al reported that shortening the maximum time for cervical ripening (from 24 to 12 hours) might increase the proportion of women who delivered vaginally within 24 hour after Foley catheter insertion (**Fruhman et al., 2017).**

As the previous studies suggested, both balloon size and ripening time might affect the efficacy of induction; however we had not been able to identify any published data that has explored these two conditions in the same trial (**Liu et al., 2019).**

Our study aims to further investigate the induction of normal labor by foley catheter.

In our study we found that there is no significant difference between 2 groups as regard maternal age, gestational age, parity, BMI and Bishop score pre induction.

In a previous study by **Gu et al. (2015)**, ninety three percent of the women were nulliparous and Bishop scores before cervical ripening were similar among groups. Maternal age and epidural use were similar between the two groups. In the Foley catheter group, gestational age was more advanced and pre-delivery body mass index (BMI) was higher.

Gu et al. (2015) illustrated that more women achieved vaginal delivery within 24 hours in 12-hour Foley catheter groups than in the 24- hour Foley catheter groups (12-hour vs. 24-hour Foley catheter: 50.4% vs. 28.5%, OR 2.548, 95% CI 1.757–3.695). When the maximum ripening time was set to12 hours, vaginal delivery rate within 24 hours was higher in the 30-mL group compared with the 80-mL study arm, although this did not reach statistical significance (30-mL/12h vs. 80- mL/12h Foley catheter: 54.5% vs 46.4%: OR 1.386, 95% CI 0.839– 2.289, Table 2). Logistic regression analysis showed that independent factors for vaginal delivery rate within 24 hours included parity, gestational age and neonatal birth weight. Correction for these factors revealed that both ripening time (12-hour vs. 24-hour Foley catheter: OR 2.445, 95% CI 0.733–8.610) and balloon size (30-mL vs. 80-mL Foley catheter: OR 1.326, 95% CI 0.405–4.342) did not affect the proportion of women delivered vaginally within 24 hours of induction.

In the present study we illustrated that there is no significant difference between 2 groups as regard Difference in BS.

It comes in disagreement with what **Kruit et al. (2017)** showed. He found that there was significant

difference between 2 groups as regard Bishop Score pre induction.

In the study in our hands, we demonstrated that there is no significant difference between 2 groups as regard Favorable cervix and unfavorable cervix.

In a study by **Gu et al. (2015)**, he found that ripening of the unfavorable cervix with an 80-mL balloon compared with a 30-mL balloon was not associated with higher rate of vaginal delivery within 24 hours of induction. The cesarean section rate, oxytocin use and neonatal outcomes were comparable among the groups. Their results were different from the report of Levy et al, who found that an 80-mL balloon was significantly associated with a higher rate of postripening dilation of 3 cm or more in primiparous women, but did not reduce cesarean section rate. The difference in characteristics of participants might be related to the difference between Levy's trial and their study, and he was concerned that a larger balloon would increase the risk of dislodging the fetal head in some cases although it might be associated with better dilation of cervix. According to their results, longer ripening time and larger balloon size had no benefits on induction outcomes. Thus they favor the use of a 30-mL Foley catheter balloon left in place for a maximum of 12 hours in term labor cervical ripening. For women with an unfavorable cervix at term, induction of labor with a Foley catheter is safe and effective. Higher balloon volume (80-mL vs. 30-mL) and longer ripening time (24 hours vs. 12 hours) would not shorten induction to delivery interval or reduce cesarean section rate.

In this study, we found that there is significant difference between 2 groups as regard Mode of delivery and as regard Indication of caesarean section.

Gu et al. (2015) Cesarean section rate was lowest (11.6%) in the group with 30-mL balloon for 12 hours although the difference was insignificant among the groups (30-mL/24h: 21.0%, 80-mL/12h: 19.0%, 80-mL/24h: 19.0%). The indications for cesarean section were similar among the groups with failure to progress and failed induction being the most common ones. Nine women (1.8%) had cesarean sections for chorioamnionitis and 3 women (0.6%) were operated for fetal distress. There was no difference in assisted vaginal delivery rates among the groups.

Tihtonen et al. (2016) found no difference in the cesarean section rates between FC and misoprostol IOL. This is reassuring and in accordance with previous studies.6–8 there were more cesarean sections due to fetal distress in the misoprostol group. This may be associated with uterine hyperstimulation, although the difference was not significant. In contrast, in the FC group, most cesarean sections were performed due to failure to progress, which was also seen in previous studies.6,18 The decision to deliver by cesarean section is always complex. Some obstetricians may have had a lower threshold for cesarean delivery in cases of FC because the FC induction after PROM had only recently been introduced at the time. Interestingly, a recent study demonstrated lower cesarean section rate of 4.5% with expectant management for 48 hours after PROM. In our opinion, expectant management for 24 to 48 hours after PROM may be the treatment of choice.

Our findings showed that there is no significant difference between 2 groups as regard insertion and removal maternal pain score.

Siti et al. and his colleagues in their study which is a randomized controlled trial performed on pregnant women at 37-41 week who were admitted for induction of labor with unfavorable cervix. They were randomly assigned into two groups, Foley's with 750 ml traction and without traction. The primary outcomes were improvement in Bishop Score, number of favorable cervix following induction and the mode of delivery. The secondary outcomes were maternal pain score, neonatal outcome, and maternal infection. They showed that the pain score was slightly higher in traction group which is not statistically significant.

A study by **Tihtonen and his colleagues in 2016** showed that they did not assess patient satisfaction. One previous study assessing satisfaction found lower pain scores in women induced with FC compared with misoprostol.8 Also in their study, opioids were more often used in the misoprostol group during the latent phase compared with the FC group, even though the difference was not statistically significant. It may suggest that women in the misoprostol group had more pain.

In this study, we illustrated that there is no significant difference between 2 groups as regard Baby birth weight.

It comes in agreement with what **Gu et al. (2015)** showed. He found that there were no differences in neonatal birth weight or neonatal admission.

In this thesis we demonstrated that there is no significant difference between 2 groups as regard Apgar score at 1 min, 5 min and NICU admission.

Gu et al. (2015) demonstrated that Neonatal outcomes, which included Apgar score and neonatal admission, were similar among the groups. Three percent of neonates required admission to either neonatal ward or neonatal intensive care unit with no perinatal death during the study. The most common reason for neonatal admission was suspected neonatal infection and the length of admission did not differ significantly among the groups.

It comes in agreement with **Gu et al. (2015)** who showed that no significant differences as regard Apgar score at 1 min or at 5 min between treatment group

and control group in nulliparous or multiparous.

The current study had some limitations. First, the study lacked sufficient power to show significant treatment differences in secondary outcomes such as cesarean section rate and maternal complications. Second, it was an open label research and the method of cervical ripening might have affected the obstetricians' decision. Third, we did not record women's satisfaction with different balloon volume and ripening time; however, none of the participants withdrew from the trial for discomfort during and after balloon insertion, which indicated the safety of device placement.

In summary, we included women with a variety of indications for induction in the present trial, which suggested that Foley catheter balloon could be safely used in cervical ripening for both obstetrical and medical indications. Furthermore, considering the low cost and easy storage of the Foley catheter, we believe it could be used for low-resource settings, such as rural and county hospitals in China.

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